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ADVANSTAR MEDICAL COMMUNICATIONS GROUP

Butrans—7 Days of Buprenorphine Delivery

Butrans is a Schedule III extended-release opioid analgesic

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

Butrans contains buprenorphine, an opioid agonist and Schedule III controlled substance with an abuse liability similar to other Schedule III opioids, legal or illicit *[see Warnings and Precautions (5.1)]*. Assess each patient's risk for opioid abuse or addiction prior to prescribing Butrans. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (eg, major depressive disorder). Routinely monitor all patients receiving Butrans for signs of misuse, abuse, and addiction during treatment *[see Drug Abuse and Dependence (9)]*.

Life-Threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of Butrans, even when the drug has been used as recommended and not misused or abused *[see Warnings and Precautions (5.2)]*. Proper dosing and titration are essential and Butrans should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of Butrans or following a dose increase.

Accidental Exposure

Accidental exposure to Butrans, especially in children, can result in a fatal overdose of buprenorphine *[see Warnings and Precautions (5.3)]*.

Parentheses refer to sections in the Full Prescribing Information.

Butrans® (buprenorphine) Transdermal System is indicated for the management of moderate to severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Limitations of Use: Butrans is not for use: as an as-needed (prn) analgesic; for pain that is mild or not expected to persist for an extended period of time; for acute pain; for postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.

CONTRAINDICATIONS

- Butrans is contraindicated in patients with: significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; known or suspected paralytic ileus; hypersensitivity (eg, anaphylaxis) to buprenorphine

WARNINGS AND PRECAUTIONS

- **Abuse Potential**
  Buprenorphine can be abused in a manner similar to other opioid agonists, legal or illicit. Assess risk for opioid abuse or addiction prior to prescribing. Routinely monitor all patients for signs of misuse, abuse, and addiction. Addiction can occur even under appropriate medical use. Misuse or abuse of Butrans by chewing, swallowing, snorting or injecting buprenorphine extracted from the transdermal system will result in the uncontrolled delivery of the opioid and pose a significant risk that could result in overdose and death
- **Life-Threatening Respiratory Depression**
  Respiratory depression is the primary risk of Butrans and may lead to respiratory arrest and death. While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of Butrans, the risk is greatest during the initiation of therapy or following a dose increase. Closely monitor patients for respiratory depression. Proper dosing and titration of Butrans are essential. Overestimating the Butrans dose when converting patients from another opioid product can result in fatal overdose with the first dose
- **Accidental Exposure**
  Accidental exposure to Butrans, especially in children, can result in a fatal overdose
- **Elderly, Cachectic, and Debilitated Patients**
  Respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics. Monitor such patients closely, particularly when initiating and titrating Butrans and when Butrans is given concomitantly with other drugs that depress respiration
- **Use in Patients with Chronic Pulmonary Disease**
  Monitor patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression for respiratory depression, particularly when initiating therapy and titrating with Butrans. Even usual therapeutic doses of Butrans may decrease respiratory drive to the point of apnea
- **Interactions with Alcohol, CNS Depressants, and Illicit Drugs**
  Hypotension, profound sedation, coma or respiratory depression may result if Butrans is added to a regimen that includes other CNS depressants, alcohol, or illicit drugs
- **QTc Prolongation**
  Avoid in patients with Long QT Syndrome, family history of Long QT Syndrome, or those taking Class IA or Class III antiarrhythmic medications
- **Hypotensive Effects**
  Butrans may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. Monitor patients after initiating or titrating
- **Use in Patients with Head Injury or Increased Intracranial Pressure**
  Monitor patients who may be susceptible to the intracranial effects of CO retention for signs of sedation and respiratory depression, particularly when initiating therapy with Butrans. Opioids may also obscure the clinical course in a patient with a head injury
- **Application Site Skin Reactions**
  In rare cases, severe application site skin reactions with signs of marked inflammation including "burn," "discharge," and "vesicles" have occurred
- **Anaphylactic/Allergic Reactions**
  Cases of acute and chronic hypersensitivity to buprenorphine have been reported both in clinical trials and in the post-marketing experience
- **Application of External Heat**
  Avoid exposing the Butrans application site and surrounding area to direct external heat sources. There is a potential for temperature-dependent increases in buprenorphine released from the system resulting in possible overdose and death
- **Use in Patients with Gastrointestinal Conditions**
  Avoid the use of Butrans in patients with paralytic ileus and other GI obstructions. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms
- **Avoidance of Withdrawal**
  When discontinuing Butrans, gradually taper the dose. Do not abruptly discontinue Butrans

ADVERSE REACTIONS

- Most common adverse reactions (≥5%) reported by patients treated with Butrans in the clinical trials were nausea, headache, application site pruritus, dizziness, constipation, somnolence, vomiting, application site erythema, dry mouth, and application site rash

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The first transdermal system to deliver 7 days of buprenorphine

Butrans® CIII
(buprenorphine) Transdermal System
5, 10, 15, and 20 mcg/hour
Butrans, Once Weekly

Please read Brief Summary of Full Prescribing Information on the following pages.

PURDUE

Butrans® CIII

(buprenorphine) Transdermal System

5, 10, 15, and 20 mcg/hour

for transdermal administration

BRIEF SUMMARY OF PRESCRIBING INFORMATION

(For complete details please see the Full Prescribing Information and Medication Guide.)

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

BUTRANS contains buprenorphine, an opioid agonist and Schedule III controlled substance with an abuse liability similar to other Schedule III opioids, legal or illicit *[see Warnings and Precautions (5.1)]*. Assess each patient's risk for opioid abuse or addiction prior to prescribing BUTRANS. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving BUTRANS for signs of misuse, abuse, and addiction during treatment *[see Drug Abuse and Dependence (9)]*.

Life-Threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of BUTRANS, even when the drug has been used as recommended and not misused or abused *[see Warnings and Precautions (5.2)]*. Proper dosing and titration are essential and BUTRANS should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of BUTRANS or following a dose increase.

Accidental Exposure

Accidental exposure to BUTRANS, especially in children, can result in a fatal overdose of buprenorphine *[see Warnings and Precautions (5.3)]*.

1 INDICATIONS AND USAGE BUTRANS is indicated for the management of moderate to severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. Limitations of Use BUTRANS is not for use: • As an as-needed (prn) analgesic • For pain that is mild or not expected to persist for an extended period of time • For acute pain • For postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time **4 CONTRAINDICATIONS** BUTRANS is contraindicated in patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected paralytic ileus • Hypersensitivity (e.g., anaphylaxis) to buprenorphine *[see Warnings and Precautions (5.12), and Adverse Reactions (6)]* **5 WARNINGS AND PRECAUTIONS 5.1 Abuse Potential** BUTRANS contains buprenorphine, a partial agonist at the mu opioid receptor and a Schedule III controlled substance. Buprenorphine can be abused in a manner similar to other opioid agonists, legal or illicit. Opioid agonists are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing BUTRANS in situations where there is concern about increased risks of misuse, abuse, or diversion. Concerns about abuse, addiction, and diversion should not, however, prevent the proper management of pain. Assess each patient's risk for opioid abuse or addiction prior to prescribing BUTRANS. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). Patients at increased risk may still be appropriately treated with modified-release opioid formulations; however these patients will require intensive monitoring for signs of misuse, abuse, or addiction. Routinely monitor all patients receiving opioids for signs of misuse, abuse, and addiction because these drugs carry a risk for addiction even under appropriate medical use. Misuse or abuse of BUTRANS by chewing, swallowing, snorting or injecting buprenorphine extracted from the transdermal system will result in the uncontrolled delivery of the opioid and pose a significant risk that could result in overdose and death *[see Overdosage (10)]*. Contact local state professional licensing board or state controlled substances authority for information on how to prevent and detect abuse or diversion of this product. **5.2 Life-Threatening Respiratory Depression** Respiratory depression is the primary risk of BUTRANS. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death. Respiratory depression from opioids is manifested by a reduced urge to breathe and a decreased rate of respiration, often associated with a "sighing" pattern of breathing (deep breaths separated by abnormally long pauses). Carbon dioxide (CO_2) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status *[see Overdosage (10)]*. While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of BUTRANS, the risk is greatest during the initiation of therapy or following a dose increase. Closely monitor patients for respiratory depression when initiating therapy with BUTRANS and following dose increases. Instruct patients against use by individuals other than the patient for whom BUTRANS was prescribed and to keep BUTRANS out of the reach of children, as such inappropriate use may result in fatal respiratory depression. To reduce the risk of respiratory depression, proper dosing and titration of BUTRANS are essential *[see Dosage and Administration (2.1, 2.2)]*. Overestimating the BUTRANS dose when converting patients from another opioid product can result in fatal overdose with the first dose. Respiratory depression has also been reported with use of modified-release opioids when used as recommended and not misused or abused. To further reduce the risk of respiratory depression, consider the following: • Proper dosing and titration are essential and BUTRANS should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. • BUTRANS is contraindicated in patients with respiratory depression and in patients with conditions that increase the risk of life-threatening respiratory depression *[see Contraindications (4)]*. **5.3 Accidental Exposure** Accidental exposure to BUTRANS, especially in children, can result in a fatal overdose of buprenorphine. **5.4 Elderly, Cachectic, and Debilitated Patients** Respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics due to poor fat stores, muscle wasting, or altered clearance compared to younger, healthier patients. Therefore, monitor such patients closely, particularly when initiating and titrating BUTRANS and when BUTRANS is given concomitantly with other drugs that depress respiration *[see Warnings and Precautions (5.2)]*. **5.5 Use in Patients with Chronic Pulmonary Disease** Monitor patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression for respiratory depression, particularly when initiating therapy and titrating with BUTRANS, as in these patients, even usual therapeutic doses of BUTRANS may decrease respiratory drive to the point of apnea *[see Warnings and Precautions (5.2)]*. Consider the use of alternative non-opioid analgesics in these patients if possible. **5.6 Interactions with Alcohol, CNS Depressants, and Illicit Drugs** Hypotension, profound sedation, coma or respiratory depression may result if BUTRANS is added to a regimen that includes other CNS depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, muscle relaxants, other opioids). When considering the use of BUTRANS in a patient taking a CNS depressant, assess the duration of use of the CNS depressant and the patient's response, including the degree of tolerance that has developed to CNS depression. Additionally, consider the patient's use, if any, of alcohol or illicit drugs that cause CNS depression. If BUTRANS therapy is to be initiated in a patient taking a CNS depressant, start with a lower BUTRANS dose than usual and monitor patients for signs of sedation and respiratory depression and consider using a lower dose of the concomitant CNS depressant *[see Drug Interactions (7.3)]*. **5.7 QTc Prolongation** A positive-controlled study of the effects of BUTRANS on the QTc interval in healthy subjects demonstrated no clinically meaningful effect at a BUTRANS dose of 10 mcg/hour; however, a BUTRANS dose of 40 mcg/hour (given as two BUTRANS 20 mcg/hour Transdermal Systems) was observed to prolong the QTc interval *[see Clinical Pharmacology (12.2)]*. Consider these observations in clinical decisions when prescribing BUTRANS to patients with hypokalemia or clinically unstable cardiac disease, including: unstable atrial fibrillation, symptomatic bradycardia, unstable congestive heart failure, or active myocardial ischemia. Avoid the use of BUTRANS in patients with a history of Long QT Syndrome or an immediate family member with this condition, or those taking Class IA antiarrhythmic medications (e.g., quinidine, procainamide, disopyramide) or Class III antiarrhythmic medications (e.g., sotalol, amiodarone, dofetilide). **5.8 Hypotensive Effects** BUTRANS may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. There is an increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g., phenothiazines or general anesthetics) *[see Drug Interactions (7.3)]*. Monitor these patients for signs of hypotension after initiating or titrating the dose of BUTRANS. **5.9 Use in Patients with Head Injury or Increased Intracranial Pressure** Monitor patients taking BUTRANS who may be susceptible to the intracranial effects of CO_2 retention (e.g., those with evidence of increased intracranial pressure or brain tumors) for signs of sedation and respiratory depression, particularly when initiating therapy with BUTRANS. BUTRANS may reduce respiratory drive, and the resultant CO_2 retention can further increase intracranial pressure. Opioids may also obscure the clinical course in a patient with a head injury. Avoid the use of BUTRANS in patients with impaired consciousness or coma. **5.10 Hepatotoxicity** Although not observed in BUTRANS chronic pain clinical trials, cases of cytolytic hepatitis and hepatitis with jaundice have been observed in individuals receiving sublingual buprenorphine for the treatment of opioid dependence, both in clinical trials and in post-marketing adverse event reports. The spectrum of abnormalities ranges from transient asymptomatic elevations in hepatic transaminases to case reports of hepatic failure, hepatic necrosis, hepatorenal syndrome, and hepatic encephalopathy. In many cases, the presence of pre-existing liver enzyme abnormalities, infection with hepatitis B or hepatitis C virus, concomitant usage of other potentially hepatotoxic drugs, and ongoing injection drug abuse may have played a causative or contributory role. For patients at increased risk of hepatotoxicity (e.g., patients with a history of excessive alcohol intake, intravenous drug abuse or liver disease), obtain baseline liver enzyme levels and monitor periodically and during treatment with BUTRANS. **5.11 Application Site Skin Reactions** In rare cases, severe application site skin reactions with signs of marked inflammation including "burn," "discharge," and "vesicles" have occurred. Time of onset varies, ranging from days to months following the initiation of BUTRANS treatment. Instruct patients to promptly report the development of severe application site reactions and discontinue therapy. **5.12 Anaphylactic/Allergic Reactions** Cases of acute and chronic hypersensitivity to buprenorphine have been reported both in clinical trials and in the post-marketing experience. The most common signs and symptoms include rashes, hives, and pruritus. Cases of bronchospasm, angioneurotic edema, and anaphylactic shock have been reported. A history of hypersensitivity to buprenorphine is a contraindication to the use of BUTRANS. **5.13 Application of External Heat** Advise patients and their caregivers to avoid exposing the BUTRANS application site and surrounding area to direct external heat sources, such as heating pads or electric blankets, heat or tanning lamps, saunas, hot tubs, and heated water beds while wearing the system because an increase in absorption of buprenorphine may occur *[see Clinical Pharmacology (12.3)]*. Advise patients against exposure of the BUTRANS application site and surrounding area to hot water or prolonged exposure to direct sunlight. There is a potential for temperature-dependent increases in buprenorphine released from the system resulting in possible overdose and death. **5.14 Patients with Fever** Monitor patients wearing BUTRANS systems who develop fever or increased core body temperature due to strenuous exertion for opioid side effects and adjust the BUTRANS dose if signs of respiratory or central nervous system depression occur. **5.15 Use in Patients with Gastrointestinal Conditions** BUTRANS is contraindicated in patients with paralytic ileus. Avoid the use of BUTRANS in patients with other GI obstruction. The buprenorphine in BUTRANS may cause spasm of the sphincter of Oddi. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms. Opioids may cause increases in the serum amylase. **5.16 Use in Patients with Convulsive or Seizure Disorders** The buprenorphine in BUTRANS may aggravate convulsions in patients with convulsive disorders, and may induce or aggravate seizures in some clinical settings. Monitor patients with a history of seizure disorders for worsened seizure control during BUTRANS therapy. **5.17 Avoidance of Withdrawal** Symptoms of withdrawal include restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Significant fluid losses from vomiting and diarrhea can require intravenous fluid administration. When discontinuing BUTRANS, gradually taper the dose *[see Dosage and Administration (2.3)]*. Do not abruptly discontinue BUTRANS. **5.18 Driving and Operating Machinery** BUTRANS may impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of BUTRANS and know how they will react to the medication. **5.19 Use in Addiction Treatment** BUTRANS has not been studied and is not approved for use in the management of addictive disorders. **6 ADVERSE REACTIONS** The following adverse reactions described elsewhere in the labeling include: • Respiratory Depression *[see Warnings and Precautions (5.2)]* • QTc Prolongation *[see Warnings and Precautions (5.7)]* • Hypotensive Effects *[see Warnings and Precautions (5.8)]* • Application Site Skin Reactions *[see Warnings and Precautions (5.11)]* • Anaphylactic/Allergic Reactions *[see Warnings and Precautions (5.12)]* • Gastrointestinal Effects *[see Warnings and Precautions (5.15)]* • Seizures *[see Warnings and Precautions (5.16)]* **6.1 Clinical Trial 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 rates in the clinical trials of another drug and may not reflect the rates observed in practice. A total of 5,415 patients were treated with BUTRANS in controlled and open-label chronic pain clinical trials. Nine hundred twenty-four subjects were treated for approximately six months and 183 subjects were treated for approximately one year. The clinical trial population consisted of patients with persistent moderate to severe pain. The most common serious adverse drug reactions (all <0.1%) occurring during clinical trials with BUTRANS were: chest pain, abdominal pain, vomiting, dehydration, and hypertension/blood pressure increased. The most common adverse events (≥ 2%) leading to discontinuation were: nausea, dizziness, vomiting, headache, and somnolence. The most common adverse reactions (≥ 5%) reported by patients in clinical trials comparing BUTRANS 10 or 20 mcg/hour to placebo are shown in Table 2, and comparing BUTRANS 20 mcg/hour to BUTRANS 5 mcg/hour are shown in Table 3 below:

Table 2: Adverse Reactions Reported in ≥ 5% of Patients during the Open-Label Titration Period and Double-Blind Treatment Period: Opioid-Naïve Patients

	Open-Label Titration Period	Double-Blind Treatment Period	
	BUTRANS	BUTRANS	Placebo
MedDRA Preferred Term	**(N = 1024)**	**(N = 256)**	**(N = 283)**
Nausea	23%	13%	10%
Dizziness	10%	4%	1%
Headache	9%	5%	5%
Application site pruritus	8%	4%	7%
Somnolence	8%	2%	2%
Vomiting	7%	4%	1%
Constipation	6%	4%	1%

Table 3: Adverse Reactions Reported in ≥ 5% of Patients during the Open-Label Titration Period and Double-Blind Treatment Period: Opioid-Experienced Patients

	Open-Label Titration Period	Double-Blind Treatment Period	
	BUTRANS	BUTRANS 20	BUTRANS 5
MedDRA Preferred Term	**(N = 1160)**	**(N = 219)**	**(N = 221)**
Nausea	14%	11%	6%
Application site pruritus	9%	13%	5%
Headache	9%	8%	3%
Somnolence	6%	4%	2%
Dizziness	5%	4%	2%
Constipation	4%	6%	3%
Application site erythema	3%	10%	5%
Application site rash	3%	8%	6%
Application site irritation	2%	6%	2%

The following table lists adverse reactions that were reported in at least 2.0% of patients in four placebo/active-controlled titration-to-effect trials.

Table 4: Adverse Reactions Reported in Titration-to-Effect Placebo/Active-Controlled Clinical Trials with Incidence ≥ 2%

MedDRA Preferred Term	BUTRANS (N = 392)	Placebo (N = 261)
Nausea	21%	6%
Application site pruritus	15%	12%
Dizziness	15%	7%
Headache	14%	9%
Somnolence	13%	4%
Constipation	13%	5%
Vomiting	9%	1%
Application site erythema	7%	2%
Application site rash	6%	6%
Dry mouth	6%	2%
Fatigue	5%	1%
Hyperhidrosis	4%	1%
Peripheral edema	3%	1%
Pruritus	3%	0%
Stomach discomfort	2%	0%

The adverse reactions seen in controlled and open-label studies are presented below in the following manner: most common (≥ 5%), common (≥ 1% to < 5%), and less common (< 1%). The most common adverse reactions (≥ 5%) reported by patients treated with BUTRANS in the clinical trials were nausea, headache, application site pruritus, dizziness, constipation, somnolence, vomiting, application site erythema, dry mouth, and application site rash. The common (≥ 1% to < 5%) adverse reactions reported by patients treated with BUTRANS in the clinical trials organized by MedDRA (Medical Dictionary for Regulatory Activities) System Organ Class were: *Gastrointestinal disorders:* diarrhea, dyspepsia, and upper abdominal pain *General disorders and administration site conditions:* fatigue, peripheral edema, application site irritation, pain, pyrexia, chest pain, and asthenia *Infections and infestations:*

urinary tract infection, upper respiratory tract infection, nasopharyngitis, influenza, sinusitis, and bronchitis *Injury, poisoning and procedural complications:* fall *Metabolism and nutrition disorders:* anorexia *Musculoskeletal and connective tissue disorders:* back pain, arthralgia, pain in extremity, muscle spasms, musculoskeletal pain, joint swelling, neck pain, and myalgia *Nervous system disorders:* hypoesthesia, tremor, migraine, and paresthesia *Psychiatric disorders:* insomnia, anxiety, and depression *Respiratory, thoracic and mediastinal disorders:* dyspnea, pharyngolaryngeal pain, and cough *Skin and subcutaneous tissue disorders:* pruritus, hyperhidrosis, rash, and generalized pruritus *Vascular disorders:* hypertension Other less common adverse reactions, including those known to occur with opioid treatment, that were seen in < 1% of the patients in the BUTRANS trials include the following in alphabetical order: Abdominal distention, abdominal pain, accidental injury, affect lability, agitation, alanine aminotransferase increased, angina pectoris, angioedema, apathy, application site dermatitis, asthma aggravated, bradycardia, chills, confusional state, contact dermatitis, coordination abnormal, dehydration, depersonalization, depressed level of consciousness, depressed mood, disorientation, disturbance in attention, diverticulitis, drug hypersensitivity, drug withdrawal syndrome, dry eye, dry skin, dysarthria, dysgeusia, dysphagia, euphoric mood, face edema, flatulence, flushing, gait disturbance, hallucination, hiccups, hot flush, hyperventilation, hypotension, hypoventilation, ileus, insomnia, libido decreased, loss of consciousness, malaise, memory impairment, mental impairment, mental status changes, miosis, muscle weakness, nervousness, nightmare, orthostatic hypotension, palpitations, psychotic disorder, respiration abnormal, respiratory depression, respiratory distress, respiratory failure, restlessness, rhinitis, sedation, sexual dysfunction, syncope, tachycardia, tinnitus, urinary hesitation, urinary incontinence, urinary retention, urticaria, vasodilatation, vertigo, vision blurred, visual disturbance, weight decreased, and wheezing. **7 DRUG INTERACTIONS 7.1 Hepatic Enzyme Inhibitors and Inducers** *CYP3A4 Inhibitors* Co-administration of ketoconazole, a strong CYP3A4 inhibitor, with BUTRANS, did not have any effect on C_{max} (maximum concentration) and AUC (area under the curve) of buprenorphine. Based on this observation, the pharmacokinetics of BUTRANS are not expected to be affected by co-administration of CYP3A4 inhibitors. However, certain protease inhibitors (PIs) with CYP3A4 inhibitory activity such as atazanavir and atazanavir/ritonavir resulted in elevated levels of buprenorphine and norbuprenorphine following sublingual administration of buprenorphine and naloxone. Patients in this study reported increased sedation, and symptoms of opiate excess have been found in post-marketing reports of patients receiving sublingual buprenorphine and atazanavir with and without ritonavir concomitantly. Atazanavir is both a CYP3A4 and UGT1A1 inhibitor. As such, the drug-drug interaction potential for buprenorphine with CYP3A4 inhibitors is likely to be dependent on the route of administration as well as the specificity of enzyme inhibition *[see Clinical Pharmacology (12.3)]*. *CYP3A4 Inducers* The interaction between buprenorphine and CYP3A4 enzyme inducers has not been studied. Monitor patients receiving concurrent therapy with BUTRANS and CYP3A4 inducers (e.g., phenobarbital, carbamazepine, phenytoin, rifampin) closely for reduced efficacy or signs of withdrawal *[see Clinical Pharmacology (12.3)]*. **7.2 Benzodiazepines** There have been a number of reports regarding coma and death associated with the misuse and abuse of the combination of buprenorphine and benzodiazepines. In many, but not all of these cases, buprenorphine was misused by self-injection of crushed buprenorphine tablets. Preclinical studies have shown that the combination of benzodiazepines and buprenorphine altered the usual ceiling effect on buprenorphine-induced respiratory depression, making the respiratory effects of buprenorphine appear similar to those of full opioid agonists. Closely monitor patients with concurrent use of BUTRANS and benzodiazepines. Warn patients that it is extremely dangerous to self-administer benzodiazepines while taking BUTRANS, and warn patients to use benzodiazepines concurrently with BUTRANS only as directed by their physician. **7.3 CNS Depressants** Concurrent use of BUTRANS and other central nervous system (CNS) depressants (e.g., sedatives, hypnotics, general anesthetics, antiemetics, phenothiazines, other tranquilizers, and alcohol) can increase the risk of respiratory depression, hypotension, and profound sedation or coma. Monitor patients receiving CNS depressants and BUTRANS for signs of respiratory depression and hypotension. When such combined therapy is contemplated, reduce the initial dose of one or both agents. **7.4 Skeletal Muscle Relaxants** BUTRANS, like other opioids, may interact with skeletal muscle relaxants to enhance neuromuscular blocking action and increase respiratory depression. **7.5 Anticholinergics** Anticholinergics or other drugs with anticholinergic activity when used concurrently with opioid analgesics may result in increased risk of urinary retention and/or severe constipation, which may lead to paralytic ileus. Monitor patients for signs of urinary retention or reduced gastric motility when BUTRANS is used concurrently with anticholinergic drugs. **8 USE IN SPECIFIC POPULATIONS 8.1 Pregnancy** *Teratogenic Effects (Pregnancy Category C)* There are no adequate and well-controlled studies with BUTRANS in pregnant women. BUTRANS should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and the fetus. In animal studies, buprenorphine caused an increase in the number of stillborn offspring, reduced litter size, and reduced offspring growth in rats at maternal exposure levels that were approximately 10 times that of human subjects who received one BUTRANS 20 mcg/hour, the maximum recommended human dose (MRHD). Studies in rats and rabbits demonstrated no evidence of teratogenicity following BUTRANS or subcutaneous (SC) administration of buprenorphine during the period of major organogenesis. Rats were administered up to one BUTRANS 20 mcg/hour every 3 days (gestation days 6, 9, 12, & 15) or received daily SC buprenorphine up to 5 mg/kg (gestation days 6-17). Rabbits were administered four BUTRANS 20 mcg/hour every 3 days (gestation days 6, 9, 12, 15, 18, & 19) or received daily SC buprenorphine up to 5 mg/kg (gestation days 6-19). No teratogenicity was observed at any dose. AUC values for buprenorphine with BUTRANS application and SC injection were approximately 110 and 140 times, respectively, that of human subjects who received the MRHD of one BUTRANS 20 mcg/hour. *Non-Teratogenic Effects* In a peri- and post-natal study conducted in pregnant and lactating rats, administration of buprenorphine either as BUTRANS or SC buprenorphine was associated with toxicity to offspring. Buprenorphine was present in maternal milk. Pregnant rats were administered 1/4 of one BUTRANS 5 mcg/hour every 3 days or received daily SC buprenorphine at doses of 0.05, 0.5, or 5 mg/kg from gestation day 6 to lactation day 21 (weaning). Administration of BUTRANS or SC buprenorphine at 0.5 or 5 mg/kg caused maternal toxicity and an increase in the number of stillborns, reduced litter size, and reduced offspring growth at maternal exposure levels that were approximately 10 times that of human subjects who received the MRHD of one BUTRANS 20 mcg/hour. Maternal toxicity was also observed at the no observed adverse effect level (NOAEL) for offspring. **8.2 Labor and Delivery** BUTRANS is not for use in women immediately prior to and during labor, where use of short-acting analgesics or other analgesic techniques are more appropriate *[see Indications and Usage (1)]*. Occasionally, opioid analgesics may prolong labor through actions which temporarily reduce the strength, duration and frequency of uterine contractions. However this effect is not consistent and may be offset by an increased rate of cervical dilatation, which tends to shorten labor. Opioids cross the placenta and may produce respiratory depression and psychophysiologic effects in neonates. Closely observe neonates whose mothers received opioid analgesics during labor for signs of respiratory depression. An opioid antagonist, such as naloxone, should be available for reversal of opioid-induced respiratory depression in the neonate in such situations. **8.3 Nursing Mothers** Buprenorphine is excreted in breast milk. The amount of buprenorphine received by the infant varies depending on the maternal plasma concentration, the amount of milk ingested by the infant, and the extent of first pass metabolism. Withdrawal symptoms can occur in breast-feeding infants when maternal administration of buprenorphine is stopped. Because of the potential for adverse reactions in nursing infants from BUTRANS, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. **8.4 Pediatric Use** The safety and efficacy of BUTRANS in patients under 18 years of age has not been established. **8.5 Geriatric Use** Of the total number of subjects in the clinical trials (5,415), BUTRANS was administered to 1,377 patients aged 65 years and older. Of those, 457 patients were 75 years of age and older. In the clinical program, the incidences of selected BUTRANS-related AEs were higher in older subjects. The incidences of application site AEs were slightly higher among subjects < 65 years of age than those ≥ 65 years of age for both BUTRANS and placebo treatment groups. In a single-dose study of healthy elderly and healthy young subjects treated with BUTRANS 10 mcg/hour, the pharmacokinetics were similar. In a separate dose-escalation safety study, the pharmacokinetics in the healthy elderly and hypertensive elderly subjects taking thiazide diuretics were similar to those in the healthy young adults. In the elderly groups evaluated, adverse event rates were similar to or lower than rates in healthy young adult subjects, except for constipation and urinary retention, which were more common in the elderly. Although specific dose adjustments on the basis of advanced age are not required for pharmacokinetic reasons, use caution in the elderly population to ensure safe use *[see Clinical Pharmacology (12.3)]*. **8.6 Hepatic Impairment** In a study utilizing intravenous buprenorphine, peak plasma levels (C_{max}) and exposure (AUC) of buprenorphine in patients with mild and moderate hepatic impairment did not increase as compared to those observed in subjects with normal hepatic function. BUTRANS has not been evaluated in patients with severe hepatic impairment. As BUTRANS is intended for 7-day dosing, consider the use of alternate analgesic therapy in patients with severe hepatic impairment *[see Dosage and Administration (2.4), and Clinical Pharmacology (12.3)]*. **8.7 Neonatal Opioid Withdrawal Syndrome** Chronic maternal use of buprenorphine during pregnancy can affect the fetus with subsequent withdrawal signs. Neonatal withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea and failure to gain weight. The onset, duration and severity of neonatal withdrawal syndrome vary based on the drug used, duration of use, the dose of last maternal use, and rate of elimination drug by the newborn. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening and should be treated according to protocols developed by neonatology experts. **9 DRUG ABUSE AND DEPENDENCE 9.1 Controlled Substance** BUTRANS contains buprenorphine, a mu opioid partial agonist and Schedule III controlled substance with an abuse potential similar to other Schedule III opioids. BUTRANS can be abused and is subject to misuse, abuse, addiction and criminal diversion. **9.2 Abuse** Abuse of BUTRANS poses a hazard of overdose and death. This risk is increased with compromise of the BUTRANS Transdermal System and with concurrent abuse of alcohol or other substances. BUTRANS has been diverted for non-medical use. All patients treated with opioids, including BUTRANS, require careful monitoring for signs of abuse and addiction, because use of opioid analgesic products carries the risk of addiction even under appropriate medical use. All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use. Drug abuse is the intentional non-therapeutic use of an over-the-counter or prescription drug, even once, for its rewarding psychological or physiological effects. Drug abuse includes, but is not limited to the following examples: the use of a prescription or over-the-counter drug to get "high", or the use of steroids for performance enhancement and muscle build up. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and includes: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal. "Drug-seeking" behavior is very common in persons with substance use disorders. Drug-seeking tactics include, but are not limited to, emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated "loss" of prescriptions, tampering with prescriptions and reluctance to provide prior medical records or contact information for other treating physician(s). "Doctor shopping" (visiting multiple prescribers) to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction. Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control. Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction. BUTRANS may be diverted for non-medical use into illicit channels of distribution. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests, as required by state law, is strongly advised. The risks of misuse and abuse should be considered when prescribing or dispensing BUTRANS. Concerns about abuse and addiction, should not prevent the proper management of pain, however. Treatment of pain should be individualized, balancing the potential benefits and risks for each patient. *Risks Specific to the Abuse of BUTRANS* BUTRANS is intended for transdermal use only. Abuse of BUTRANS poses a risk of overdose and death. This risk is increased with concurrent abuse of BUTRANS with alcohol and other substances including other opioids and benzodiazepines *[see Warnings and Precautions (5.6), and Drug Interactions (7.2)]*. Compromising the transdermal delivery system will result in the uncontrolled delivery of buprenorphine and pose a significant risk to the abuser that could result in overdose and death *[see Warnings and Precautions (5.1)]*. Abuse may occur by applying the transdermal system in the absence of legitimate purpose, or by swallowing, snorting or injecting buprenorphine extracted from the transdermal system. **9.3 Dependence** Both tolerance and physical dependence can develop during chronic opioid therapy. Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Tolerance may occur to both the desired and undesired effects of drugs, and may develop at different rates for different effects. Physical dependence results in withdrawal symptoms after abrupt discontinuation or a significant dose reduction of a drug. Withdrawal also may be precipitated through the administration of drugs with opioid antagonist activity, e.g., naloxone, nalmefene, or mixed agonist/antagonist analgesics (pentazocine, butorphanol, nalbuphine). Physical dependence may not occur to a clinically significant degree until after several days to weeks of continued opioid usage. BUTRANS should not be abruptly discontinued *[see Dosage and Administration (2.3)]*. If BUTRANS is abruptly discontinued in a physically-dependent patient, an abstinence syndrome may occur. Some or all of the following can characterize this syndrome: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other signs and symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate. Infants born to mothers physically dependent on opioids will also be physically dependent and may exhibit respiratory difficulties and withdrawal symptoms *[see Use in Specific Populations (8.7)]*. **10 OVERDOSAGE *Clinical Presentation*** Acute overdosage with BUTRANS is manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, bradycardia, hypotension, partial or complete airway obstruction, atypical snoring and death. Marked mydriasis rather than miosis may be seen due to severe hypoxia in overdose situations. ***Treatment of Overdose*** In case of overdose, priorities are the re-establishment of a patent and protected airway and institution of assisted or controlled ventilation if needed. Employ other supportive measures (including oxygen, vasopressors) in the management of circulatory shock and pulmonary edema as indicated. Cardiac arrest or arrhythmias will require advanced life support techniques. Naloxone may not be effective in reversing any respiratory depression produced by buprenorphine. High doses of naloxone, 10-35 mg/70 kg, may be of limited value in the management of buprenorphine overdose. The onset of naloxone effect may be delayed by 30 minutes or more. Doxapram hydrochloride (a respiratory stimulant) has also been used. Remove BUTRANS immediately. Because the duration of reversal would be expected to be less than the duration of action of buprenorphine from BUTRANS, carefully monitor the patient until spontaneous respiration is reliably re-established. Even in the face of improvement, continued medical monitoring is required because of the possibility of extended effects as buprenorphine continues to be absorbed from the skin. After removal of BUTRANS, the mean buprenorphine concentrations decrease approximately 50% in 12 hours (range 10-24 hours) with an apparent terminal half-life of approximately 26 hours. Due to this long apparent terminal half-life, patients may require monitoring and treatment for at least 24 hours. In an individual physically dependent on opioids, administration of an opioid receptor antagonist may precipitate an acute withdrawal. The severity of the withdrawal produced will depend on the degree of physical dependence and the dose of the antagonist administered. If a decision is made to treat serious respiratory depression in the physically dependent patient with an opioid antagonist, administration of the antagonist should be begun with care and by titration with smaller than usual doses of the antagonist. **17 PATIENT COUNSELING INFORMATION** *See FDA-approved patient labeling (Medication Guide)* *Abuse Potential* Inform patients that BUTRANS contains buprenorphine, a Schedule III controlled substance that is subject to abuse. Instruct patients not to share BUTRANS with others and to take steps to protect BUTRANS from theft or misuse. *Life-Threatening Respiratory Depression* Discuss the risk of respiratory depression with patients, explaining that the risk is greatest when starting BUTRANS or when the dose is increased. Advise patients how to recognize respiratory depression and to seek medical attention if they are experiencing breathing difficulties. *Accidental Exposure* Instruct patients to take steps to store BUTRANS securely. Accidental exposure, especially in children, may result in serious harm or death. Advise patients to dispose of unused BUTRANS folding in half and flushing down the toilet. *Risks from Concomitant Use of Alcohol and other CNS Depressants* Inform patients that the concomitant use of alcohol with BUTRANS can increase the risk of life-threatening respiratory depression. Inform patients that potentially serious additive effects may occur if BUTRANS is used with other CNS depressants, and not to use such drugs unless supervised by a health care provider. *Important Administration Instructions* Instruct patients how to properly use BUTRANS, including the following:

1. To carefully follow instructions for the application, removal, and disposal of BUTRANS. Each week, apply BUTRANS to a different site based on the 8 described skin sites, with a minimum of 3 weeks between applications to a previously used site.
2. To apply BUTRANS to a hairless or nearly hairless skin site. If none are available, instruct patients to clip the hair at the site and not to shave the area. Instruct patients not to apply to irritated skin. If the application site must be cleaned, use clear water only. Soaps, alcohol, oils, lotions, or abrasive devices should not be used. Allow the skin to dry before applying BUTRANS.

Hypotension Inform patients that BUTRANS may cause orthostatic hypotension and syncope. Instruct patients how to recognize symptoms of low blood pressure and how to reduce the risk of serious consequences should hypotension occur (e.g., sit or lie down, carefully rise from a sitting or lying position). *Driving or Operating Heavy Machinery* Inform patients that BUTRANS may impair the ability to perform potentially hazardous activities such as driving a car or operating heavy machinery. Advise patients not to perform such tasks until they know how they will react to the medication. *Constipation* Advise patients of the potential for severe constipation, including management instructions and when to seek medical attention. *Anaphylaxis* Inform patients that anaphylaxis has been reported with ingredients contained in BUTRANS. Advise patients how to recognize such a reaction and when to seek medical attention. *Pregnancy* Advise female patients that BUTRANS can cause fetal harm and to inform the prescriber if they are pregnant or plan to become pregnant.

Healthcare professionals can telephone Purdue Pharma's Medical Services Department (1-888-726-7535) for information on this product.

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Manufactured by: LTS Lohmann Therapie-Systeme AG, Andernach, Germany

U.S. Patent Numbers 5681413; 5804215; 6264980; 6315854; 6344211; RE41408; RE41489; RE41571.

This brief summary is based on Butrans Prescribing Information 303135-0A, Revised 07/2013

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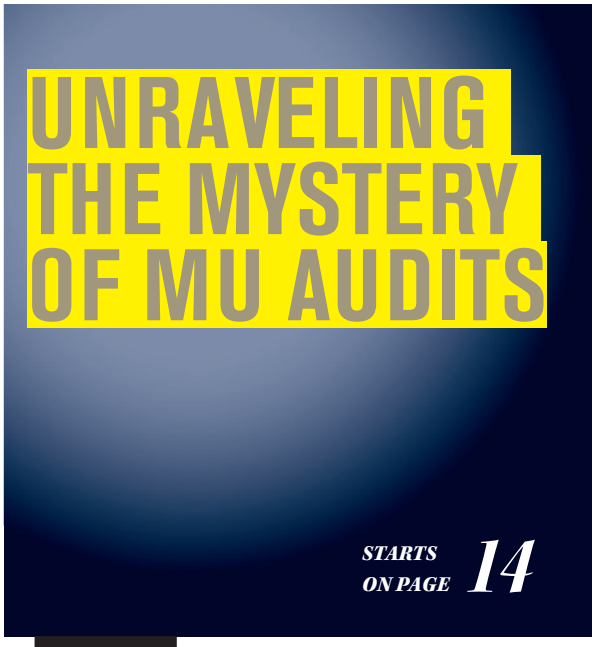

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—Judy Bee PRACTICE MANAGEMENT CONSULTANT

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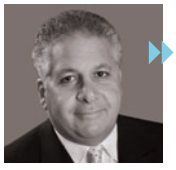

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from the Trenches

> I feel that these MOC requirements are not really making us better physicians. Rather, they are just another hurdle…for us to jump over. If you speak to any practicing physician, I don't think you will find any who believe that any of these activities make us better physicians, nor do they prove that we are providing up-to-date medical care.
>
> **Brigitta Moresea, MD,** CANTON, OHIO

MOC DOESN'T IMPROVE MEDICAL CARE

I was very interested to read the article about maintenance of certification (MOC) and its need to be abolished. ("MOC must go: One physician's viewpoint," January 25, 2014.) I am a pediatrician practicing in Ohio. I have been board certified since 1993. I have continued to go through the motions to stay board certified but with each new hurdle, I get more frustrated.

I recently had to retake my recertification exam and was completely dumbfounded. I took an on-line board review course and put in over 100 hours in to studying because I really had no idea what to expect. I truly felt well prepared but thought that a lot of the information I reviewed was not anything that a private practitioner did on a daily basis.

I took the test in November and was completely blown away. There was not a single question on general pediatric anticipatory guidance, something that I talk about at least 15 times a day. There was nothing on asthma management, atopic dermatitis, acne, or sleep problems. Instead, I had a multitude of esoteric questions as if I were an emergency physician, geneticist, or neonatologist. I was so disgusted after I took the test that I wrote a note to the American Board of Pediatrics stating my disappointment.

I feel that these MOC requirements are not really making us better physicians. Rather, they are just another hurdle (like we don't have enough) for us to jump over. If you speak to any practicing physician, I don't think you will find any who believe that any of these activities make us better physicians, nor do they prove that we are providing up-to-date medical care.

Brigitta Moresea, MD
CANTON, OHIO

MOC NOT NEEDED AS LONG AS CME IS MAINTAINED

I am 74 and have been in family medicine for over 45 years. I took my family physician boards for the first time in 1975, and passed them. I have taken my recertification exams 4 times since then, passing each time. I have kept up my CME as required, and even teach medical students.

My board certification expired in 2009. I did not take the exam again, since I felt that five times was enough. I also mistakenly thought that I would remain in a situation in case I ever decided to retake the exam. However, I see no need to do this at my stage of life, since I do not know how long I will continue practicing.

I have discovered that I am not considered board eligible, unless I complete three requirements, including one "self-assessment module," for $600. I do comply with the other two requirements. I feel this is grossly

> A nonprofit organization is allowed to generate surplus revenues above expenses as long as those revenues are used or saved for the purposes outline in the organization's application for not-for-profit status. The money saved by being tax-exempt can be legitimately used for the goals of the organization.
>
> **Marlene A. Harvey, DO,** WILLIAMSTOWN, MICHIGAN

unfair, and that I should be considered grandfathered as a board-certified family physician, or at least be granted an emeritus position. I feel the recertification process is nothing more than a way to make money, and should be done away with as long as continuing medical education requirements are maintained.

I have been offered a certificate, congratulating me for passing my boards five times, "suitable for framing." Just thought I would offer my opinion on the MOC situation.

Enrico J. DiRienzo, MD
PENNDEL, PENNSYLVANIA

MOC IS ALL BURDEN AND NO BENEFITS

I definitely oppose the MOC programs. They are just another burden imposed on physicians with no benefit to patients or physicians by an organization like many government agencies that put forth regulations to justify their existence.

David Hubler, MD
CEDAR HILL, TEXAS

MEANING OF 'NONPROFIT' IS MISUNDERSTOOD

Craig Wax, DO's letter about the tax-exempt status of many hospitals reveals a common misunderstanding of the term "nonprofit." ("Hospitals should not be exempt from taxes, January 10, 2014.) This status describes those entities who do not have shareholders or owners who receive profits or dividends from the revenues of the business.

A nonprofit organization is allowed to generate surplus revenues above expenses as long as those revenues are used or saved for the purposes outlined in the organization's application for not-for-profit status. The money saved by being tax-exempt can be legitimately used for the goals of the organization.

Marlene A. Harvey, DO
WILLIAMSTOWN, MICHIGAN

'HYBRID' PAYMENT SYSTEM SHOULD REDUCE COSTS

I thank Lee Morgentaler, DO for his comment that it is a constant struggle for him and all of us to get the maximum allowable fee paid ($60). Under the proposed "hybrid" physician payment formula, the 60% of the maximum allowable fee should be paid without hassle within 7 days.

I also agree that primary care physicians are in general underpaid. Since this hybrid system should save costs from diminishing the so-called 33% unnecessary follow-up visits, tests, procedures and surgeries, there should be a great savings. Most of it should go back to reimbursing primary care physicians through a more realistic fee schedule.

K.J. Lee, MD, FACS
NEW HAVEN, CONNECTICUT

TELL US

medec@advanstar.com

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

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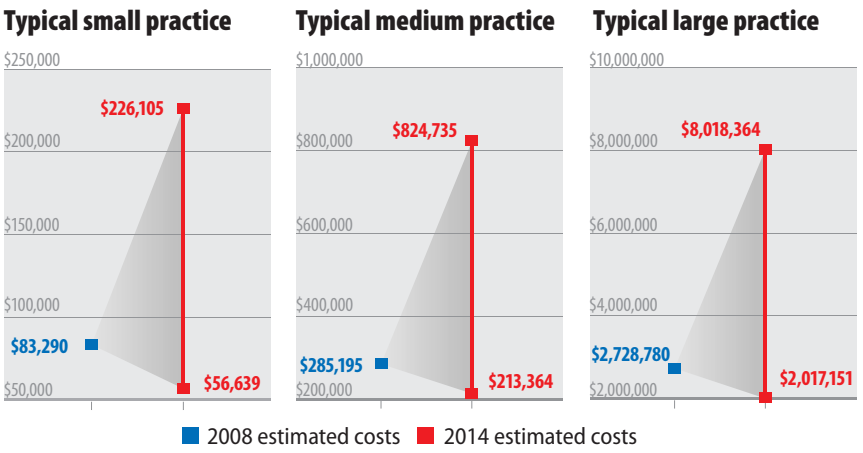
2015 EDITION EHR CRITERIA RELEASED

The Office of the National Coordinator for Health Information Technology (ONC) has issued proposals for the 2015 edition of electronic health record (EHR) certification criteria.

This is the first time ONC has proposed an edition of certification criteria separate from meaningful use regulations. Comments on the proposal will be accepted through April, and the final rule is expected in summer.

"The proposed 2015 Edition EHR certification criteria reflect ONC's commitment to incrementally improving interoperability and efficiently responding to stakeholder feedback," said Karen DeSalvo, MD, MPH, national coordinator for health IT.

Compliance with the 2015 edition would be voluntary. EHR developers that have certified EHR technology to the 2014 edition would not need to recertify to the 2015 Edition for customers to participate in meaningful use incentive programs. Healthcare providers would not need to upgrade to 2015 Edition software to attest to meaningful use.



Source: Nachimson Advisors, LLC Methodology: The practices sizes are hypothetical. A small practice is three physicians, a medium-sized practice is 10 physicians, and a large practice is 100 physicians.

STUDY: ICD-10 IMPLEMENTATION COSTS LIKELY MUCH HIGHER THAN PREVIOUSLY REPORTED

A new study from Nachimson Advisors updates the firm's landmark 2008 study on implementation costs for practices moving to International Classification of Diseases—10th Revision (ICD-10). The 2014 update provides cost ranges based on new information.

The report, commissioned by the American Medical Association, updates an oft-cited 2008 report detailing the cost of implementing ICD-10 in small, medium, and large medical practices.

Nachimson Advisors says in the report that "no actual implementation experience existed" when it published its 2008 estimates. This new report is based on "some real world experience documenting implementation costs."

"The results of our 2014 study demonstrate that costs to implement ICD-10 may be much higher than what was estimated in 2008, especially for physicians who must pay for upgrades to their electronic health record and practice management systems," the report reads.

The costs estimates in the new report are presented in a range. (See graphic.) The costs include both pre-implementation—including training, software upgrades, and testing—and post-implementation costs, such as productivity losses and payment disruptions.

Along with the report, the AMA has renewed calls to delay ICD-10 implementation, now set for October 1, 2014. The AMA wrote a letter to the U.S. Department of Health and Human Services outlining the hardships physicians are facing from ICD-10.

PRIMARY CARE SURVEY:

Docs focused on efficiency, emerging business models

A NEW SURVEY of American physicians show that the vast majority are struggling to engage their patients, cope with impacts of the Affordable Care Act (ACA) and deal with changing reimbursement models.

The national survey of family physicians and internal medicine doctors was conducted by Ipsos in April 2013 for Wolters Kluwer Health, a healthcare publishing firm.

The results show that 67% of the surveyed physicians believe the ACA is a "top contributor" to rising healthcare costs. Three out of five physicians say that uninsured patients are driving up costs.

Regarding healthcare technology, physicians said that progress is being made on electronic health records functionality, but that too little progress has been made in the areas of ease of use (56%), improving patient relationships (61%), and increasing efficiency (66%).

The surveyed physicians top focus in the next three to five years is: Increasing their practice efficiency (48%); exploring different business models, including joining a hospital system or a Patient-Centered Medical Home (34%); and adopting technology to help with evidence-based decision making (34%).

A striking finding is that 33% say they are likely to leave the practice of medicine in the next year or two. The top reasons? They said it's difficult to make their practice profitable and the field of medicine is no longer rewarding to them.

The survey is a bi-annual survey first conducted in 2011. More than 300 primary care physicians were surveyed from a national sample.

Top challenges reported by U.S. physicians:

91%	Managing shifting reimbursement models with payers
90%	Financial management of their practices
88%	Patient engagement; spending time with patients
84%	Dealing with the impacts of the Affordable Care Act
83%	Keeping up with the latest research
78%	Improving patient care
77%	Using health information technology in the practice
73%	Managing increasing patient volumes

Source: Wolters Kluwer Health, 2013 Physician Outlook Survey

NIH, PHARMA FORM COALITION TO SEARCH FOR NEW THERAPIES

The National Institutes of Health (NIH), Food and Drug Administration, 10 biopharmaceutical companies, the Pharmaceutical Research and Manufacturers of America, and several nonprofit organizations have launched an unprecedented public/private partnership to "transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets of disease," the NIH said in a statement.

The goal of the Accelerating Medicines Partnership (AMP) is to note the "molecular indicators of disease," known as biomarkers, and to determine which diseases would be the best targets for research into new treatments, being the most likely to respond. The undertaking will begin with 3- to 5-year pilot projects in three disease areas: Alzheimer's disease, type 2 diabetes, and the autoimmune disorders of rheumatoid arthritis and lupus.

The AMP partners have developed research plans and are sharing costs, expertise, and $230 million under an organization intended to elicit the contributions of each team member.

Doctor's Bag

The latest in drugs, devices, technology, and more

FDA APPROVES TREATMENT FOR CHRONIC LYMPHOCYTIC LEUKEMIA

The U.S. Food and Drug Administration (FDA) has expanded the use of ibrutinib (Imbruvica) for chronic lymphocytic leukemia (CLL) patients who have had at least one previous therapy. Imbruvica blocks the enzyme that allows cancer cells to grow and divide. In November 2013, the FDA granted Imbruvica accelerated approval to treat mantle cell lymphoma if patients had received one prior therapy.

Imbruvica for CLL also received priority review and orphan-product designation because the drug demonstrated the potential to be a significant improvement in safety or effectiveness in the treatment of a serious condition and is intended to treat a rare disease, respectively.

FDA's accelerated approval of Imbruvica for CLL is based on a clinical study of 48 previously treated participants. Nearly 58% of participants had their cancer shrink after treatment, results showed.

In the clinical study, common side effects observed include thrombocytopenia, diarrhea, bruising, neutropenia, anemia, upper respiratory tract infection, fatigue, musculoskeletal pain, rash, pyrexia, constipation, peripheral edema, arthralgia, nausea, stomatitis, sinusitis and dizziness.

Pharmacyclics 1 (408) 774-0330 | www.pharmacyclics.com/imbruvica.html

FDA APPROVES THREE-TIMES-A-WEEK COPAXONE

The FDA has approved a supplemental new drug application (sNDA) for three-times-a-week COPAXONE 40mg/mL, a new dose of COPAXONE. This new formulation will allow for a less frequent dosing regimen administered subcutaneously for patients with relapsing forms of multiple sclerosis (MS). Daily COPAXONE 20 mg/mL will continue to be available.

The approval is based on a study of more than 1,400 patients, which showed that a 40 mg/mL dose of COPAXONE administered subcutaneously three times per week significantly reduced relapse rates at 12 months and demonstrated a favorable safety and tolerability profile in patients with relapsing-remitting MS.

Three-times-a-week COPAXONE 40mg/mL is available for shipping to distribution outlets. Teva's Shared Solutions provides free injection training and ongoing compliance and adherence support services.

Teva Pharmaceutical Industries, Ltd. www.tevapharm.com

TWO NEW POINT-OF-CARE INNOVATIONS

athenahealth, Inc., a provider of cloud-based services for electronic health records (EHRs), practice management, and care coordination, and Epocrates, developer of medical applications for physicians, have announced two point-of-care innovations to improve providers' access to information during care.

Key drug monograph content from Epocrates Rx will be available as part of athenaClinicals. Providers using it will gain streamlined access to information on dosing, contraindications, adverse reactions, and other safety information for brand and generic drugs without having to leave their EHR interface.

Epocrates' upgraded InteractionCheck features a new Drug Interaction Overview section. Providers can access profiles of a drug's interaction potential and risks. These features are exclusively found in the Epocrates mobile app or on Epocrates Online.

athenahealth, Inc.
Epocrates, Inc.

www.athenahealth.com/innovation

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A new class action settlement with Baxter will provide payments to distributors and healthcare providers who purchased IG or albumin directly from Baxter or CSL.

A $64 million settlement has been reached with Baxter International Inc. and Baxter Healthcare Corporation (collectively, "Baxter") in a lawsuit about whether manufacturers of IG and albumin unlawfully agreed to restrict output and to fix, raise, maintain, or stabilize prices. Baxter denies all of these claims and says that it did nothing wrong.

IG (or "immunoglobulin") and albumin are plasma-derivative protein therapies used by hospitals and other healthcare providers in the treatment of certain illnesses.

TWO SEPARATE SETTLEMENTS.

This Baxter settlement is separate from a prior settlement with CSL Limited, CSL Behring LLC, and CSL Plasma Inc. (collectively, "CSL") along with a trade association called Plasma Protein Therapeutics Association ("PPTA"). Even if you previously participated in the settlement with CSL and PPTA, you have separate legal rights and options in this new settlement with Baxter.

WHO IS INCLUDED?

The Court decided that the Settlement Class includes all distributors, hospitals and other healthcare providers in the United States, who purchased IG and/or albumin directly from Baxter or CSL, at any time from January 1, 2005 through December 31, 2009.

WHAT DOES THE SETTLEMENT PROVIDE?

Each Settlement Class Member who submits a valid Claim Form will receive a payment based on the total dollar amount of its purchases of IG and/or albumin in the United States, including its territories, directly from Baxter and CSL between January 1, 2005 and December 31, 2009.

HOW DO YOU ASK FOR A PAYMENT?

To receive a payment you must submit a Claim Form by **April 7, 2014**. Claim Forms have been mailed to Settlement Class Members who are known to Baxter and CSL. The Claim Form is also available at the website or by calling 1-866-287-0504.

Even if you submitted a claim in the settlement with CSL and PPTA, you will not receive a payment from the Baxter settlement unless you submit a Baxter claim. If you want to receive payments from both settlements, two separate claims must be submitted.

YOUR OTHER OPTIONS.

If you do not want to be legally bound by the settlement, you must exclude yourself from the Settlement Class by **March 3, 2014**, or you will not be able to sue, or continue to sue, Baxter about the legal claims this settlement resolves, ever again. If you exclude yourself, you cannot get a payment from the settlement. Also, if you previously requested exclusion from the settlement with CSL and PPTA, you must submit a separate exclusion request to be excluded from the Baxter settlement. If you stay in the settlement, you may object to it by **March 31, 2014**. A Detailed Notice available at the website or by calling 1-866-287-0504 explains how to exclude yourself or object and has more information about the settlement.

The United States District Court for the Northern District of Illinois will hold a hearing in the case, known as *In re: Plasma-Derivative Protein Therapies Antitrust Litigation*, Case No. 09-CV-7666, on April 16, 2014, to consider whether to approve the settlement, and a request by Plaintiffs' Counsel for attorney fees of $21.33 million and payments of $50,000 to the Class Representatives. You or your own lawyer, if you have one, may ask to appear and speak at the hearing at your own cost, but you do not have to.

UNRAVELING THE MYSTERY OF MU AUDITS

7 strategies to protect your practice

by **PAMELA LEWIS DOLAN** *Contributing author*

As of December 2013, the Centers for Medicare and Medicaid Services (CMS) had doled out more than $19 billion in meaningful use incentive payments. As the agency inches closer to its $27 billion budget, there's evidence that it's increasing its auditing activities. Physicians should assume they will be audited, and prepare accordingly.

HIGHLIGHTS

01 Auditors are looking for discrepancies between what was submitted during the attestation process and what was actually done.

02 Physicians must have proof a security risk assessment was conducted and a corrective action plan has been drafted. Experts say this is one of the requirements that trips up physicians.

CMS AND Figliozzi and Co., the Garden City, New York, accounting firm contracted to facilitate the Medicare meaningful use auditing program, have not reported the number of audits that have been conducted. But many close to the auditing process say they have seen evidence of audits increasing in frequency in recent months—and that some physicians are not prepared when the auditors come calling.

"Medicare is not going to make us aware of why, neither is Figliozzi," says David Zetter, founder of Zetter HealthCare, a Mechanicsburg, Pennsylvania-based healthcare consulting firm, and a member of the National Society of Certified Healthcare Business Consultants. He adds that, in his experience, some physicians just "aren't doing what they attested to do."

Attorney Clinton Mikel, JD, says he has also seen anecdotal evidence that audits are occurring more frequently. "From a policy perspective, it makes sense that [audits are] increasing because it is such a hot focus area and, frankly, it's a way to recoup money," says Mikel, who is a partner at the health law firm The Health Law Partners.

Medical Economics sought to contact officials at CMS and Figliozzi on meaningful use audits and whether they are increasing in frequency. CMS would not provide data on the number of audits that have been conducted. Peter J. Figliozzi, CPA, managing partner of Figliozzi and Co., said his firm is "precluded by CMS from disclosing any information."

The Health Information Technology for Economic and Clinical Health Act portion

Meaningful Use audit: Documentation request list

When auditors come to your practice seeking information on your meaningful use attestation, they will provide you with a form similar to this, explaining specifically what documentation they need your practice to provide.

PART I - GENERAL INFORMATION	
1	As proof of possession of a Certified Electronic Health Record Technology (CEHRT) system, provide a copy of your licensing agreement with the vendor or invoices. Please ensure that the licensing agreements or invoices are for the product and version of the CEHRT system utilized during your attestation period.
2	Please provide a response to the following questions: **a.** At how many offices or other outpatient facilities do you see your patients? **b.** Please list each office or other outpatient facility where you see patients and indicate whether or not you utilize Certified Electronic Health Record Technology (CEHRT) in each office or other outpatient facility. **c.** If you utilize more than one office or other outpatient facility, please supply documentation which proves that 50% or more of your patient encounters during the EHR reporting period have been seen in offices or outpatient facilities where you utilize a CEHRT system. **d.** Do you maintain any patient medical records outside of your CEHRT system? **e.** If yes, please supply documentation proving that more than 80% of the medical records of unique patients seen during the attestation period are maintained in a CEHRT system at each office or other outpatient facility where a CEHRT system is being used.
PART II - CORE AND MENU SET OBJECTIVES / MEASURES	
3	Provide the supporting documentation (in either paper or electronic format) used in the completion of the Attestation Module responses (i.e. a report from your EHR system that ties to your attestation). **Please Note:** If you are providing a summary report from your EHR system as support for your numerators/ denominators, please ensure that we can identify that the report has actually been generated by your EHR (i.e. your EHR logo is displayed on the report, or step by step screenshots which demonstrate how the report is generated by your EHR are provided.) To support YES/NO attestation measures, please supply documentation such as screenshots from your EHR system.

Source: Centers for Medicare and Medicaid Services

of the 2009 stimulus law, which created the meaningful use program, requires CMS to audit participants in the meaningful use program. It tapped Figliozzi to conduct them. Audits for the Medicaid incentive program are carried out by each state.

Post-payment audits began in 2011, when the meaningful use program began. In November 2012, U.S. Department of Health and Human Services' (HHS) Office of Inspector General published a report criticizing CMS for not doing enough to prevent improper payments. The report recommended that CMS conduct prepayment audits to verify attestation documents.

"Doing so would strengthen [CMS] oversight of the anticipated $6.6 billion in incentive payments," the report stated, referring to CMS' estimate of incentive amounts to be paid out between 2011 and 2016. "Verifying

"FROM A POLICY PERSPECTIVE, IT MAKES SENSE THAT [AUDITS ARE] INCREASING BECAUSE IT IS SUCH A HOT FOCUS AREA AND, FRANKLY, IT'S A WAY TO RECOUP MONEY."

— CLINTON MIKEL, JD, THE HEALTH LAW PARTNERS.

self-reported information prior to payment could also reduce the need to identify and recover erroneous payments after they are made."

CMS Administrator Marilyn Tavenner initially rejected the idea of prepayment audits, saying they would delay payments and create a burden. Despite the initial response, CMS instructed Figliozzi to begin conducting prepayment audits in 2013, to be performed in addition to post-payment audits.

These seven strategies will help ensure a smooth audit that ends with a positive result for your practice.

NO. 1: ASSUME YOU'LL BE AUDITED

The best thing a physician can do to ensure an audit goes well is assume they will be audited before they attest and prepare for it.

Lynn Grigsby, MSIS, MBA, the meaningful use services manager at the Kentucky Regional Extension Center, says she gives eligible professionals a list of documents they should retain, which are the same documents the auditors will ask for.

They essentially perform a pre-audit and keep those records on file, Grigsby says.

"That way if they are ever audited, they have everything in one spot and it doesn't take much time," she explains.

Because some physicians are chosen for audits at random, there is no way to completely eliminate the possibility of being audited.

"However, by verifying the physician meets the specific requirements for meaningful use program participation ... and keeping records of the registration/attestation processes and documentation—for at least 6 years—the physician will have a solid foundation for responding to the audit," says Laura Kreofsky, principal of Impact Advisors, a Naperville, Ill.-based consulting firm.

NO. 2: HANDLE AUDIT PROMPTLY

Complying with the demands of an audit means accomplishing a long list of tasks. But there are also things physicians should avoid doing. Getting angry at the auditors tops the list of Daniel Gottlieb, JD, partner in the Chicago-based law firm McDermott Will & Emery LLP.

"It's obviously not helpful. Our experience has been that CMS actually wants to pay out the money," Gottlieb says. "They want to encourage EHR use. And, keep in mind that the incentive program was part of the stimulus bill. So if the money is not paid out, it's not stimulative."

It's also important to respond right away after receiving an audit letter, Mikel says. Getting the necessary documents in order can be a time-consuming process. Auditors generally allow 14 days to respond to an audit notice.

Mikel also advises physicians not to engage the auditors on their own, outside of the document exchange. Often, physicians mistakenly believe that information presented during an offline exchange with the auditors satisfied a particular request; then they get penalized for failing to send the required documentation.

Many also make the mistake of responding to certain document requests with only a statement, according to Gottlieb.

"Auditors love screen shots," he says. "If all the provider responds with is a simple statement that, 'We did X, Y, and Z,' that is not going to be adequate."

NO. 3: PHYSICIANS TAKE CHARGE

Many small practices leave the legwork of meaningful use to practice managers. Zetter says while it is good to have some level of trust in the practice manager or whomever is in charge of the legwork, it's always smart for physicians to

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➔16 verify for themselves that the work is being done and not simply assume.

"If you don't, that's blind assumption. And you are taking a big chance and putting yourself at risk, as well as your entity, your corporation, whatever the case may be, and that's not very smart nowadays," Zetter says.

NO. 4: AVOID DISCREPANCIES

The auditors are looking for discrepancies between what was submitted during the attestation process and what was actually done, Grigsby says.

Practices know they are being audited when they receive an e-mailed letter from Figliozzi alerting them to the audit. Attached to that letter will be a document request list. (See table "Meaningful use audit: Documentation request list" on page 15.) The process is the same for both prepayment and postpayment audits. Every physician who is

Elements of a risk assessment

A risk assessment is required for compliance with the HIPAA Security Rule, and is a major piece of any meaningful use audit. Here is an outline of the assessment process.

1 Scope of the analysis
The scope of the risk assessment includes the potential risks and vulnerabilities to the confidentiality, availability, and integrity of all electronic protected health information (EPHI) that an organization creates, receives, maintains, or transmits.

2 Data collection
An organization must identify where the EPHI is stored, received, maintained, or transmitted.

3 Identify and document potential threats and vulnerabilities
Organizations must identify and document reasonably anticipated threats to EPHI.

4 Assess current security measures
Document the security measures your practice uses to safeguard EPHI, whether security measures required by the Security Rule are already in place, and if current security measures are configured and used properly.

5 Determine the likelihood of threat occurrence
Practices must document all threat and vulnerability combinations—with associated likelihood estimates—that may impact the confidentiality, availability, and integrity of EPHI within an organization.

6 Determine potential impact of threat occurrence
An organization must assess the magnitude of the potential impact resulting from a threat triggering or exploiting a specific vulnerability. This should include documentation of all potential impacts associated with the occurrence of threats triggering or exploiting vulnerabilities that affect the confidentiality, availability, and integrity of e-PHI within an organization.

7 Determine the level of risk
Organizations should assign risk levels for all threat and vulnerability combinations identified during the risk analysis.

8 Finalize documentation
The Security Rule requires the risk analysis to be documented but does not require a specific format.

9 Periodic review and updates
The risk analysis process should be ongoing. In order for an entity to update and document its security measures "as needed," which the Rule requires, it should conduct continuous risk analyses to identify when updates are needed. Some organizations perform these processes biannually, annually, or every three years.

Source: U.S. Department of Health and Human Services

Because some physicians are chosen at random, there is no way to completely eliminate the possibility of being selected for an audit.

audited must produce the same documents, which fall into these three categories:

- **Proof that the EHR system used to meet meaningful use requirements is certified.**
- **Documentation that quality measure, core, and menu objective data were accurate.**
- **Proof a security risk assessment was conducted and a corrective action plan has been drafted.**

NO. 5: ENSURE EHR CERTIFICATION

To satisfy the certification requirements, physicians will need documentation from their vendors confirming the version of the EHR system they are using. Some vendors may have older versions of their EHRs that are not certified. A list of certified EHR products is kept on the Office of the National Coordinator's website. Physicians should monitor any upgrades to their systems to ensure that changes don't affect the certification status, Gottlieb says.

NO. 6: DOCUMENTATION IS KEY

"Above all, it is critical physicians have an auditable source for all data used for registering and attesting to meaningful use," Kreofsky says. "This not only includes the data presented on the meaningful use reports generated by the EHR, but evidence of all 'yes/no' objectives."

Objectives requiring the generation of reports that include numerators and denominators must include supporting documentation showing the denominator is accurate and a report showing the numerator met the required threshold. Cross referencing with practice management system patient population data may be necessary to show the denominator is accurate.

The yes/no objectives relate to functionality that is turned on during the duration of the reporting period. Kreofsky says doctors can accomplish this by printing dated screen shots from their EHRs showing the function was turned on during the reporting period.

Because eligible professionals only need to show that certain functions were turned on, not actually used, Gottlieb says it's important to check multiple times throughout the reporting period that those functions are, in fact, turned on. He had a hospital client that had to return its incentive bonus when an audit revealed someone in the information technology department had turned a certain function off by accident. Because it was a function that was not used, it went unnoticed.

NO. 7: COMPLETE A SECURITY RISK ASSESSMENT

Experts agree the security risk assessment is one of the requirements that trip up many physicians. (See sidebar "Elements of a risk assessment," page 18.)

A risk analysis is something all physician practices should have had in place since 2005, when the Health Insurance Portability and Accountability Act (HIPAA) Security Rule went into effect. Yet it's a concept many are still not familiar with, says Zetter.

"I know some clients that we have followed up on after the fact come in stating they need assistance, and we find out they blatantly lied about it," he says, adding that the client attested to having had done a risk assessment only to later admit they didn't know what it was.

Neglecting the risk assessment can not only place physicians at risk of paying back incentive money, but they also risk a penalty from the U.S. Department of Health and Human Service's Office for Civil Rights for not being in compliance with HIPAA, says Gottlieb.

Mikel agrees the risk assessment is one of the most difficult requirements for physicians to understand and to comply with because it is an ever-evolving document.

Each time a change is made in the practice, or new technology is adopted, the risk assessment must specifically address it. He has seen auditors rule that a risk assessment is invalid because it did not specifically name the brand of EHR being used.

Managing transitions of care

Effective care transition management is a key to achieving value-based care for your patients

by **ELIZABETH W. WOODCOCK, MBA, FACMPE, CPC,**
and **DEBORAH WALKER KEEGAN, PHD, FACMPE,** *Contributing authors*

HIGHLIGHTS

01 Develop a timeline that runs from when a patient referral is made to the appointment day. Don't forget to include adequate time for your staff to process the referring physician's data.

02 Identify the key facilities in the community that your patients use for care. Approach each of these facilities to discuss patient care hand-offs — both their needs and yours.

03 Two new Current Procedural Terminology (CPT) codes were introduced in 2013 to cover transitional care management (TCM).

While it is easy to feel powerless during care transitions and difficult to influence the processes and handoffs taking place outside your practice's walls, don't despair: You can build a rigorous transition of care process that can make a difference in how your practice operates. ▸▸

▸▸ **IDEALLY, A CARE TRANSITION** is a value-based, patient-centric event that does not disrupt the continuity of care.

Unfortunately, the process of moving patients from one setting to another, or transferring their care between providers, is an uncertain process. All too often delays, disruptions, and miscommunications lead to confusion, unnecessary costs and care, and, ultimately a great deal of frustration for patients and physicians alike.

The most frequent pitfalls in the transition process are:

- poor communication between facilities and providers;
- insufficient engagement in the transition process by patients and caregivers; and
- failure by the local medical community to demand and clearly designate strict accountability for managing the transition.

Here are steps your practice can take to improve care transitions for your patients.

1/ Formalize your inbound patient referral process

Your electronic health record (EHR) may have tools to help communicate information you want to know about a new or referred patient, but

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> Care transitions can be an opportunity for you and your practice's care team to find common goals with the other physicians and facilities that also provide care to your patients."

5 keys to managing transitions of care

1 Formalize your inbound patient access

Your practice will need to create a predictable process for handling the transition of patients among care settings. This can be facilitated by managing the process through follow-up communication alerts to physicians and patients, timelines, and processes to capture provider notes.

2 Focus on logistics

Understand how information flows outside of your practice. Identify the key facilities and contacts. Address patient care handoffs, and provide a telephone number or a secure, web-based email box for physicians, the hospital's case managers, or discharge planning team.

3 Get paid for the work

Two transitional care Current Procedural Terminology codes were introduced in 2013: 99495 and 99496. Use them to reimburse for your time/services, and pay attention to what services may be performed by licensed clinical staff under the direction of a physician.

4 Set up new ways to collaborate

Care transitions can be an opportunity to better communicate with patients and other providers. Use this as an opportunity to educate patients about the care plan, instructions related to follow-up care, and appropriate contacts during the transition.

5 Focus on stopping hospital readmissions

One in five patients discharged from a hospital experience an adverse event within 3 weeks of discharge. To help stop hospital readmissions, pay special attention to high-risk patients (chronic obstructive pulmonary disease or congestive heart failure) and those with "ambulatory-sensitive conditions" that can be managed in an outpatient setting (diabetes, asthma).

➔20 don't expect any system to perform the whole job by itself.

List the information you need to manage the care of patients you accept from other providers. If your EHR doesn't provide an electronic consult request form, create one. Make sure that the form is in a format the transferring facility or provider can easily view, such as a text file or Excel spreadsheet. Even a hard copy printout will work. Design it in the form of a checklist of all critical elements—patient history, records, medications, and other information—that you want on hand either before or during the patient's visit. If you want patients or referring providers to send more information, make sure to also tell them when you need the data.

Develop a timeline that runs from when a patient referral is made to the appointment day. Don't forget to include adequate time for your staff to process the referring physician's data if it is not in a format that can be transferred directly into your EHR.

The time you spend to establish standard protocols for the transition of patients from other settings into your practice will be well

> "Your electronic health record (EHR) may have tools to help communicate data you want to know about a new or referred patient, but don't expect any system to perform the whole job by itself."

worth it to you, your patients, and your support staff.

2/ Focus on the logistics of external referrals

When you refer patients for care outside of your office walls, focus on the logistics. How does the information travel from your practice to the physicians, hospitals, or those other resources involved in your patient's care? Importantly, understand the information that the other provider or facility has requested to always receive—hold staff accountable for always including that information when a patient's records and treatment plan are transferred.

Likewise, develop processes to ensure that your practice's contact at the receiving institution knows what information you want regarding your patient's condition and the current course of his or her care, and when you need it.

Assign and accept accountability. Identify the key facilities in the community that your patients use for care. Approach each of these facilities to discuss patient care hand-offs—both their needs and yours. For example, if you refer a patient for a magnetic resonance imaging procedure, determine:

- what the imaging center needs from you in order to make the patient's appointment;
- how soon the patient can be scheduled for an appointment;
- how and when the information — the image and accompanying interpretation, in this case — will be sent to your practice;
- what the staff at that facility likely tell your patient about when and how the results will be reported to the patient; and
- who is responsible for getting in touch with you and what the protocols are for the communication of critical results

Provide a telephone number or a secure, web-based email box for physicians, the hospital's case managers, or discharge planning team members to reach you.

You may want to know about the facility's internal handoffs of care during your patient's stay, or just to learn of certain major events. This direct channel helps to avoid delays, and, importantly, prevent no-shows when a follow-up visit is to be scheduled with you.

Many medical practices establish a protocol for their nursing staff to call all newly discharged or transferred patients within 48 hours after the discharge. This valuable contact can clarify follow-up on care instructions, detect complications and, often, get a general sense of the patient's immediate well-being.

3/ Get paid

Streamlining the transition of care need not be an unreimbursed expense to your practice.

In 2013, two new Current Procedural Terminology (CPT) codes were introduced to cover transitional care management (TCM). The new codes are selected based on the complexity of the patient.

Importantly, the codes require you to communicate with the patient and/or caregiver (through direct contact, telephone, or electronically) within two business days of the patient's discharge, and conduct a face-to-face visit within seven to 14 days post-discharge, depending on the patient's complexity level.

Select the proper CPT code based on the level of medical decision-making and the timing of the face-to-face visit. The codes and descriptions are:

99495: Transitional care management services: Communication (direct contact, telephone, or electronic) with the patient and/or caregiver within two business days of discharge;

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> It's no longer adequate to wait and hope that the patient absorbs the "right" information to keep him or her healthy; engage with providers and caregivers across the care continuum to ensure that care transitions are managed effectively.

➔22 medical decision making of at least moderate complexity during the service period; and a face-to-face visit within 14 calendar days of discharge.

99496: Includes the above, and medical decision-making of high complexity and a face-to-face visit within seven calendar days of discharge.

Pay attention to what services may be performed by licensed clinical staff under the direction of the physician or other qualified health care professional. These include:

- communication (direct contact, telephone, electronic) with the patient and/or caregiver regarding aspects of care;
- communication with home health agencies and other community services utilized by the patient;
- Education of the patient and/or family/ caretaker to support self-management, independent living and activities of daily living;
- Assessment and support for treatment regimen adherence and medication management;
- Identification of available community and health resources
- Facilitating access to care and services needed by the patient and/or family.

The codes are billable at the end of the 30-day period, can be used by only one physician or provider, and may be reported only once during the 30-day period, even if the patient is re-admitted.

While any physician or other qualified healthcare professional may use both the discharge code and appropriate TCM code, a TCM code cannot be used by a physician who also reports a service to the patient within a global period of 10 or 90 days.

4/ Collaborate

Care transitions can be an opportunity for you and your practice's care team to find common goals with the other physicians and facilities that provide care to your patients.

These goals can include:

- educating patients about the care plan and the signs of a worsening condition,
- offering patients clear instructions about follow-up care, and
- identifying the resources the patient should contact with questions and concerns.

While you probably won't be at patients' bedsides when they are discharged, you'd still like to know what discharging physicians and facility staff communicate to the patients and their caregivers.

Look also to how the care team provides the information to the patient. Do instructions and other knowledge come in multiple formats such as printed hard copies, web-based information, and/or instructional videos? Do those materials seem like they would be understandable and engaging to your average patient and his or her caregivers?

It's no longer adequate to wait and hope that the patient absorbs the "right" information to keep him or her healthy; engage with providers and caregivers across the care continuum to ensure that care transitions are managed effectively.

5/ Improve performance

Hospital readmissions are prime targets for the outcomes improvement and cost containment efforts of Medicare and many other public and private insurers.

One in five patients discharged from the hospital to home experiences an adverse event—an injury related to medical management, not the underlying disease— within three weeks of discharge. Researchers also concluded that 66% of these events were drug-related adverse events, many of which could have been avoided or mitigated.

Whether or not bundled payment or other new reimbursement strategies have taken hold in your market, you still have much to gain by working with your local hospital to reduce the frequency of readmissions by your patients.

Efforts to reduce hospital readmissions through better care coordination among providers often target specific types of patients, such as those with ambulatory-sensitive conditions that can be optimally managed in the outpatient setting (such as diabetes or asthma), or patients who are at high risk (such as patients with chronic obstructive pulmonary disease or congestive heart failure).

6/ Focus on prevention

Learn about your own readmissions before

investing in more prevention techniques such as care and case outreach, 24-hour nurse triage hotlines to answer patients' questions, and patient education materials that are appropriate to the patient's education level, language, and culture.

Those all have potential, but first, look for patterns in your readmitted patients. Key points to determine and assess are the readmitted patient's diagnosis, last visit date with your practice, and most recent communication with your practice—even the time of day and day of the week.

Once you have your data, look for opportunities to prevent future readmissions. After addressing the communication roadblocks or accountability failures within your practice, look for opportunities to collaborate with other providers in the community. Addressing these barriers creates value for patients, and the healthcare system.

7/ Form a Patient-centered Medical Home

To take the effort a giant step further, primary care and other types of medical practices are eying the medical home concept.

Studies indicate that a relationship with a medical home is associated with better health, on both the individual and population levels, with lower overall costs of care and with reductions in health disparities between disadvantaged and more socially advantaged populations.

The medical home's focus on patient advocacy can provide the attention needed to smooth transitions of care. Even if your practice chooses not to seek formal recognition as a medical home, the medical home concept provides food for thought and, possibly, a lead on changes you can make within your practice to improve the care transition process.

The next step in care transitions: The Patient-Centered Medical Home (PCMH)

Here are four ways your practice can move towards the PCMH model and improve care transitions for your patients.

1. Review operating principles

Practices seeking to become a PCMH must change their operations to fit with the Patient Centered Primary Care Collaborative's Joint Principles of the PCMH. That includes rules for patient relationships with physicians, care coordination, and exchange of health records. An electronic health record (EHR) system is vital. More information can be found at: www.pcpcc.net/joint-principles

2. Select a care coordinator

A PCMH requires a patient care coordinator to oversee the process, someone who is computer-savvy and empathetic. It's about population management.

3. Consider seeking recognition

Although an official stamp of approval isn't required for practices to brand themselves as PCMHs, formal recognition has many benefits. Most medical homes recognized by the National Committee for Quality Assurance (NCQA) receive financial rewards from Medicaid or private payers.

4. Communicate with patients

Practices should reach out to patients when they begin their PCMH transformation. Patient engagement is critical to the success of the venture.

Consider including patients in your redesign plans, because their insights can help you evaluate workflow and improve the patient experience.

Read more *Medical Economics* coverage of PCMHs at: http://bit.ly/McG4GZ

Practical Matters

4 WAYS TO PROTECT YOUR PRACTICE'S SCHEDULE AGAINST EMERGENCIES

by **JUDY BEE** *Contributing author*

There are many ways a doctor's schedule can get derailed — an expecting mother is ready to deliver her baby, a patient in respiratory distress needs immediate attention, or there is an influx of patients with influenza requesting to see a doctor. Do you have a scheduling disaster plan?

PRACTICES THAT make an effort to learn from their own schedule experiences do a much better job of booking appointments that reflect reality. Here are four ways to help your practice keep its schedule on track. Will these tactics make every day run smoothly? No. Remember, your service will not improve if you don't take a realistic approach to scheduling.

Calculate the doctor's rate

A doctor who says she wants to see four patients an hour, but who can only see three per hour, will be an hour behind schedule by noon. Time the doctor from the first scheduled appointment start time until she's finished with the last patient, and divide the time by the number of patients.

Do this every day, and keep a record to determine the average number of patients you can reasonably count on treating.

Track work-ins

Each day, have the check-in person tally and record the number of patients scheduled before the day starts, the number of patients that actually show up, the number of patient appointments scheduled the same day as work-ins, and the number of patients rescheduled by the practice due to an emergency that takes the physician out of the office. Do this every day so that you have some facts (and not just the doctor's optimism) to work with.

Build a schedule disaster plan

For example, at an OB/GYN practice where the solo physician did all her own deliveries, the data showed she was called out of the office about 1.5 times per week.

That inconvenienced the 10 patients who were scheduled simultaneously with the delivery and impacted her schedule for the rest of the day. She was scheduled so tight into the future that there was no space available to move patients that preferred to reschedule.

The solution: Save Thursday afternoon for "open" space to reschedule patients affected by the interruption.

Then if there are open Thursday time-slots by late Tuesday, then make them available for all patients.

Include in-office emergencies

Often there are patients who are too sick to wait until the next day to be seen—that's an office emergency. If they can wait a couple of days, it's an urgency. Your historical data will identify your busiest days—usually Monday and Friday.

Don't schedule routine physicals or in-office procedures on Monday. Leave open spaces in the afternoon so that you can offer same-day service.

Keep Fridays light. A patient who can wait a day on Friday could flare into an after-hours emergency over the weekend. If your history tells you Wednesdays and Thursdays are the lowest in same-day demand, load up your schedule with longer appointments those days.

Monitor your activity and note the number of same-day calls. Adjust open spaces daily based on no shows and cancellations.

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

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Legally Speaking

THE SUNSHINE ACT: HOW TO ENSURE THE ACCURACY OF YOUR DISCLOSURES

by **GREGORY R. SMITH, JD** *Contributing author*

The Physician Payment Sunshine Act (the Sunshine Act) was enacted as part of the Patient Protection and Affordable Care Act. Designed to increase the transparency of financial relationships in the healthcare industry, the Sunshine Act requires the collection and reporting of certain financial transactions to the Centers for Medicare and Medicaid Services (CMS).

PHYSICIANS ARE not required to register with CMS or to send them any information.

Generally, manufacturers and applicable group purchasing organizations (GPOs) are required to submit annual reports to CMS on or before March 31.

For 2013 only, CMS has announced that it would collect data in two phases. Phase I began February 18, 2014, and ends March 31, 2014. During this time, manufacturers and GPOs will submit corporate profile information and aggregate payment data.

Phase II begins in May 2014. Manufacturers and GPOs will register for the Open Payments system, submit "detailed 2013 payment data," and attest to the accuracy of the data. Both phases will be completed by August 1, 2014, at which time physicians will be able to review the data and correct inaccuracies.

After the data has been reported to CMS, but before it is made public, physicians will have 45 days to review the information and work with the applicable manufacturers and GPOs to make corrections. After the initial 45-day period, applicable manufacturers and GPOs will have an additional 15 days to submit corrections based on any disputes. If the dispute cannot be resolved, CMS will publish the information and mark it as disputed. The parties should continue to try resolving the dispute.

Physicians should keep track of payments received from applicable manufacturers and GPOs, and dispute inaccurate data promptly. Consumers are becoming increasingly savvy about researching their healthcare providers, and it is important that physicians ensure the accuracy of any information that could potentially affect their practice. ◘

A physician's checklist

To ensure that CMS receives accurate information about financial transactions in which they are involved, physicians should take the following steps:

- ☑ **Keep documentation of all payments and other transfers of value received from applicable manufacturers and GPOs, as well as documentation of ownership and investment interests.**
- ☑ **To facilitate payment tracking, CMS has developed free mobile apps to track payments and other transfers of value made throughout the year. The Open Payment app may be downloaded from the iTunes or Google Play store.**
- ☑ **Register with CMS' Open Payments system and subscribe to the CMS listserve to receive program updates.**
- ☑ **Review all information reported about your ownership and investment interests in, and financial relationships with, manufacturers and GPOs.**
- ☑ **Work with the reporting entities to correct errors promptly.**

Gregory R. Smith, JD, *is a partner at Garfunkel Wild, P.C. in Great Neck, New York. Send your legal and practice management questions to* ***medec@advanstar.com****.*

Medical Economics EHR Best Practices Study

THIRD IN A CONTINUING SERIES

Post-implementation: Making the EHR system work for you

After months of using electronic health records (EHR) with patients, you should be getting to know your system. Here are some ways to maximize your EHR's features.

by **DONNA MARBURY AND ALISON RITCHIE,** *editors*

HIGHLIGHTS

01 Take a close look at workflow processes to find ways to improve effciency using your EHR system.

02 Rely on your vendor and built-in dashboards for help in attesting to Meaningful Use and PQRS incentive programs.

Functionality and expenses are the two biggest sore spots most physicians feel regarding their EHR choice—*Medical Economics* found that 70% of doctors feel that their EHR system wasn't worth the cost or effort. By now, you are aware of your EHRs perks and problems. But there may still be more ways to maximize your system, with the goal of doing business more efficiently. Your staff may need more training, and your workflow processes may need to be evaluated to work more in your favor.

HERE ARE tips to fine-tune your EHR to fit seamlessly into your practice workflow:

ATTESTING TO MEANINGFUL USE

Use the quality metrics dashboard provided by your EHR vendor

Many vendors have a dashboard that tracks quality measures. Follow the instructions provided by the vendor to ensure proper documentation. George Ellis Jr., MD, FACP, a participant and *Medical Economics* chief medical adviser, says his practice was able to attest to Stage 1 of Meaningful Use 100 days after his go-live date simply by following the instructions provided by his vendor, athenahealth.

Consider joining a health information exchange

Of the 17 core objectives in Meaningful Use Stage 2, three involve the exchange of electronic health information. This has been a concern for providers because many EHR

2014-2015 Physician quality reporting system (PQRS) timeline

DATE	MILESTONES
March 21, 2014	▮ Last day for groups to submit 2013 data through the Group Practice Reporting Option (GRPO) Web Interface
March 31, 2014	▮ Last day to submit 2013 PQRS data through registry reporting method ▮ Last day for Maintenance of Certification (MOC) Program entities to submit 2013 quality data ▮ Last day for Qualified Clinical Data Registries to submit measure information
September 30, 2014	▮ Last day for groups to register to participate in the GPRO for the 2014 PQRS program year via web interface, registry, EHR reporting or Consumer Assessment of Healthcare Providers and Systems reporting methods
November 1, 2014	▮ Eligible professionals who participated in the 2013 PQRS program can begin requesting an informal review of their 2013 PQRS results
December 31, 2014	▮ Reporting for the 2014 PQRS program year ends for both group practices and individuals (Note: 2014 program year data will determine the 2014 PQRS incentive payment and the 2016 payment adjustment)
January 1, 2015	▮ Reporting for the 2015 PQRS program year begins for both group practices and individuals (Note: 2015 program year data will determine the 2017 payment adjustment) ▮ Payment adjustments begin for both group practices and individuals who did not satisfactorily report quality data to CMS in 2013
February 27, 2015	▮ Last day for Maintenance of Certification Program entities to submit 2014 quality data ▮ Last day that 2014 claims will be processed to be counted for PQRS reporting to determine the 2014 incentive payment and 2016 payment adjustment
February 28, 2015	▮ Last day to submit 2014 Clinical Quality Measures for dual participation in PQRS and the Medicare EHR Incentive Program
December 31, 2015	▮ Reporting for the 2015 PQRS program year ends for both group practices and individuals (Note: 2015 program year data will determine the 2017 payment adjustment)

Source: Centers for Medicare and Medicaid Services

systems lack interoperability. Health information exchanges (HIE) give members access to a centralized electronic repository where they can send and receive patient continuity of care documents.

Connect with local hospitals and providers to exchange information

Many physicians site exchanging electronic health information as their biggest concern when attesting to Meaningful Use Stage 2. One solution is to contact your local hospitals and other healthcare providers in your area. Start building a small network with them and discuss other data exchange opportunities.

Documentation is key

If you accept Meaningful Use money, then you may be audited. A failed audit means giving back incentive money.

A primary reason practices fail these audits is because they do not have the documentation to support their attestation numbers. Read more about preparing for an audit on page. 14.

Plan ahead

Even if your EHR hasn't been upgraded to MU2 requirements, it's never too early to start thinking about the necessary changes to workflow that will require of your practice and your staff.

Vendors participating in the study

ABEL Medical Software
www.abelmedicalsoftware.com

Amazing Charts
www.amazingcharts.com

Aprima
www.aprima.com

athenahealth
www.athenahealth.com

CureMD
www.curemd.com

McKesson Physician Practice Group
www.mckesson.com

MedNet Medical Solutions
www.mednetmedical.com

Practice Fusion
www.practicefusion.com

Vitera
www.viterahealth.com

ESTABLISH PQRS REPORTING

The Physician Quality Reporting System (PQRS) is an incentive program available through the Centers for Medicare and Medicaid Services (CMS) for monitoring the way practices manage some of the most common preventive services and chronic illnesses.

Attesting using an EHR system should be easy if you work with your vendor to pick the measures you want to attest to, because it should automatically populate through your EHR's quality dashboard.

PROTECTING PATIENTS' HEALTH INFORMATION

Ensure Health Insurance Portability and Accountability Act (HIPAA) compliance

Completing a security risk analysis is the biggest risk for practices attesting to Meaningful Use, according to Mark Norris, the chief executive officer of Medical Records Services, Inc. Consider hiring a consulting company to conduct a security audit on your EHR system. This analysis should be done annually to ensure HIPAA compliance.

Be cautious when allowing patients to view your computer screen

When showing a patient an X-ray or lab result on your computer screen, make sure no other patient names or information are visible to the patient.

PATIENT ENGAGEMENT

Encourage patients to visit the patient portal on your website

The portal allows patients to access their records, schedule appointments, pay bills, and update their contact information. Meaningful Use State 2 will require that at least 5% of a practice's patients access their health records through a patient portal.

Practices can create brochures to help patients log on to the portal the first time, but they may need to dedicate additional time and resources to help. Ellis says one member of his staff is responsible for showing the patient portal to patients each shift.

"This management tool can help streamline administrative functions before, during, and after a patient encounter. The patient portal takes some strain off the front desk by decreasing telephone calls and copying laboratory reports, because patients have access to these documents online," Ellis says. "My portal helps me reduce the number of interruptions between patient visits."

Include patients in the EHR process

An EHR system changes the way physicians interact with patients during an examination. Recent studies show EHRs can interfere with the physician-patient relationship. So it's important for providers to be conscious of their interaction with patients in the exam room to ensure they don't miss any nonverbal cues from patients. A recent study by Northwestern University found that physicians spend one-third of their time looking at their EHR, whereas physicians using paper charts spent only 9% of their time looking at them. If possible, try to position your computer so it is off to the side, rather than between you and the patient.

Determine patient satisfaction

Conducting a patient satisfaction survey can help you determine the level of impact that has had on your practice. Judy Bee, a practice management consultant, recommends keeping patient surveys simple. Don't include more than 10 questions. Use the feedback to improve the services at your practice.

EVALUATING PRODUCTIVITY

Process analysis

It might take your practice 6 to 9 months to return to its previous level of productivity. Your goal should be to improve productivity, though many practices have had problems with that. If you were careful about documenting your workflow process in the beginning, it should be easier for you to look at your major processes to evaluate whether they are working more efficiently.

Determine:

- how many steps each process contains,
- what forms to use,
- what staff members are involved in each step,
- what information gets collected at each step, and
- what end result is expected of each step.

Tap your super users

Communicating with your designated 'super users' on a weekly basis is a good way to keep issues on your radar. It could be overwhelming if there is no structure to log staff issues and complaints about the EHR system, so rely on your super users to help your staff with issues, and field those con-

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ABOUT THE STUDY

On December 31, 2013, the *Medical Economics* EHR Best Practices Study concluded. The findings will be unveiled to readers in 2014 as part of our ongoing technology coverage. The study was created to help physicians better understand practical approaches to use electronic health record (EHR) systems. The study recruited 29 physicians and 9 EHR vendors to test these systems over a 2-year period. Physicians reported their findings, such as unanticipated costs and implementation strategies.

For more information about EHRs, go to *medicaleconomics.com/ehrbestpractices.*

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For more best practices related to EHR implementation go to *medicaleconomics.com/ehrbestpractices*

Topics include:

- scheduling
- billing
- collecting payments

Also, find previous coverage related to EHR pre-implementation

Topics include:

- selecting a vendor
- migrating data
- establishing connectivity
- preparing staff members
- plan for productivity challenges

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cerns that need to be brought to the vendor.

IMPROVING SYSTEM MAINTENANCE

Using templates with care

Your vendor can assist you with creating templates for your most common patient visits, such as physical exams. However, it is important to use templates only as a starting point. You should be able to customize your template during each patient visit, to capture relevant information. Using templates can be a way to make visits and documentation more efficient, but you also want to avoid the appearance of cloning, or copying information from one patient chart to the next because of identical fields.

Expanding to tablets and kiosks

Accessing your EHR system via a tablet or mobile device will give you the freedom to review patient records and lab work out of the office, or anytime you aren't sitting in front of your computer. With some EHR systems the mobile version is limited, so make sure you check with your vendor about the differences in services before you invest in buying tablets for your entire staff.

A patient check-in kiosk in your waiting area can help your office run more efficiently by allowing patients to update their own records, reason for coming, and payment information before they see a physician. Not all EHR systems have kiosks available. Some run through tablets mounted to a display. Others are full systems that can be costly.

Check with your vendor to weigh whether the cost of a kiosk is worth the increased efficiency.

REVENUE CYCLE MANAGEMENT

Vendors offer costly, yet efficient revenue cycle management (RCM) services that streamline insurance eligibility, collections, and coding claims to ensure the billing process goes as quickly as possible. However,

Meaningful Use criteria for each stage

Stage 1 2011-2012 Data capture and sharing	Stage 2 2014 Advance clinical processes	Stage 3 2016 Improved outcomes
Meaningful Use criteria focus on:	Meaningful Use criteria focus on:	Meaningful Use criteria focus on:
▮ Electronically capturing health information in a standardized format	▮ More rigorous health information exchange (HIE)	▮ Improving quality, safety, and efficiency, leading to improved health outcomes
▮ Using that information to track key clinical conditions	▮ Increased requirements for e-prescribing and incorporating lab results	▮ Decision support for national high-priority conditions
▮ Communicating that information for care coordination processes	▮ Electronic transmission of patient care summaries across multiple settings	▮ Patient access to self-management tools
▮ Initiating the reporting of clinical quality measures and public health information	▮ More patient-controlled data	▮ Access to comprehensive patient data through patient-centered HIE
▮ Using information to engage patients and their families in their care		▮ Improving population health

Source: HealthIT.gov

some of the standard features of your EHR system can help you develop your own efficiencies using RCM.

The first place to start is with pre-visit verification. By "batching," or verifying eligibility for multiple appointments through a clearinghouse prior to appointments, you can reduce your practice's denial rate by up to 50%. Also, if your system can verify a patient's insurance within 24 hours, you can make sure patients with new insurance policies are still covered before their appointments.

Automating tasks that don't need your staff's expertise can save time and money. By implementing online bill pay and e-statements, you can shorten the revenue cycle by making it more convenient for patients and spend less money on printing paper invoices.

CONTINUE TO VET THE VENDOR AND SYSTEM

Evaluate your vendor

What are the systems' strengths? What are its weaknesses? Does the system function the way the vendor promised that it would? When an issue occurs, how quickly is it resolved? What updates, if any, will be necessary for your practice to achieve Meaningful Use and transition to ICD-10? Is the vendor prepared for those updates? These questions will help you determine necessary improvements and help you better communicate those issues with your vendor.

Communicate with your vendor

Consultant Derek Kosiorek, CPEHR, CPHIT, compares entering a relationship with an EHR vendor with a marriage. "You need to select a partner with whom you can get along and trust, communicate openly, and who will have your back when times get tough," he says. Your vendor will likely be in constant communication with your practice during the go-live implementation, and may even send in-person help. But don't let communication end there. Create a spreadsheet listing problems that occur with the system or any additional templates your practice needs to improve workflow.

Share your best practices at: medec@advanstar.com

Tech Talk

ONLY CREDENTIALED MEDICAL ASSISTANTS CAN ENTER EHR ORDERS

Q One of my colleagues says that only "credentialed medical assistants" are permitted to enter orders in electronic health records (EHR) per Meaningful Use Stage 2. Can you explain?

A: AS OF JANUARY 2013, only credentialed medical assistants have been permitted to enter medication, radiology, and laboratory orders into the EHR to count toward meeting the Meaningful Use thresholds under the Medicare and Medicaid EHR Incentive programs.

According to Meaningful Use 2 core measure 1, any licensed healthcare professionals can enter orders into the medical record for purposes of including the order in the numerator for the objective of computerized physician order entry (CPOE).

The order must be entered by someone who could exercise clinical judgment in the event that the entry generates any alerts about possible interactions or other clinical decision support aids. This necessitates having the CPOE occur when the order first becomes part of the patient's medical record, and before any action can be taken on the order.

The Centers for Medicare and Medicaid Services (CMS) did not specify any particular credentialing agency for medical assistants, but did say that the credentialing would have to be obtained from an organization other than the employing agency.

The credentialing should be obtained from an agency accredited by the National Commission for Certifying Agencies or the American National Standards Institute.

Many working medical assistants have not graduated from an accredited program and thus are not eligible to sit for a certification examination. The American Association of Medical Assistants, the certifying agency for medical assistants, says these individuals are not eligible for certification.

According to CMS, a non-certified individual, such as a scribe, is not qualified to enter these orders in the computerized provider order entry because there is no licensing or credentialing of scribes, so there is no guarantee of their qualifications for accuracy in such a position.

Documentation required

To qualify for payments under the EHR incentive programs, providers will be required to present documentation of all entries, many of whom are automatically entered by the EHR system.

CMS auditors have the authority to determine the entry of medication. Laboratory and radiology orders have been made by the licensed healthcare professional or credentialed medical assistant.

If the auditors find that the order entry was performed by an individual other than a licensed professional or credential medical assistant, it could constitute a violation. In that case it is possible that the order entry by the individual would not be counted toward meeting the Meaningful Use thresholds.

Consequently, the eligible professional may not meet all the core objectives and as a result would not receive the incentive. ◘

*The answer to our reader's question was provided by **Maxine Lewis, CMM, CPC, CPC-I, CCS-P,** president of Medical Coding & Reimbursement in Cincinnati, Ohio. 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

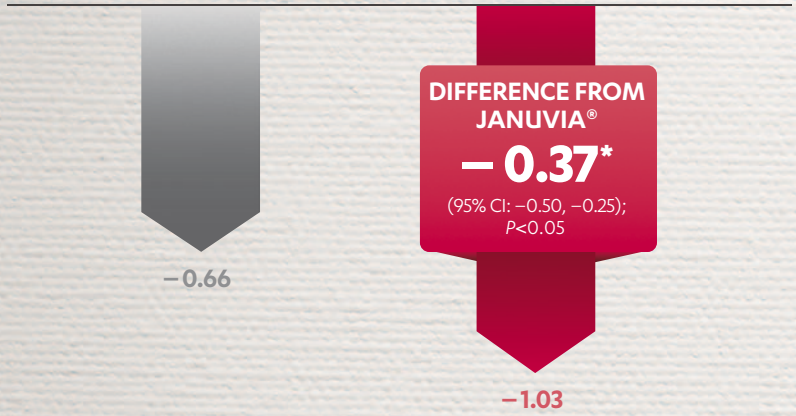
CONTRAINDICATIONS

- 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]*.

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OVERDOSAGE

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

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

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

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

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

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

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

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

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

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

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

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

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

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

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

Active ingredient made in Belgium

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

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

Licensed from Mitsubishi Tanabe Pharma Corporation

10282400

K02CAN13080B

janssen

Money

EMPLOYING FAMILY MEMBERS:
Lower your tax burden and help your family get ahead on retirement

by **DAVID J. SCHILLER, JD** *Contributing author*

HIGHLIGHTS

01 The primary financial advantage of employing family members is that doing so will reduce your income taxes.

02 If your practice is unincorporated, the wages paid to children under age 18 are not subject to Social Security or Medicare tax.

When you focus on taxes and children, you likely think of personal exemptions or taking a child care credit or college-related tax credits. However, you can realize an even greater tax shelter opportunity through your children's low tax brackets.

UNLIKE WHEN children have "unearned income," which is subject to the "kiddie tax" (meaning their income is taxed at your bracket), earnings through employment are taxed in the child's bracket, which is almost always lower than yours.

If your child is in a zero or other low tax bracket, his or her wages will avoid most of the federal income taxes that they would incur if the compensation were paid to you. When you factor in the phase-out of itemized deductions and personal exemptions and payroll taxes, some physicians have marginal tax brackets higher than 50%. If you're in that position, you can avoid substantial taxes by adding your children to your payroll. That's because your practice can deduct the child's pay and avoid taxes on this money in your higher bracket.

Furthermore, if your practice is unincorporated, the wages paid to children under age 18 are not subject to Social Security or Medicare tax, which they would be if they were paid to you. The annual wages of the children up to $6,100 are completely sheltered from federal tax through the child's annual standard deduction. The tax savings for the family as a whole is compelling and

> THE ADVANTAGE OF EMPLOYING FAMILY MEMBERS IS THAT DOING SO WILL REDUCE YOUR INCOME TAXES, GIVE THEM A JOB, AND ALLOW THEM TO FUND ROTH IRAs, PROVIDING THEM A JUMP START ON RETIREMENT.

the children can build up money for retirement, college, or other purposes.

Your child could even participate in your practice's 401(k) plan if he or she meets the minimum age and service requirements. However, if you reduce these requirements so that they qualify, the lower requirements would also apply to the rest of your staff.

USE WAGES TO FUND RETIREMENT ACCOUNTS

The best use of the children's compensation is to make annual contributions to a Roth Individual Retirement Account (IRA), which has no minimum age limit for contributions. You can only contribute to a Roth if you have earned income of at least the contribution amount (up to the $5,500 annual limit). Using a traditional pre-tax IRA instead does not make sense because the tax deduction is irrelevant when the child is in a low or zero federal tax bracket. Whether the child is in a high tax bracket at the time of retirement is not important since the Roth IRA should not ever be subject to taxation on its growth so long as distributions occur after age 59-1/2.

If the child's wages are used to fund the Roth IRA, and it is fully funded throughout childhood, it is likely that the investments will grow and be worth millions 40 to 50 years later due to tax-free compounding.

Working with family: The Do's and the Don'ts

While having physicians' family members on the payroll can be a help to a medical practice, it can also present complications that may prove difficult to manage given the personal relationships and the dynamics of an employer-employee relationship.

Practice management consultant Judy Bee has some tips for physicians considering adding family to the staff.

1

Don't hire anyone you can't fire. Be explicit when bringing a family member on board that good performance is necessary to continue working for the practice.

2

Don't expect other staff members to provide adequate feedback on your family member's performance. The best thing to do is foster an open environment where every worker is treated equally.

3

If your spouse is the office manager—a common arrangement in many practices—he or she must set a shining example of a good employee. He or she must be held to the same performance standards that apply to any manager.

4

If the spouse-manager makes a decision, you should publicly support it. If you have questions, raise them in private. If there are too many decisions that are not consistent with your goals and values, then you may have the wrong manager.

5

Put the supervision of a family member in the hands of another staffer. Make it clear to your family member that you can't save him or her from termination if they don't perform well.

Unlike a traditional IRA, a Roth IRA does not compel distributions at age 70 1/2; there are no mandatory distributions to the account owner.

Furthermore, even if the child uses his or her earnings for purposes other than funding a Roth, the fact that the child has earned income would by itself permit you to contribute to the child's Roth IRA out of your own funds. Since a Roth IRA does not have to be funded directly out of the beneficiary's earned income. The funds will grow tax-free over many decades and you will help the child get a good start funding his or her future retirement. If the funds are needed for college, they could be withdrawn penalty-free from the Roth IRA, although the growth would then be subject to income taxes.

I opened our kids' IRA at Vanguard Mutual Fund Family using the Social Security numbers for my four children, listing myself as the guardian in the title. Each monthly statement is sent to my address and the children's names are on the accounts followed by the words "a minor."

I have noticed that as our children turn are reaching age 21, the statements continue to come to me. One of these days, I may get around to telling my children about their IRAs. In the interim, I continue to make all of the decisions regarding the investments of "their" money. An advantage of the children not knowing about this wealth is that such knowledge could stunt their initiative to someday begin contributing their own funds towards their retirements.

HOW TO PAY YOUR CHILDREN

Payments to the children for services to your practice should be made with irregular amounts and at irregular times and based upon a reasonable hourly wage for their services. If, instead, you write one check annually for $5,500 (to fund the Roth IRA the maximum amount), it will appear that they are not bona fide employees and you risk having your practice lose the tax deductibility of the payment of wages.

RESPONDING TO GOVERNMENT INQUIRIES

Some of my clients have had their grandchildren on their payrolls. In the case of very young children, sometimes a form letter will come from the Social Security Administration inquiring whether a mistake has been made because of the age of the employee. The government is focused on one person using another's Social Security number in case an illegal alien is using someone else's number. If you receive such an inquiry, you should respond by stating that the child or grandchild is your employee, rather than ignoring the inquiry.

The primary advantages of employing family members are that doing so reduces your income taxes, gives the child a job, and allows him or her to fund a Roth IRA for many years, providing the child with a head start on retirement plan funding and allowing them to enjoy many decades of tax-free compounding. The saved income taxes can also be used to fund a 529 Plan for their future college expenses and to help them build up a nest egg for their later years. ■

David J. Schiller, JD, is an attorney specializing in tax and estate planning, and is a **Medical Economics** *editorial consultant. He practices in Norristown, Pennsylvania.*

Financial Strategies

HANDLING HIGH-DEDUCTIBLE PATIENTS REQUIRES COMMUNICATION, POLICIES

by **DREW HAYNES, EA, CHBC** *Contributing author*

In the near future, patients will cover more of their healthcare bills as deductibles increase along with access to insurance. It could mean a financial hit if the challenges presented by the trend toward high-deductible health plans are not handled properly by medical practices.

IN ORDER to survive in this healthcare economy, you and your medical practice must be willing to change with it. High-deductible health plans are becoming the new norm. Upfront and honest communication with patients, combined with a solid financial policy is a great place to start.

Patients should be required to sign the policy and a copy should be given to them. It is your responsibility to make sure that patients understand their financial responsibility right from the start.

There are two types of patients you must consider: Those that can't afford to pay the bill and those who only want to pay after a procedure is completed.

In a perfect world, every patient would have the financial means to pay their full out-of-pocket expense in advance, and everyone would be happy. However, some patients just can't afford to pay their portion of the bill. Your financial policy should outline how patients with financial concerns should be treated. Payment plans, when implemented correctly, can be a viable option.

There are two key aspects to an effective payment plan. First, figure out what portion of the bill the patient can afford, and get that amount upfront. Upfront payment, even a small amount, can help a practice's cash flow.

Second, set up automated payments. It is valuable to have a bank account or a credit card on file that can be charged automatically over the course of the agreed-upon payment plan. This makes it convenient for the patient and ensures that you will be paid.

If a patient does not express concerns about paying for a procedure, then payment at the time of service is ideal. This method is becoming more popular and is the most effective collection strategy. It can be challenging to get a patient to pay for a procedure after they have received the service.

Requiring upfront payments may make you uncomfortable but it is a valuable tool in today's healthcare environment.

Upfront payment must also be addressed clearly in your financial policy. Consider wording such as this: "If you must undergo a procedure, we will contact your insurance company to ensure your eligibility and obtain an estimate of covered benefits. On or before the day of your procedure, you are required to pay any out-of-pocket costs. After the procedure is completed and payment is received from your insurance company, any remaining balance must be paid in full within X number of days. If payment from your insurance company results in a credit balance, that balance will be refunded to you within X number of days."

Making patients aware of their responsibility in advance allows them to ask questions and develop a plan that fits their financial needs. Your staff should be well trained on how to handle any concerns patients might have.

Drew Haynes, EA, CHBC, *is an accountant and certified healthcare busines consultant with Medical Resources Group, Inc., in Louisville, Kentucky. Send your practice management questions to* ***medec@advanstar.com****.*

Protect assets through impermeable trusts and proper estate planning

Like layers of gauze protecting a wound, separate LLCs can shield your assets from inside and outside liability risks.

If your home, automobiles, rental properties are part of the same company or trust, they are all vulnerable as part of a single business structure. A solution is to create separate LLCs.

Getty Images/David Arky

Protect your assets by incorporating your practice

While limited liability corporations often are the go-to method for incorporating a physician's practice, there are further considerations every practice owner should make

by **STEVEN ABERNATHY** *and* **BRIAN LUSTER** *Contributing authors*

HIGHLIGHTS

01 An LLC offers tax benefits and could save a physician major headaches. However, it needs to be set up properly.

02 Each new business or property may require a new LLC wrapper to protect that business. If not, you could have all of your assets drawn into litigation.

Physicians are innovative thinkers, but their formal education does not reveal the nuances between different corporate structures. These options, including limited liability corporations (LLCs), S corporations, and C corporations, provide physicians with a range of options when considering how to incorporate a medical practice.

The key is to consider what will work best for your practice now as well as laying the groundwork for future endeavors—and potentially save you hundreds of thousands of dollars over time.

Just as infection is prevented by sterilizing instruments, asset breaches are avoided by "wrapping" them in the gauze of impermeable trusts and proper estate planning. Physicians and their practices often have substantial assets at risk, and proper protection needs to be established early on. One key point, no matter what asset structure is used, is to know the importance of separate entities. If your practice, home, automobiles, summer home, rental properties, and other assets are part of the same company or trust, you hold liability for the sum total of all of these assets—thus any legal conflict (malpractice, divorce, battle with business partners, etc.) could make everything within the single structure vulnerable. We strongly advise against that.

So what structures are recommended to set up your medical practice, protect assets, and establish any new business endeavors?

An LLC is often favored by physicians, with good reason. An LLC offers tax benefits and can save a physician major headaches. However, it needs to be set up properly. There is no better method of keeping wealth untouched by creditors than by ensuring it remains untouchable. This is the essence of asset protection.

THE CONSEQUENCES OF INCORPORATING IMPROPERLY

Let's take a look at the predicament of the fictitious "Dr. Stevens," who learned the hard way.

He owned multiple assets including a speedboat, vacation home, an apart-

LLC Points to Consider

- ☑ LLCs offer "best of both worlds" between partnerships and corporations because they don't require formalities, maintenance, and rules of corporations.
- ☑ An LLC's taxation, like a partnership, is pass-through resulting in only one layer of tax.
- ☑ A partnership requires at least two parties, but, LLCs can be formed with one member.
- ☑ The LLC is a pass -through entity, so if you earn $100,000, the LLC makes nothing. The income passes through to the owner.
- ☑ The LLC is not a taxable entity. (This isn't a loophole!)
- ☑ LLCs offer different share classes. Typically different share classes will have different rights and responsibilities regarding ownership, voting, and other decision making.
- ☑ LLCs have limited life, so when a member leaves an LLC, the business is usually dissolved. This means members must fulfill all remaining legal and business obligations to close the business. The members who remain may start a new LLC. A possible work around is to add provisions in the operating agreement prolonging the life of the LLC should a member opt to leave the business.
- ☑ An LLC's members are self-employed and must pay self-employment tax contributions towards Medicare and Social Security. The entire net income of the LLC is subject to this tax.

ment building, a brokerage account, and a plot of undeveloped land.

One day, Stevens' son and two of his friends went on a joyride in the speedboat. His son hit a dock at full speed, crippling his two friends. Alcohol was involved and Stevens was hit with a multi-million dollar lawsuit, far in excess of the speedboat's policy limits.

At this point, you might expect to hear that Stevens' remaining assets were all held in his own name. If this were the case, Stevens would be in dire straits since the plaintiffs would almost certainly win at trial, attach a lien on Stevens' remaining assets, and seize or foreclose in satisfaction of the judgment. Worse yet, if the vacation home were to be foreclosed upon, it would be treated as a taxable sale: if the jury returned with a $2 million verdict and Dr. Stevens had bought the home for $1 million, he would not only lose his equity, but also be slapped with a tax bill on his $1 million gain.

Dr. Stevens believed he was adequately protected. Years earlier he was advised by a patent lawyer to put his brokerage account, vacation home, and land in a corporation. Doing so, it was explained to him, would insulate him from liability due to the limited liability benefits of a corporation.

This was poor advice. While it is true that a corporation provides a level of protection from liability, this typically only applies to negligent actions of the corporation itself. And since the damage was the result of the speedboat accident (which was not owned by the corporation), there was nothing to stop the plaintiffs from simply seizing the stock and then dissolving the company. In addition, his corporation was subject to taxation at both the corporate and shareholder level, meaning his brokerage account gains were taxed twice.

Worse, there were a bevy of corporate formalities required that Stevens failed to keep up.

Next, we'll show you how to avoid Stevens' pitfalls.

THE SOLUTION: MULTIPLE LLCs

Stevens would have been better served by placing his assets, including the speedboat, in separate LLCs—which are ideal vehicles for asset protection since they protect from both inside and outside liability.

If Stevens' brokerage account and land were in separate LLCs, the plaintiffs would have a difficult time directly seizing them.

This example illustrates outside liability. That is, liability not related to the property. Since there is nothing for the litigants to go after, the rest of his assets are protected. In such a case, the litigants would most likely accept the insurance company's policy limit.

Inside liability involves liability stemming from the property itself. For example, suppose a tenant slipped on the sidewalk of Stevens' rental property. If this property was in an LLC, he would be safe from claims stemming from the injury since Stevens' outside assets are shielded from negligent actions associated with the business.

At the heart of the LLC, asset protection is the ability to increase one's bargaining power. Since Stevens' assets outside of the LLC were protected, his pockets are suddenly much shallower, making him a far less tantalizing target for personal injury attorneys. He is now in a better position to settle the case for a fraction of what he is being sued.

As discussed earlier, if the medical practice owns the building and/or expensive equipment, (referred to legally as Property,

plant, and equipment, or PP&E) and it were to depreciate, this would allow for a tax deduction (sheltered income).

OTHER INCORPORATION OPTIONS

Yet there are times where physicians choose to structure their medical practices in an S Corporation, also called a sub-S, or, in some cases, a C corporation.

For the most part, S corporations are free from federal income tax. However, they must pay taxes on certain capital gains and passive income, according to the internal revenue service (IRS). They have a pass-through structure, meaning that net losses—or profits—are passed through to shareholders. The IRS explains it as follows: "On their tax returns, the S corporation's shareholders include their share of the corporation's separately stated items of income, deduction, loss, and credit, and their share of nonseparately stated income or loss."

A great advantage of the pass-through configuration of an S corporation is that its profits are only taxed once—at the shareholder level, so they are able to avoid dividend double taxation. These structures can also keep net profits as operating capital.

It's important to note, however, that all profits are considered as if they were distributed to shareholders. So an S Corporation shareholder might be taxed on income never received. If you're the only owner—perhaps a physician establishing a solo practice with few employees—then an S-corporation is likely to be a good business structure for the practice itself. There is also only one share class, so everyone holding shares will have the same shareholder rights. This may be an advantage as a practice grows—for example, a more junior physician could develop equity in a growing practice and be incentivized through a greater investment in the business.

On the other hand, a founding partner, who will have A-shares, may want junior partners to have B-shares. This would be beneficial in a large practice that might want younger physicians to have equity, however, retain less voting control. This

REMEMBER, EACH "NEW" BUSINESS OR PROPERTY MAY REQUIRE A NEW LLC WRAPPER TO PROTECT THAT BUSINESS.

S & C corporations

S-corporations have only one share class. C corporations have several share classes.

S corporations might be subject to special taxes if the corporation has retained earnings from any previous tax year in which the company was taxed as a C corporation. (This may be unusual for a medical practice, but it is not impossible.)

C corporations allow assets to stay within the company, yet are taxed on all income generated at the corporate level, even if the income is paid out in the form of dividends.

One major disadvantage of the C-corporation is taxation at two levels: the corporate level and the individual (employee) level. A large corporation, such as IBM, is taxed at 36% and the company can do what it wants with the profits (or what management and the board of directors wants). However, 64% will stay within the company, a taxable entity.

distinction in share classes also allows for different "calls" on the income of the business: A-shares participate in profit-sharing first, while B-shares participate later. Of course, specific financial structuring needs to be clearly expressed within the corporate documents.

SERIES LLCs

As described in the Stevens example, it is generally advisable to set up multiple LLCs for protection. Certain states (Texas and Illinois are two) allow the use of the Series LLC, which is structured with a "father" LLC and several "children" LLCs.

Each "child" LLC has its own books and members. Series LLCs separate assets into their own entities, minimize liability, and reduce paperwork and formation costs. Rules vary for LLCs state by state, so you'll want to be clear about the laws in yours.

Separate LLCs, or in some cases parent/child LLCs, should be created to own the land and/or the equipment, as more asset protection may be available if the practice is structured as an LLC rather than an S corporation.

LIMITED LIABILITY PARTNERSHIPS

Another potential corporate structure option is a limited liability partnership, or LLP. This only requires a partnership agreement, whereas an LLC requires an operating agreement. Often an LLC is employed because it solves some of the problems inherent in both corporate and partnership structures.

Remember, each "new" business or property may require a new LLC wrapper to protect that business; you don't want someone to fall on your property and have all of your assets drawn into litigation.

All corporate structures have distinct advantages and disadvantages over time. Depending on where you practice medicine, we recommend consulting a professional who knows not only how the law applies in the state where you practice medicine, but understands how best to structure your overall wealth enterprise.

Steven Abernathy and Brian Luster are physicians' advocates and founders of the first Physician Family Office (PFO) in the country.

The pros and cons of investing in real estate

Knowing when it's the right investment can determine whether you see profit or losses from your real estate venture

by **MARISA MANLEY, JD** *Contributing author*

HIGHLIGHTS

01 Consider both sides of the real estate equation before deciding whether to invest. A deliberate process is more likely to promote your success.

02 Medical practices investing in real estate must consider changing demographics and methods of medical practice which may affect their ability to sell at some time in the future.

Real estate has long been a popular investment vehicle for medical professionals—from single practitioners to large practice groups. These investments often have been motivated by tax savings, as well as by cash flow and asset appreciation.

If the real estate you invest in is also real estate you occupy for your offices, there may also be feelings of pride, greater security, and a notion that it's just common sense to own. After all, as the saying goes, why pay someone else's mortgage—the landlord's—when you can pay your own?

Practices that invest in real estate for their own use may choose to buy or build a free-standing building that they occupy alone or with additional space for rent-paying tenants. A medical practice may choose a condominium in a medical office building, may become limited partners or joint venturers with experienced developers in a multi-tenanted building, or in a building that they occupy as sole tenant. Doctors, of course, may also invest in real estate they do not occupy.

But proceed with caution. Despite common appreciation of real estate as an investment, and the different forms an investment can take, there are good reasons for doctors not to invest in real estate.

Investing in real estate offers the potential for significant benefits: Pride of ownership, a feeling of greater security, possible tax benefits in the form of depreciation, cash flow from tenants, and increased asset value. Yet none of these benefits is assured, and there is the potential for economic loss and friction in a medical practice that may diminish the collegiality and even the viability of the practice group.

Consider both sides of the equation before you decide to invest in real estate. A deliberate process will most likely promote your success.

Let's take a look at six issues every practice should consider before committing to buy real estate. We'll focus on investments for a practice's own needs, although many of the issues apply to every real estate investment, whether you are an owner/occupier or an off-site investor.

1/ Capital intensive

Compared with leasing the space you need for your medical practice, buying real estate is always more capital-intensive.

With leasing, a landlord funds part of your capital needs, the infrastructure and the interior build-out. When you purchase property, you must fund these needs. Even with the leverage that real estate provides, this often means that capital that could be used for equipment, software, and other enhancements to your practice competes with real estate needs. Consider which investment, real estate or practice-specific enhancements, is likely to give you the greater return.

Younger practices, those expanding into new markets, and practices in highly competitive markets may find that capital is best deployed to buy new equipment rather than a real estate nest egg.

2/ Real estate is not liquid, and has high transaction costs

Simply put, when you want to sell there may not be acceptable buyers.

Because each real estate parcel is unique, it must be valued as an individual unit—not as one of many fungible stocks or bonds. The valuation you offer may not be shared by buyers. Even if you find a buyer fairly readily at an acceptable price, consider the transaction costs you will incur—most likely brokers' fees, legal fees, and possibly some type of transfer tax.

> Consider the transaction costs you will incur—brokers' fees, legal fees, and transfer taxes.

3/ Market risk

As a real estate investor, you will be exposed to changes in the real estate market that affect the value of your investment.

These changes may relate to the demographics of a particular area, the particular use of the property, or even the obsolescence of the building or condo you are so fond of. I know of a medical practice in Virginia that spent $1 million to buy a building once occupied by pediatricians. It had most of the infrastructure they required, but they were not able to build a sustainable practice at the location. Several years later, they put it on the market. Two years later it still had not sold.

Ultimately, the practice sold the building for less than $600,000. Their assessment of what would be a good location for their practice turned out to be wrong, and while they worked through this issue, the market changed, leaving them with an asset worth far less than the amount they paid for it.

@ MORE RESOURCES Real estate content at MedicalEconomics.com:

- **Don't count on real estate to fund your retirement** http://bit.ly/1boUX4Z
- **The tax benefits of owning your office** http://bit.ly/1bOpYji
- **'Good guy' lease provisions can benefit your practice** http://bit.ly/1gKeJaQ

4/ Management intensive

When you invest in real estate, to assure a successful investment, you must accept complex management responsibilities—maintenance, upgrades, compliance with changing building codes, and more.

If you have tenants in your investment real estate, this will impose another set of responsibilities—avoiding vacancies, negotiating transaction terms, responding to tenant complaints, and similar responsibilities.

Even if you hire a managing or leasing agent to handle these tasks, you must hire and manage these contractors, and ultimately, you are responsible for their performance—whether it's code compliance or keeping tenants satisfied and your building full. Be sure you are committed to the full-time responsibility this requires.

5/ Conflicts of interest

In some practices, one or just a few of the partners may choose to own the real estate the practice occupies.

Such a situation can create conflicts of interest and may subject the practice to stress and friction. If the partners who own the practice want to increase the practice's rent to reflect current market conditions, other partners may object.

When the partners who own the real estate insist it's time to put a new roof on the property, the non-owning partners may not see the same necessity—they may argue for a repair instead. We recently worked with a group of physicians trying to decide whether to renew a lease at their existing location or move to a new space with more contemporary amenities and closer to important referral sources.

The partners were divided on the move. The partners who had an ownership interest in the building where the practice is now located wanted to stay. Other partners preferred a move. In any situation like this where some partners feel they are subsidizing the economic interests of others, the culture of the practice may suffer.

6/ Exit strategy

For most real estate investments, success is determined when the property is sold or refinanced.

Medical practices investing in real estate must consider changing demographics and methods of medical practice which may affect their ability to sell at some time in the future. For example, in Manhattan, for many years, medical condos in high-end apartment buildings were sought after, and a good investment.

Recently, however, these properties have gotten harder to sell. Fewer physicians entering the market wish to practice on their own or in small groups, so the demand for these spaces is much reduced.

In many suburban markets, office vacancy rates are high and medical practices no longer believe that they must be located in medical office buildings on or near a hospital campus. This means that medical office space competes against a much larger group of properties in a market that favors tenants, not owners.

A physician who owns an office building in an upstate Connecticut town recently approached us for advice. In the past, she was able to fill her spaces with ease. Now, her building has been vacant for several years. She's reluctant to invest in the building upgrades and tenant improvements that the market demands, so it's likely that her space will remain vacant while current market conditions persist or she will have to accept lower rents and possibly tenants she finds less desirable. ◻

Investing in real estate offers the potential for significant benefits: Pride of ownership, a feeling of greater security, possibly tax benefits in the form of depreciation, cash flow from tenants, and increased asset value. However, none of these benefits is assured, and there is the potential for economic loss.

Medical Economics
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Trends

Preventing and treating COPD

Why taking a chronic care approach to smoking cessation is an effective way to battle the third leading cause of death in the United States

by **PAMELA LEWIS DOLAN** *Contributing author*

HIGHLIGHTS

01 Because of its cost to society and the healthcare system, COPD is increasingly included in payer pay-for-performance programs that reward physicians for improved outcomes.

02 The Affordable Care Act expanded smoking cessation programs by requiring marketplace plans to cover them. For physicians, this means some smoking cessation treatments will be reimbursed.

When conveying the severity of nicotine addiction, Elyse Carroll likes to tell the story of a former patient who, five days after coming off a ventilator and nearly dying, snuck outside the hospital doors, found a cigarette butt on the ground, lit it up, and smoked it. It takes 4 seconds for nicotine to enter the bloodstream, and the negative health outcomes can be life long. ▸▸

▸▸ **AND WHILE** the challenges for patients in conquering the behavioral and physical addiction of smoking have been well documented, so too has its link to the third leading cause of death in the United States--chronic obstructive pulmonary disease (COPD). According to the COPD Foundation, the vast majority (90%) of people with COPD have smoked. COPD most often occurs in people 40 years of age and older who have a history of smoking.

The National Institutes of Health says approximately 12 million adults in the United States are diagnosed with COPD, and 120,000 die from it each year. An additional 12 million are thought to have the condition but remain undiagnosed. An estimated $37 billion is spent in the U.S. annually treating COPD, which is an umbrella term for lung diseases including emphysema, chronic bronchitis, refractory asthma, and some forms of bronchiectasis.

"When you can't breathe, that causes you anxiety and stress. What's a trigger to smoke? Anxiety and stress. One of the symptoms of their chronic disease is one of their triggers."

—ELYSE CARROLL, RESPIRATORY DISEASE MANAGER, HOSPITAL FOR SPECIAL CARE, NEW BRITAIN, CONNECTICUT

Exacerbating the issue, says Carroll, a respiratory disease manager at Hospital for Special Care in New Britain, Connecticut, is the fact that the presence of COPD can actually make it harder to quit smoking.

"Just think about when you have COPD and you can't breathe," Carroll explained. "When you can't breathe, that causes you anxiety and stress. What's a trigger to smoke? Anxiety and stress. One of the symptoms of their chronic disease is one of their triggers."

Because of its cost to society and the healthcare system overall, COPD is increasingly included in payer pay-for-performance programs that reward physicians for improved outcomes. Because of the association between smoking and COPD, efforts to reduce COPD rates and improve outcomes for those already diagnosed must include smoking cessation programs. And researchers have found that treating smoking like a chronic disease is the most effective way to confront tobacco dependence and reduce the risks of COPD.

BENEFITS OF A CHRONIC DISEASE APPROACH

The process of successfully quitting smoking is not dissimilar when compared with managing a chronic disease. In fact, the U.S. Public Health Service designated tobacco dependence a chronic condition in 2000 because it often requires repeated intervention and multiple attempts to quit successfully.

"Tobacco dependence disorder is a chronic relapsing condition, yet treatment is delivered in discrete episodes of care that yield disappointing long-term quit rates," wrote Anne Joseph, MD, MPH, professor of medicine at the University of Minnesota School of Medicine, coauthor of a 2011 study published in *JAMA Internal Medicine* that looked at chronic disease management for tobacco dependence.

Joseph's research found that a chronic disease approach—targeting the goal of quitting smoking but incorporating failures, setting interim goals, and continuing care until the desired outcome is achieved—is

By the numbers

133,965
Number of Americans who died of COPD in 2009, the third leading cause of death.

$29.5 BILLION
The national cost of treating COPD in 2010.

2
Women are twice as likely to be diagnosed with chronic bronchitis as men.

12.7 MILLION
Number of U.S. adults estimated to have COPD in 2011.

4%
Rate of COPD prevalence in Washington state, the lowest in the United States.

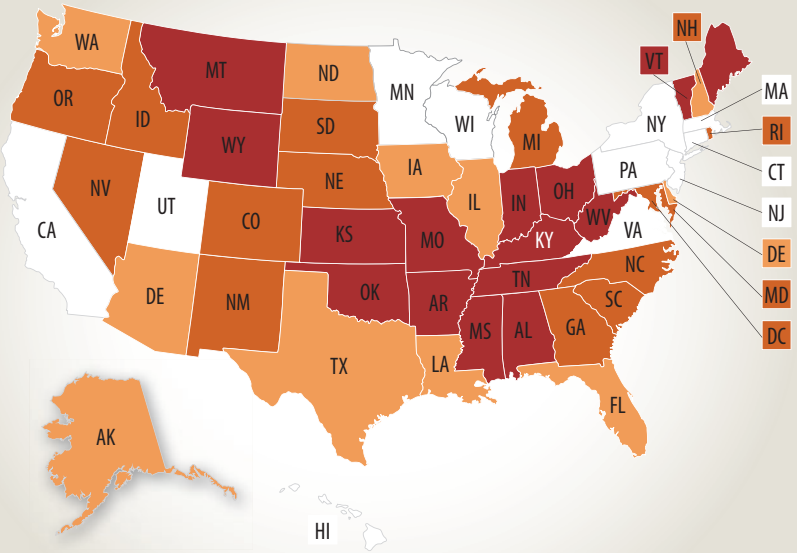
9%
Rate of COPD prevalence in Alabama and Kentucky, the highest in the United States.

90%
Estimated percent of COPD deaths that are caused by smoking.

51%
Number of COPD patients who say their conditions limit their ability to work.

Source: American Lung Association

Chronic obstructive pulmonary disease in the United States: Age-standardized death rate, 2010



Source: CDC National Vital Statistics System data obtained from http://wonder.cdc.gov.
COPD as underlying cause of death was defined by ICD-10 codes J40-J44.
Death reates (per 100,000 U.S. population) were age-adjusted to the 2000 U.S. standard population

approximately 75% more effective than short-term, discrete approaches.

Someone trying to quit smoking typically goes through relapses, much like chronic disease sufferers, according to Joseph. Instead of treating those relapses as the end of the journey to quit, physicians can help patients figure out the reasons for the relapses and ways they can address them, she says. And if they cannot completely quit, there are benefits to reducing the amount they smoke, she adds.

When patients relapse, they feel like they failed, says Xavier Soler, MD, PhD, a member of the COPD Foundation Educational Review Working Group and an assistant professor of medicine in the division of pulmonary and critical care at the University of California San Diego. It's up to physicians to show some compassion, he says.

If someone comes to a doctor with a condition such as hypertension or diabetes, they are placed on medications, a diet, and/or an exercise regimen. If their condition isn't controlled by the prescribed regimen, physicians don't consider them a lost cause, says Soler.

"You are going to say: 'Let's review why you went off the diet, or whatever the reason … and figure out what was not working,'" he says. The same approach should be taken with smoking cessation.

IMPLEMENTING A CHRONIC SMOKING CESSATION PROGRAM

There are many methods that can be used in smoking cessation, says Richard Novitch, MD, director of pulmonary rehabilitation, and the pulmonary function/blood Gas Laboratory at Burke Rehabilitation Hospital in White Plains, New York. Studies have found nicotine replacement therapy (NRT)

> "THERE'S GOOD DATA TO SUPPORT THE FACT THAT THERE ARE PEOPLE WHO ARE INTERESTED IN QUITTING WHO DON'T ACCESS SERVICES."
>
> – ANNE JOSEPH, MD, MPH, PROFESSOR OF MEDICINE AT THE UNIVERSITY OF MINNESOTA SCHOOL OF MEDICINE.

can increase the likelihood of success for patients attempting to quit smoking. Novitch says some patients need only NRT, while others need to combine NRT with medications such as Bupropion Hcl or varenicline.

The first step practices can take is to treat smoking status as a vital sign, Joseph says. Just like blood pressure and temperature are recorded for every patient, at every visit, so should smoking status. If they identify as a smoker, the next question should be whether they want to quit. Asking at every visit will also help physicians identify those who relapsed.

The Affordable Care Act provided for the expansion of smoking cessation programs by requiring marketplace plans to cover them. For physicians, this means some smoking cessation treatments, including in-office counseling, will be reimbursed. However, there is a wide variation in the types of treatments that are covered and whether there is coverage for medications or NRTs.

Carroll says many plans allow physicians to bill for a 3- to 10-minute session or a session of more than 10 minutes. Many cover up to four sessions, twice a year.

The first one to three months of a smoking cessation program is when the physical part of the addiction is addressed, says Carroll. This is when withdrawal symptoms are treated, usually with NRT and/or medication.

An open dialogue with patients during these first few months will help physicians know what course to take and if it needs to be modified. For example, Novitch has often seen first quit attempts fail because of under-prescribing of NRT.

After the physical addiction is addressed, the treatment moves toward the psychological and social issues. Identifying triggers and celebrating milestones are very important during this phase. Carroll says patients who make it through a year have the best chances for long-term success.

Joseph says that once a patient has expressed an interest in quitting, it remains on the table until they have succeeded, no matter how many failed attempts. Physicians should continue working with them and make modifications as needed, which may include the goals themselves. Some patients may need to focus on cigarette reduction instead of quitting entirely. Joseph compares it to patients who fall off of a diet.

"This doesn't mean you now go out and binge eat," Joseph says.

THE INVESTMENT AND REWARD

Implementing a chronic smoking cessation program will require buy-in from everyone on the staff of a medical practice, says Paul Scalise, MD, senior vice president of medical affairs and chief of staff at the Hospital for Special Care.

Often, the physician has only 15 minutes to see a patient so he or she can't be the only one on staff committed to this, says Scalise. Medical technicians can start the discussion when they bring the patient in, he says. The same applies to the nurse, when taking the patient's vital signs.

Practices may consider hiring someone to facilitate counseling sessions or to conduct follow-up phone calls and outreach. Existing staff members can also be trained as smoking cessation counselors, Joseph says.

There are also community-based resources to which physicians can refer patients. There are 1-800 quit lines in every state, says Novitch. In addition to counseling and support, many provide NRT starter kits free of charge. Also, local hospitals often host support groups that are free to patients. But, warns Joseph: "You can outsource so much that you lose the benefit."

Physicians may check a box saying he or she referred the patient to a 1-800 number, but fail to do any follow-up, Joseph says. Some patients might prefer getting treatment from a provider with whom they have

The Affordable Care Act provided for the expansion of smoking cessation programs by requiring marketplace plans to cover them. For physicians, this means some smoking cessation treatments, including in-office counseling, will be reimbursed.

a relationship. They may feel too distanced from their healthcare provider going to a program outside the practice.

There's benefit to proactive outreach, as well. "There's good data to support the fact that there are people who are interested in quitting who don't access services," says Joseph.

Most electronic health record systems allow smoking status to be recorded as discrete data. Using this data, population-based reports can be generated that list every patient who identified as a smoker. Joseph says she uses these reports to reach out to the identified smokers to see if they want help quitting and to inform them of existing programs.

Because so many COPD cases can be linked to smoking, "To ignore smoking is to ignore the fact that [COPD] even exists," says Scalise.

After a patient has been diagnosed with COPD, his or her conditions are made worse if they continue to smoke, says Soler. Studies have shown those who quit live longer. This is increasingly important as physician payment models shift toward outcomes-based compensation.

Reducing the number of smokers won't mean physicians are less busy though, says Stephen Karbowitz, MD, director of the division of pulmonary medicine at New York Hospital Queens. Reducing the number of middle-age COPD patients will allow physicians more time to treat the older, sicker population, he says. Reducing the number of smokers "wouldn't necessarily reduce costs, but would help to keep them from rising."

Novitch disagrees. He says savings could be realized almost immediately. One major source of savings would be the reduced visits to the emergency department, he says.

"Smoking cessations is one of the most positive things we can do for patients' health ... and maybe our bottom lines," says Novitch.

Risk Factors for COPD

Major

- Smoking
- Existing impaired lung function
- Increasing age
- Male gender
- Occupational hazards (e.g., gold and coal mining, silica exposure in glass or ceramics industries, cotton and grain dust, toluene diisocyanate asbestos)
- AAT deficiency*: Genetic disorder contributing to the risk of COPD, especially emphysema

Minor

- Air pollution: Unclear if there is risk of COPD; however, air pollution worsens symptoms in existing pulmonary dysfunction and increases ED admissions for COPD
- Bronchial reactivity
- Family History
- Nutritional status
- Race
- Respiratory tract infections
- Socioeconomic status

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Read more about treating COPD at MedicalEconomics.com's resource center:

www.modernmedicine.com/resource-center/copd

FIVE GREAT WINES for under $100

1. Chateau Rieussec Sauternes 1er Grand Cru, 2009
Price: $83.99
The Wine Advocate describes the palate of this white wine as "stunning" and "very viscous in the mouth with tangy grapefruit, honey and white peach." At 97 points, it's one of the highest rated wines, while remaining at an affordable price.

2. Cune Rioja Imperial Gran Reserva, 2004
Price: $63.00
Named Wine Spectator's 2013 Wine of the Year, this Spanish, red wine may be hard to find. Rioja only made 4,000 cases.

3. Saint Theodoric le Grand Pin Chat du Pape, 2011
Price: $74.99
This full-bodied, red wine has "gorgeous fruit, solid mid-palate depth, and an elegant, ethereal texture that flows through the lengthy finish," according to the Wine Advocate.

4. Christophe Bonnefond Les Rochains Cote Rotie, 2009
Price: $94.99
International Wine Cellar says Christophe is "pure and elegant but deeply concentrated, with a pliant, velvety texture to the complex red and dark berry, floral and mineral flavors."

5. Chateau Garraud Lalande de Pomerol, 2010
Price: $24.99
Total Wine named this its top wine of 2013. It recommended pairing this full-bodied, red wine with red meats and assorted cheeses.

Thinkstock/iStock/mindstyle

These fun family getaways are the cure for cabin fever

By Donna Marbury

Most of the country has been covered in a blanket of snow, and with spring on the horizon, many people just want to get out of the house to thaw. Spring break is a perfect time for the family to get outside and explore. Below are our picks from the Travel Channel's top family spring break vacations:

ATLANTIS RESORT

Paradise Island, Bahamas
www.atlantis.com

This well-known resort island features programs just for kids, culinary classes, and even a Lego Construction room. On top of the water activities including swimming with dolphins and a water park, this vacation spot will keep you busy!

RANCHO DE LOS CABALLEROS

Wickenburg, Arizona
www.ranchodeloscaballeros.com

For those who are cowboys and cowgirls at heart, this resort will give you the ranch experience that includes horseback riding in the desert and campfires, but also golfing and a luxurious spa.

SANDY LANE

St. James, Barbados
www.sandylane.com

This upscale resort in the Caribbean offers three golf courses, a world-class spa, and plenty of sports activities overlooking a captivating beach.

LOEWS CORONADO BAY

San Diego, California
www.loewshotels.com/en/

This Southern California resort is close to the San Diego Zoo and Wild Animal Park, but also features surfing classes, gondola rides and other outdoor and water sports activities for the whole family.

SOUTH SEAS ISLAND RESORT

Captiva Island, Florida
www.southseas.com

Located in South Florida 30 miles from Fort Myers, this beachside resort offers an Ocean Discovery Center, family wildlife exhibitions, along with golf courses, dining, and shopping.

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The Last Word

HOW IMPORTANT ARE YOUNG ADULTS TO THE ACA'S INSURANCE EXCHANGES?

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

Since the startup of the Affordable Care Act's (ACA) insurance exchanges, a great deal of media and public attention has focused on the participation rate of young adults. Both supporters and opponents of the law have assumed that without substantial numbers of people in the 18-35 age range enrolling in insurance plans, the exchanges would be forced into a "death spiral" of ever-rising premiums and declining enrollment.

BUT IS THAT assumption accurate?

According to a recent report from The Commonwealth Fund, a health policy think tank, the answer appears to be "not entirely." Earlier this year The Commonwealth Fund brought together about two dozen health insurance actuaries, health plan representatives, researchers, and federal officials to explore the role of young adult participation in the success or failure of the insurance exchanges.

Their conclusion: While young adult participation is important, it is only one factor, and not even the most important one, for determining whether the exchanges will succeed.

(Through the end of January, about 3.3 million young adults had enrolled, accounting for 25% of total plan enrollment.)

The true key, according to the symposium participants, will be the overall health status of all enrollees in the exchanges. That's because the ACA allows insurance companies to charge older adults up to three times more than younger adults—less than they were permitted before passage of the ACA but still substantial flexibility. So even if young adult enrollment falls short of projections, it will have less impact on insurers than would overall enrollment that turns out to be less healthy than expected, since insurers are now required to set a single risk pool for each state and can no longer set premiums based on an individual's health status.

Sara Collins, vice president for The Commonwealth Fund's healthcare coverage and access program, says the enrollment numbers for young adults have been treated in the media and the public as a proxy for the overall state of the risk pool. "There has been no consensus on what the actual rate of participation needs to be to ensure stability. So we wanted to convene a group of experts, including actuaries who are setting premiums for 2014 based on their risk pool expectations, as well as economists and health policy analysts to explore the issue," she says.

Collins adds that most companies offering plans through the exchanges have their own internal projections for young adult participation. "It's pretty clear that if there's lower than expected participation among young adults, when they start looking at 2015 you're not going to see a jump in premiums to the extent that it will cause people to leave the market. It won't create a so-called premium death spiral."

Some other major limitations on the possibility of a premium death spiral in the next few years include:

- **three risk-sharing programs built into the ACA, designed to lower claims costs and offset insurer losses during the first three years of the exchanges;**
- **the law's requirement that health plans justify premium increases of 10% or more;**
- **the ACA's medical loss ratio requirement, mandating that plans spend a set percentage of their premiums on medical care; and**
- **some plans may also hold down premiums by narrowing their provider networks.**

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