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ADVANSTAR
MEDICAL COMMUNICATIONS GROUP

NEW 7.5 mcg/hour Now Available

Butrans—7 Days of Buprenorphine Delivery

Butrans is a Schedule III extended-release opioid analgesic

WARNING: ADDICTION, ABUSE and MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; and NEONATAL OPIOID WITHDRAWAL SYNDROME

Addiction, Abuse, and Misuse

Butrans exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing Butrans, and monitor all patients regularly for the development of these behaviors or conditions *[see Warnings and Precautions (5.1) and Overdosage (10)]*.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of Butrans. Monitor for respiratory depression, especially during initiation of Butrans or following a dose increase. Misuse or abuse of Butrans by chewing, swallowing, snorting or injecting buprenorphine extracted from the transdermal system will result in the uncontrolled delivery of buprenorphine and pose a significant risk of overdose and death *[see Warnings and Precautions (5.2)]*.

Accidental Exposure

Accidental exposure to even one dose of Butrans, especially by children, can result in a fatal overdose of buprenorphine *[see Warnings and Precautions (5.2)]*.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of Butrans during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available *[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 pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use: Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risk of overdose and death with extended-release opioid formulations, reserve Butrans for use in patients for whom alternative treatment options (eg, non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Butrans is not indicated as an as-needed (prn) analgesic.

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

Addiction, Abuse, and Misuse

- Butrans contains buprenorphine, a Schedule III controlled substance. Butrans exposes users to the risks of opioid addiction, abuse, and misuse. As modified-release products such as Butrans deliver the opioid over an extended period of time, there is a greater risk for overdose and death, due to the larger amount of buprenorphine present. Addiction can occur at recommended doses and if the drug is misused or abused. Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing Butrans, and monitor all patients during therapy for the development of these behaviors or conditions. Abuse or misuse of Butrans by placing it in the mouth, chewing it, swallowing it, or using it in ways other than indicated may cause choking, overdose and death

Life-Threatening Respiratory Depression

- Serious, life-threatening, or fatal respiratory depression has been reported with modified-release opioids, even when used as recommended, and if not immediately recognized and treated, may lead to respiratory arrest and death. The risk of respiratory depression is greatest during the initiation of therapy or following a dose increase; therefore, 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 to Butrans, especially in children, can result in respiratory depression and death due to an overdose of buprenorphine

Neonatal Opioid Withdrawal Syndrome

- Prolonged use of Butrans during pregnancy can result in neonatal opioid withdrawal syndrome which may be life-threatening to the neonate if not recognized and treated, and requires management according to protocols developed by neonatology experts

Interactions with Central Nervous System Depressants

- Hypotension, profound sedation, coma, respiratory depression, or death may result if Butrans is used concomitantly with other CNS depressants, including alcohol or illicit drugs that can cause CNS depression. Start with Butrans 5 mcg/hour patch, monitor patients for signs of sedation and respiratory depression, and consider using a lower dose of the concomitant CNS depressant

Use in Elderly, Cachectic, and Debilitated Patients and Patients with Chronic Pulmonary Disease

- Closely monitor elderly, cachectic, and debilitated patients, and patients with chronic obstructive pulmonary disease because of the increased risk of life-threatening respiratory depression. Consider the use of alternative non-opioid analgesics in patients with chronic obstructive pulmonary disease if possible

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 during dose initiation or titration

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 for signs of sedation and respiratory depression. Avoid the use of Butrans in patients with impaired consciousness or coma

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

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

Visit Butrans.com for more information or to print the Butrans Trial Offer and Butrans Savings Cards

The first transdermal system to deliver 7 days of buprenorphine

Butrans® CIII

(buprenorphine) Transdermal System

5, 7.5, 10, 15, and 20 mcg/hour

Butrans, Once Weekly

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

PURDUE

Butrans® Ⓒ Ⅲ

(buprenorphine) Transdermal System

5, 7.5, 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: ADDICTION, ABUSE and MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; and NEONATAL OPIOID WITHDRAWAL SYNDROME

Addiction, Abuse, and Misuse

BUTRANS® exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing BUTRANS, and monitor all patients regularly for the development of these behaviors or conditions *[see Warnings and Precautions (5.1) and Overdosage (10)]*.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of BUTRANS. Monitor for respiratory depression, especially during initiation of BUTRANS or following a dose increase. Misuse or abuse of BUTRANS by chewing, swallowing, snorting or injecting buprenorphine extracted from the transdermal system will result in the uncontrolled delivery of buprenorphine and pose a significant risk of overdose and death *[see Warnings and Precautions (5.2)]*.

Accidental Exposure

Accidental exposure to even one dose of BUTRANS, especially by children, can result in a fatal overdose of buprenorphine *[see Warnings and Precautions (5.2)]*.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of BUTRANS during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available *[see Warnings and Precautions (5.3)]*.

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 Addiction, Abuse, and Misuse** BUTRANS contains buprenorphine, a Schedule III controlled substance. As an opioid, BUTRANS exposes users to the risks of addiction, abuse, and misuse. As modified-release products such as BUTRANS deliver the opioid over an extended period of time, there is a greater risk for overdose and death, due to the larger amount of buprenorphine present. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed BUTRANS and in those who obtain the drug illicitly. Addiction can occur at recommended doses and if the drug is misused or abused *[see Drug Abuse and Dependence (9)]*. Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing BUTRANS, and monitor all patients receiving BUTRANS for the development of these behaviors or conditions. Risks are 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). The potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed modified-release opioid formulations such as BUTRANS, but use in such patients necessitates intensive counseling about the risks and proper use of BUTRANS, along with intensive monitoring for signs of addiction, abuse, or misuse. Abuse or misuse of BUTRANS by placing it in the mouth, chewing it, swallowing it, or using it in ways other than indicated may cause choking, overdose and death *[see Overdosage (10)]*. Opioid agonists such as BUTRANS are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing BUTRANS. Strategies to reduce these risks include prescribing the drug in the smallest appropriate quantity and advising the patient on the proper disposal of unused drug *[see Patient Counseling Information (17)]*. 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** Serious, life-threatening, or fatal respiratory depression has been reported with the use of modified-release opioids, even when used as recommended. Respiratory depression, from opioid use, if not immediately recognized and treated, may lead to respiratory arrest and death. 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)]*. Carbon dioxide (CO_2) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids. 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. To reduce the risk of respiratory depression, proper dosing and titration of BUTRANS are essential *[see Dosage and Administration (2)]*. Overestimating the BUTRANS dose when converting patients from another opioid product can result in fatal overdose with the first dose. Accidental exposure to BUTRANS, especially in children, can result in respiratory depression and death due to an overdose of buprenorphine. **5.3 Neonatal Opioid Withdrawal Syndrome** Prolonged use of BUTRANS during pregnancy can result in withdrawal signs in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. Neonatal opioid 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 opioid withdrawal syndrome vary based on the specific opioid used, duration of use, timing and amount of last maternal use, and rate of elimination of the drug by the newborn. **5.4 Interactions with Central Nervous System Depressants** Hypotension, profound sedation, coma, respiratory depression, and death may result if BUTRANS is used concomitantly with alcohol or other (CNS) depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, 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, evaluate the patient's use of alcohol or illicit drugs that cause CNS depression. If the decision to begin BUTRANS therapy is made, start with BUTRANS 5 mcg/hour patch, monitor patients for signs of sedation and respiratory depression and consider using a lower dose of the concomitant CNS depressant *[see Drug Interactions (7.2)]*. **5.5 Use in Elderly, Cachectic, and Debilitated Patients** Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients. 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)]*. **5.6 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. **5.7 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 Dosage and Administration (2.2) and 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 (7.2)]*. 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 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. **5.18 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 serious adverse reactions are described elsewhere in the labeling:

• Addiction, Abuse, and Misuse *[see Warnings and Precautions (5.1)]* • Life-Threatening Respiratory Depression *[see Warnings and Precautions (5.2)]* • QTc Prolongation *[see Warnings and Precautions (5.7)]* • Neonatal Opioid Withdrawal Syndrome *[see Warnings and Precautions (5.3)]* • Hypotensive Effects *[see Warnings and Precautions (5.8)]* • Interactions with Other CNS Depressants *[see Warnings and Precautions (5.4)]* • 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 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. **7.2 CNS Depressants** The concomitant use of BUTRANS with other CNS depressants including sedatives, hypnotics, tranquilizers, general anesthetics, phenothiazines, other opioids, and alcohol can increase the risk of respiratory depression, profound sedation, coma and death. Monitor patients receiving CNS depressants and BUTRANS for signs of respiratory depression, sedation, and hypotension. When combined therapy with any of the above medications is considered, the dose of one or both agents should be reduced *[see Dosage and Administration (2.2) and Warnings and Precautions (5.4)]*. **7.3 Drugs Affecting Cytochrome P450 Isoenzymes** *Inhibitors of CYP3A4 and 2D6* Because the CYP3A4 isoenzyme plays a major role in the metabolism of buprenorphine, drugs that inhibit CYP3A4 activity may cause decreased clearance of buprenorphine which could lead to an increase in buprenorphine plasma concentrations and result in increased or prolonged opioid effects. These effects could be more pronounced with concomitant use of CYP2D6 and 3A4 inhibitors. If co-administration with BUTRANS is necessary, monitor patients for respiratory depression and sedation at frequent intervals and consider dose adjustments until stable drug effects are achieved *[see Clinical Pharmacology (12.3)]*. *Inducers of CYP3A4* CYP450 3A4 inducers may induce the metabolism of buprenorphine and, therefore, may cause increased clearance of the drug which could lead to a decrease in buprenorphine plasma concentrations, lack of efficacy or, possibly, development of an abstinence syndrome in a patient who had developed physical dependence to buprenorphine. After stopping the treatment of a CYP3A4 inducer, as the effects of the inducer decline, the buprenorphine plasma concentration will increase which could increase or prolong both the therapeutic and adverse effects, and may cause serious respiratory depression. If co-administration or discontinuation of a CYP3A4 inducer with BUTRANS is necessary, monitor for signs of opioid withdrawal and consider dose adjustments until stable drug effects are achieved *[see Clinical Pharmacology (12.3)]*. **7.4 Muscle Relaxants** Buprenorphine may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression. Monitor patients receiving muscle relaxants and BUTRANS for signs of respiratory depression that may be greater than otherwise expected. **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** *Clinical Considerations* *Fetal/neonatal adverse reactions* Prolonged use of opioid analgesics during pregnancy for medical or nonmedical purposes can result in physical dependence in the neonate and neonatal opioid withdrawal syndrome shortly after birth. Observe newborns for symptoms of neonatal opioid withdrawal syndrome, such as poor feeding, diarrhea, irritability, tremor, rigidity, and seizures, and manage accordingly *[see Warnings and Precautions (5.3)]*. *Teratogenic Effects - Pregnancy Category C* There are no adequate and well-controlled studies in pregnant women. BUTRANS should be used during pregnancy only if the potential benefit justifies the potential risk to 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** Opioids cross the placenta and may produce respiratory depression in neonates. BUTRANS is not for use in women during and immediately prior to labor, when shorter acting analgesics or other analgesic techniques are more appropriate. Opioid analgesics can prolong labor through actions that 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. **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)]*. **9 DRUG ABUSE AND DEPENDENCE 9.1 Controlled Substance** BUTRANS contains buprenorphine, a Schedule III controlled substance with an abuse potential similar to other Schedule III opioids. BUTRANS can be abused and is subject to misuse, addiction and criminal diversion *[see Warnings and Precautions (5.1)]*. **9.2 Abuse** 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 to addicts and drug abusers. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated claims of 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, like other opioids, can 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. Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to reduce abuse of opioid drugs. *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 (5.4) and Drug Interactions (7.2)]*. Intentional compromise of 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 (8.1)]*. **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** Advise the patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use). *Addiction, Abuse, and Misuse* Inform patients that the use of BUTRANS, even when taken as recommended, can result in addiction, abuse, and misuse, which could lead to overdose and death *[see Warnings and Precautions (5.1)]*. Instruct patients not to share BUTRANS with others and to take steps to protect BUTRANS from theft or misuse. *Life-Threatening Respiratory Depression* Inform patients of the risk of life-threatening respiratory depression, including information that the risk is greatest when starting BUTRANS or when the dose is increased, and that it can occur even at recommended doses *[see Warnings and Precautions (5.2)]*. Advise patients how to recognize respiratory depression and to seek medical attention if breathing difficulties develop. *Accidental Exposure* Inform patients that accidental exposure, especially in children, may result in respiratory depression or death *[see Warnings and Precautions (5.2)]*. Instruct patients to take steps to store BUTRANS securely and to dispose of unused BUTRANS by folding the patch in half and flushing it down the toilet. *Neonatal Opioid Withdrawal Syndrome* Inform female patients of reproductive potential that prolonged use of BUTRANS during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated *[see Warnings and Precautions (5.3)]*. *Interaction with Alcohol and other CNS Depressants* Inform patients that potentially serious additive effects may occur if BUTRANS is used with alcohol or 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. *Disposal* Instruct patients to refer to the Instructions for Use for proper disposal of BUTRANS. Patients can dispose of used or unused BUTRANS patches in the trash by sealing them in the Patch-Disposal Unit, following the instructions on the unit. Alternatively, instruct patients to dispose of used patches by folding the adhesive side of the patch to itself, then flushing the patch down the toilet immediately upon removal. Unused patches should be removed from their pouches, the protective liners removed, the patches folded so that the adhesive side of the patch adheres to itself, and immediately flushed down the toilet. Instruct patients to dispose of any patches remaining from a prescription as soon as they are no longer needed.

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

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440-891-2778 / gdecenzo@advanstar.com

KEN SYLVIA **Vice President, Group Publisher**
732-346-3017 / ksylvia@advanstar.com

DAVID A. DePINHO **Publisher/Group Editor**
732-346-3053 / ddepinho@advanstar.com

PUBLISHING & SALES

MONIQUE MICHOWSKI
National Account Manager
732-346-3098 / mmichowski@advanstar.com

ANA SANTISO
National Account Manager
732-346-3032 / asantiso@advanstar.com

MARGIE JAXEL
Director of Business Development, Healthcare Technology Sales
732-346-3003 / mjaxel@advanstar.com

TOD McCLOSKEY
Account Manager, Display/Classified & Healthcare Technology
440-891-2739 / tmccloskey@advanstar.com

JOANNA SHIPPOLI
Account Manager, Recruitment Advertising
440-891-2615 / jshippoli@advanstar.com

DON BERMAN
Business Director, eMedia
212-951-6745 / dberman@advanstar.com

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GAIL KAYE
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Sales Support

RENÉE SCHUSTER
List Account Executive
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Permissions
440-891-2742 / mcannon@advanstar.com

EDITORIAL

GEORGE G. ELLIS JR., MD, FACP
Chief Medical Adviser

JEFFREY BENDIX, MA
Senior Editor
440-891-2684 / jbendix@advanstar.com

CHRIS MAZZOLINI, MS
Content Manager
440-891-2797 / cmazzolini@advanstar.com

DONNA MARBURY, MS
Content Specialist
440-891-2607 / dmarbury@advanstar.com

ALISON RITCHIE
Content Associate
440-891-2601/aritchie@advanstar.com

KEN TERRY
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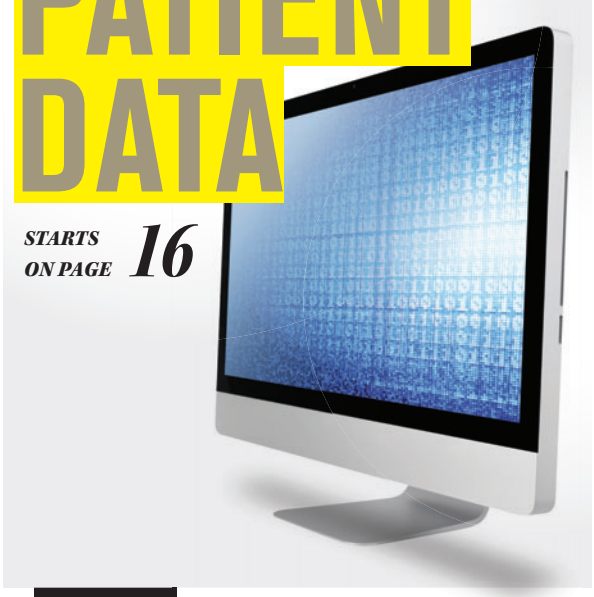

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Reference: 1. Waters DD, Brotons C, Chiang CW, et al. Lipid treatment assessment project 2: a multinational survey to evaluate the proportion of patients achieving low-density lipoprotein cholesterol goals. *Circulation*. 2009;120:28-34.

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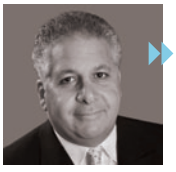

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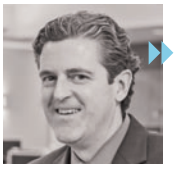

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from the Trenches

> We estimate that 15 physicians will retire within five to seven years in our area—each of us has 4,000 patients. We have been unable to recruit a single primary care physician in roughly six years. This is a true crisis.
>
> **Kristofer Sandlund, MD,** ZANESVILLE, OHIO

PRIMARY CARE PHYSICIANS MUST LEARN TO SAY 'NO'

I cannot thank you enough for your series on "Fighting Back." Primary care physicians [PCPs] are more discouraged than at any time in the past three decades, and your magazine is the first and only to give truly particle advice on how to survive this crisis.

Beyond that, by asking for our suggestions, you have truly honored your readers. Few would even consider listening to us. In fact, nobody else is—not the government, nor insurance companies, not the American Medical Association, and certainly not the American Academy of Family Physicians.

There are two major consequences of this crisis that must be averted. First, the death of outpatient physician-delivered primary care, and the subsequent transformation to physician extender primary care, with inadequately trained providers.

I have been and continue to be the one of the biggest supporter of nurse practitioners [NPs] and physician assistants in our community. I was the first to hire an NP 15 years ago and I regularly mentor NP students. However, overall it's just being done wrong, but that is another subject.

The more important crisis is the lack of quality healthcare for our senior citizens. It has already begun in our area. Medicare patients cannot find PCPs taking new Medicare patients. Recently I had a patient who moved, and who then drove 90 minutes to see me for an appointment—absolutely no PCPs in her new area are taking on new Medicare patients.

We estimate that 15 physicians will retire within five to seven years in our area—each of us has 4,000 patients. We have been unable to recruit a single PCP in roughly six years. This is a true crisis.

My solution (a small piece of it) is to communicate to PCP's to learn to say "no." This means saying no to multi-billion dollar industries that expect us to work for them for free. It's difficult at first, but the following decisions have allowed us to continue providing quality medical care for our Medicare patients:

First: no home healthcare. Do you know of any company that requires so much work of a physician and expects it for free? But it's not free. Every phone call, every order, every form and every fax costs you money, as well as precious personal time. Do you believe that new coding in 2015 will allow you to be reimbursed for this in a fair manner? Not a chance. So why do it at all?

Second: no durable medical goods. I'm not talking about the nebulizer or glucometer that you ordered for your patient. I am talking about the diabetic shoes, the inserts, the electrical stimulation units, the sleep apnea equipment, the post surgical supplies, the vacuum devices, the scooters, the chair

> A month later I was given my license back but Capson has a clause in its contract that automatically terminates med mal regardless of what caused the loss of license....I want all doctors to check for that clause. With the way medicine is going these days and the draconic ways of state medical boards, we should all be very afraid.
>
> **Ronald F. Chalifoux, Jr., DO,** MCMECHEN, WEST VIRGINIA

lifts, and on and on. Remember that you are liable for fraud every time you order these. The government doesn't care that you were paid nothing, so your documentation had better be thorough—or better yet, just say no.

Third: no to extended-care facilities. Do you receive constant calls and paperwork to fill out from these expensive facilities? What do they pay you for your services?

I recently saw a new billboard for a facility that now offers "memory services" to help with their patients with dementia. In less than a week, I was faxed a two-page order form for these therapies. The facility bills for this, yet they "forget" to pay you. My response was "no," and when given the same old line, "Then there is nobody else who can order it", I respond, "Gee, you should hire some physicians."

Fourth: No cataloging and filing records. About three years ago, our daily fax count averaged from 300 to 500 pages each day—records from every patient visit of any kind. Of course, 98% of these records are computer-driven junk. It sometimes can be difficult even to tell why the patient was there.

We notified all specialists and hospitals that we would receive no faxes due to the expense. Our patients are instructed that we will call or access and print the tests that we truly need, which usually consist of less than 2% of the total. We simply cannot collect and keep all of these meaningless collections of bureaucratic fodder.

Outpatient primary care is dying on the vine. The true tragedy is for our Medicare patients. Learn to say "no," so that you can continue to say "yes" to our senior citizens. Our practice will never turn them away.

Thank you again for your wonderful magazine and website!

Kristofer Sandlund, MD
ZANESVILLE, OHIO

DOCTORS SHOULD BE AWARE OF MALPRACTICE TERMINATION CLAUSES

I enjoyed the April 10, 2014 article regarding coverage limits. ("The importance of coverage limits in malpractice insurance.")

I was insured by Capson medical malpractice until August 2014. On July 25, 2014, the West Virginia osteopathic medical board temporarily suspended my license after receiving misinformation from the West Virginia Bureau of Public Health.

A month later, I was given my license back but Capson stated that it has a clause in its policy that automatically terminates a provider from its med mal policy regardless of what caused the loss of license.

I find that insane but want all doctors to check for that clause. With the way medicine is going these days and the draconic ways of state medical boards, we should all be very afraid.

Roland F. Chalifoux Jr., DO
MCMECHEN, WEST VIRGINIA

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REPORT: HOSPITALS IN EXPANDED MEDICAID STATES TO SAVE $4.2 BILLION

Hospitals will save $5.7 billion this year in uncompensated care costs due to the implementation of the Affordable Care Act (ACA), according to a new report by the U.S. Department of Health and Human Services (HHS).

Hospitals in states that have expanded Medicaid under the ACA are expected to save up to $4.2 billion, or 74% of the total savings, while hospitals in states that have not expanded Medicaid are projected to save up to $1.5 billion.

HHS says the savings are the result of the large number of Americans who gained health insurance through the ACA. As of July, nearly 8 million Americans had enrolled in Medicaid and the Children's Health Insurance Program, according to HHS. "Today's news is good for families, businesses, and taxpayers alike. It's yet another example of how the Affordable Care Act is working in terms of affordability, access, and quality," said HHS Secretary M. Sylvia Burwell.

ICD-10: PROGRESS REMAINS SLOW AMONG SMALL PRACTICES

Small medical practices have slowed in their preparation for implementing the International Classification of Diseases—10th revision (ICD-10), according to a recent survey from the Workgroup for Electronic Data Interchange (WEDI).

Originally scheduled to launch this year, the switch to the ICD-10 code set was delayed until October 1, 2015. But it seems the extra time has allowed many providers to delay their preparation efforts.

In a letter sent to U.S. Department of Health and Human Services Secretary Sylvia Mathews Burwell along with the survey results, WEDI Chair Jim Daley says this lack of preparation is cause for concern because it will leave little time for remediation and testing.

"It appears the delay has negatively impacted provider progress, causing two-thirds of provider respondents to slow down efforts or place them on hold," Daley said in the letter. "While the delay provides more time for the transition to ICD-10, many organizations are not taking full advantage of this additional time."

3 out of 4 small practice providers:

Do not know when they will complete an impact assessment or have delayed it until 2015.

2 out of 3 providers:

Have not begun external testing

7 out of 8 providers:

Say the ICD-10 delay has impacted their preparation timeline

Source: WEDI survey of 324 providers, 87 vendors and 103 health plans

The Vitals continues on page 13

OIG report: Medicaid managed care programs need more oversight

WITH UP TO 18 million new people expected to enroll in Medicaid by 2018, the Centers for Medicare and Medicaid Services (CMS) needs to exercise tighter control over the program to ensure that patients have adequate access to quality care, a new government report concludes.

After examining Medicaid managed care organizations in 33 states throughout the country, the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) found widely varying standards for access to care, ranging from one primary care provider (PCP) per 100 Medicaid enrollees to one PCP per 2,500 enrollees. In addition, standards often are not specific to certain types of providers, or to population density.

"State standards vary widely and are often not specific to providers who are important to the Medicaid population, such as pediatricians, obstetricians, and high-demand specialists," the report says. "In addition, these standards often apply to all areas within a state and do not take into account differences between urban and rural areas. Without standards for specific provider types or areas, states may not be able to hold plans accountable for ensuring adequate access to care."

The most common types of Medicaid access standards are those that limit the distance or amount of time patients have to travel to see a provider, those that require appointments to be provided in a certain period of time, and those requiring a minimum number of providers in relation to the number of enrollees.

In terms of distance to a PCP, and among the 15 states that distinguish between urban and rural areas in their standards, standards ranged from six to 30 miles in urban areas and 15 to 60 miles in rural areas. Waiting times for a routine PCP appointment varied from 10 to 45 days, and 10 to 60 days to see a specialist.

Among the states with standards for the number of enrollees per PCP, for four states the required ratio is one PCP for one to 599 enrollees, for nine states the ratio is one to between 600 and 1999 enrollees, and for seven states the ratio is one to 2000 enrollees or more.

The report found further that only a handful of states use direct tests, such as actually calling providers, to determine how well programs are complying with access standards. Instead, these states rely on outside contractors to assess plan compliance, most of whom use methods such as on-site visits, enrollee satisfaction surveys, and reviews of policies and procedures.

In an official response to the report, CMS Administrator Marilyn Tavenner said CMS agrees with all the recommendations and is taking steps to implement them.

The OIG report recommends that CMS:

1. Strengthen its oversight of state standards and ensure that states develop standards for key providers.
2. Strengthen its oversight of states' methods to assess plan compliance and ensure that states conduct direct tests of access standards.
3. Improve states' effort to identify and address violations of access standards.
4. Provide technical assistance and share effective practices.

JUDGE RULES AGAINST INSURANCE SUBSIDIES FOR FEDERAL EXCHANGES

A federal judge in Oklahoma has ruled that subsidies paid to people who purchased a health plan through the federal healthcare exchange established under the Affordable Care Act (ACA) are invalid.

The ruling stemmed from a lawsuit brought against the ACA by Oklahoma Attorney General Scott Pruitt. He said in a statement that "The administration and its bureaucrats in the IRS handed out billions in illegal tax credits and subsidies and vastly expanded the reach of the health care law because they didn't like the way Congress wrote the Affordable Care Act."

The ruling marks another chapter in the tortuous life of the ACA, which has been subjected to lawsuits and other legal challenges since its inception. Other federal courts in Richmond, Virginia, and Washington, D.C., have heard appeals and issued conflicting rulings, with the Richmond court upholding the legality of the subsidies. A three-judge panel in Washington, D.C. initially ruled against the subsidies, but that decision was vacated by the full court.

END-OF-LIFE CARE REQUIRES IMPROVED DOCTOR-PATIENT COMMUNICATION

Improved physician communication, increased palliative care training, and revised payment systems will be key to transforming end-of-life care planning in the U.S., according to a recent report from the Institute of Medicine (IOM).

The report, "Dying in America," examines end-of-life care and the barriers that prevent effective planning and delivery of care to patients, including a limited number of palliative care specialists and a lack of financial incentives within the system.

Five end-of-life care recommendations:

- focused patient-centered, family-oriented care delivery,
- improved physician-patient communication and advanced-care planning,
- increased palliative care training and professional development,
- reformed payment systems to encourage planning conversations, and
- increased public education and patient engagement

Source: IOM

Consumers report mixed feelings toward ACA healthcare exchanges

CONSUMERS WHO bought healthcare insurance through the online exchanges during the first open enrollment period were dissatisfied with the overall experience, but increasingly pleased with many specific aspects of the exchanges, and with the quality of the coverage.

Those somewhat contradictory findings emerge from The Commonwealth Fund's most recent tracking survey regarding the implementation and effects of the Affordable Care Act, conducted from early April to early June. Sixty-five percent of respondents who purchased coverage on the federal exchange, and 55% who did so on a state exchange, described their experience as either "fair" or "poor."

At the same time, however, 57% said it was "very easy" or "somewhat easy" to compare the premium costs of different plans, compared with 37% in October 2013, when the exchanges started up. Similarly, 48% said it was "very" or "somewhat" easy to compare potential out-of-pocket costs, up from 34%, and 47% found it "easy" or "somewhat easy" to compare benefits coverage, up from 30%.

Asked to rate their healthcare insurance overall, 68% of those who purchased coverage on the exchanges said it was good, very good, or excellent. By contrast, 86% of respondents with employer-provided coverage gave it a positive evaluation.

"These findings suggest that the process of enrolling was challenging for many people who went to the marketplaces, but the significant need for insurance coverage among uninsured Americans who could not afford it prior to the law, meant that people were largely willing to put up with the complexities of selecting health insurance so that they could finally have health insurance," Sara Collins, Ph.D., vice president for healthcare coverage and access for The Commonwealth Fund told *Medical Economics*.

Opinions regarding some aspects of the exchanges varied by income, age and political affiliation. For example, 49% of those with incomes less than 138% of the poverty level said it was somewhat or very easy to find an affordable plan, compared with 36% of those with incomes 400% of the poverty level or higher.

The authors say the difference is probably due to the "cost protections and improved affordability for adults with lower incomes, who may be eligible for Medicaid or receive premium and cost-sharing subsidies for health plans sold through the marketplace."

The survey found that the ACA appears to be succeeding thus far in making healthcare insurance more affordable and available to Americans with low and moderate incomes. Nearly two-thirds (65%) of low- or moderate-income adults said it was very or somewhat easy to afford their premiums, while 54% of adults with incomes of 250% or more of the poverty level said it was very or somewhat easy.

On the other hand, 79% of those with incomes above 250% of the poverty level and employer coverage said it was easy or somewhat easy to pay their premiums, compared with 54% of those with incomes below that level. Consequently, say the authors, "while the insurance market reforms have made it far easier for people without employer coverage to gain access to comprehensive benefits without being charged more based on their health status, employer-based insurance continues to be a better deal for people with higher incomes."

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THE BATTLE OVER PATIENT DATA

How to secure your access

by **JOHN MORRISSEY** *Contributing author*

Who owns patient data in an electronic health record (EHR)? It's a simple question with a complex answer. No longer confined to the shelves of a physician's office, patient data is now shared and used by a myriad of organizations across healthcare: Other physicians and health systems, the EHR vendor, payers, and researchers, not to mention patients themselves. While primary care physicians often originate the medical record, the resulting data are not theirs alone.

HIGHLIGHTS

01 Protect your practice with a contract that clearly spells outs how and when an EHR vendor can use patient data

THE IMPLICATION? The traditional concept of ownership is unraveling as patient data migrates away from paper charts and takes up residence in the cloud. Experts now counsel physicians against the concept of data ownership entirely. Instead, they encourage physicians to consider themselves "stewards" of the data within their possession and administrative control. (See "data stewardship," page 17).

This grey area has serious consequences for physicians, particularly concerning their relationship with their EHR vendors, the third party who has most access—and control—over patient data. Too often, physicians give vendors the upper hand on data rights by not addressing them when drawing up the contract, says Adam Greene, JD, a partner with the law firm Davis Wright Tremaine and an expert on healthcare tech-

nology and privacy. "To be perfectly blunt, more often than not these details are not addressed up front," Greene says. "You have pretty generic language, and oftentimes that can come back to haunt the physician.

Questions of data rights should be "top of mind when they're contracting," Greene adds. "And if they feel like the contract with the EHR vendor does not provide enough details on this front, they should ask the questions, and if they feel like they need to get the answers in writing, they should push for that."

It can prevent trouble down the road. Full Circle Health Care, a physician's practice in Presque Isle, Maine, had its access to data for 4,000 patients blocked by its EHR vendor after a dispute over billing practices, according to a report in the Boston *Globe*.

"I'm incredulous they think it is OK to hold us hostage like that," E. Victoria Grover, the practice owner, told the newspaper.

Medical practices shouldn't let a vendor hold them hostage over data rights. The key: protect your practice with a contract that clearly spells outs how and when an EHR vendor can use patient data.

LEVERAGING YOUR POSITION

One point is clear: EHR vendors do not have outright ownership of patient data, even if it lives within their system.

Under the Health Insurance Portability and Accountability Act (HIPAA), business associates, including EHR vendors, must return or destroy patient health information upon termination of the agreement, Greene says.

"That really kind of undercuts any claim that they have ownership," Greene says. "While HIPAA doesn't use the word ownership in any place, it undermines any argument that the vendor owns the data."

The agreement with the vendor, then, must be about more than wrangling an affordable price, says Deven McGraw, JD, a healthcare attorney with the firm Manatt, Phelps & Phillips.

In practice, the EHR vendor may be the more powerful party, particularly in negotiations with small practices, McGraw says. Not reading or understanding contract terms can lead physicians to sign away "pretty significant rights to that data" to the vendor. During negotiations, physicians should clearly spell out EHR data rights

Data stewardship

"DATA OWNERSHIP IS A LITTLE BIT OF A TRICKY ISSUE, and a red herring in some respects," says Deven McGraw, an expert in the area of data rights with the healthcare law firm Manatt, Phelps & Phillips.

"The presumption [among physicians] is that to the extent that there is any ownership at all of that record, it was a record they created for their own business purposes and they are likely the presumed owners of that information," McGraw says. "Having said that, HIPAA and other laws create a shared set of rights and responsibilities with respect to those data that makes ownership a very awkward construct for speaking about how those rights and responsibilities ought to be divvied up."

Bound volumes filed on shelves didn't pose nearly as many issues of possession and rights as when data became electronic, says Joy Pritts, an expert on patient rights and privacy and former chief privacy officer for the Office of National Coordinator for Health Information Technology (ONC).

As a legal concept, ownership has traditionally been thought of as a bundle of rights and responsibilities, but that concept as applied to EHRs is "unraveling as data becomes more liquid," Pritts says. "It's not a piece of paper; it's more organizations and more people contributing different pieces. That makes it more complicated."

So where does that put physicians in the larger scheme? "Practices are seeing themselves as stewards of the data," says Robert Tennant, senior policy adviser at the Medical Group Management Association (MGMA). "They still believe, and they're correct, that they own the data, but the more astute ones realize that they are in fact the stewards."

Stewardship: Responsible management of something entrusted to you

"THE CONCEPT OF EHR DATA OWNERSHIP IS UNRAVELING AS DATA BECOMES MORE LIQUID."

– JOY PRITTS, FORMER CHIEF PRIVACY OFFICER WITH THE OFFICE OF NATIONAL COORDINATIOR FOR HEALTH INFORMATION TECHNOLOGY

Getty Images/E+/Rustem GURLER (computer); Getty Images/iStock Vectors/polygraphus (screen)

ADDRESS DATA MINING UP FRONT

Would you have a problem with an EHR vendor selling your patient data?

If this doesn't sit well with practices, the initial contract negotiation is the place to do something about it, says Mary Griskewicz, MS, senior director of healthcare information systems for the Healthcare Information and Management Systems Society.

Using de-identified patient data for research purposes is a part of many vendors' business models. "Once the information has been de-identified, then the vendor can use that information or disclose it however it wants without HIPAA limiting it, so they could potentially sell this de-identified information," says Adam Greene, JD, a partner with law firm Davis Wright Tremaine.

A contract for IT services is complicated, and "a lot of times the practices are relying on the vendor, and they're not having the contract reviewed by their own legal team," says Robert Tennant, senior policy adviser at the Medical Group Management Association.. The vendor basically sets the data-use terms, "and if it's in the contract that the vendor has control over the data, then I think the practice is going to be in trouble," he says.

When she was an information officer involved in contracting, Griskewicz always stipulated that upon termination, all data in the vendor's possession had to be destroyed, not just personal health information.

She also scanned contract language for generalizations such as the right to use data for research purposes, which she called "a major red flag for physicians when they're entering into contracts." 'Research' is a broad term, and it may entitle the vendor to more than an EHR customer thinks, she says.

in the business associates agreement and contract with the vendor. But many don't take advantage of this opportunity for leverage.

The consequences of overlooking data rights can be severe for physicians, McGraw says. The EHR vendor gains the upper hand and increases the likelihood that physicians won't have the contract language needed to control the relationship as a customer. Furthermore, it can limit their ability to migrate the data easily and inexpensively to a new EHR vendor in the event of a future decision to part ways.

It's never too late to revisit the contract in an attempt to address these issues, even if the contract has already been signed, and a practice realizes it didn't pay enough attention to data rights, Greene says. But success "frequently comes down to a matter of leverage." Unfortunately, the only option a physician would have is to say they don't like the terms and to go elsewhere. Physicians have limited leverage to negotiate these contracts with big EHR vendors, even at the beginning, but "there's nothing barring a physician from trying to do so."

Every physician negotiating a contract with a vendor should have the right to unfettered data access for patient care and follow-up, quality improvement, patient management, reporting and overall population health, says Mary Griskewicz, MS, FHIMSS, senior director of healthcare information systems for the Healthcare Information and Management Systems Society.

That's not to say EHR vendors have no claim to the use of data residing in their products. The terms of the associate agreement and the purchase contract can grant vendors an array of permitted uses that are within HIPAA parameters, McGraw says. "I've seen arrangements as basic as, 'We'll store your records and provide you with access to a much more advanced set of services,' where they're doing quality reporting for the physician, they're creating limited data sets out of the data and making them available for research purposes."

To sweeten the deal, a vendor may reduce the price of services such as record management "in exchange for the ability to mine data out of the record," McGraw says. HIPAA limits don't apply to data that are de-identified, e.g. stripped of elements that could trace the

➔ 20

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Dispersing responsibility

With ownership comes responsibility. But as ownership of patient data becomes more difficult to pin down in the age of electronic health records (EHRs) and cloud storage, federal policy concerning protection of health information and liability has also shifted, experts say.

The result is that data ownership is dispersed in ways that take some of the liability off physicians and other providers when a data breach occurs.

Initially, Health Insurance Portability and Accountability Act regulations made only "covered entities"—healthcare providers, health plans and claims clearinghouses—subject to its privacy stipulations. Covered entities were liable for any misuse of data to which they entrusted business associates.

But legislation enacted in 2009, along with the Affordable Care Act (ACA), modified the HIPAA privacy sections to update the handling of personal health information, delineating data-use responsibilities under new healthcare realities.

Federal regulations were extended to cover business associates, such as EHR vendors and other third parties that gain access to patient data.

"Those contractors are now, due to recent HIPAA changes, directly accountable for how they handle data in ways that were not the case before HITECH," says Joy Pritts, an expert on healthcare technology. "The regulators can and will go after the business associate for bad behavior. So the fact that the data may have come from your records does not give you downstream liability for everything that happens. Liability has been significantly limited."

That comes with a caveat, explains Deven McGraw, JD, a healthcare attorney with Manatt, Phelps & Phillips. Providers "would continue to be on the hook if they were getting indications that their business associate was being irresponsible with the data and they didn't take action to terminate the agreement," she says. "You can't bury your head in the sand if there are some indicators that reasonably should have led you to conclude that this person is being irresponsible with data."

"Liability has been significantly limited."

The close scrutiny of business associates that providers originally had to perform is now discouraged. "You arguably should not try to really control the actions of your business associates, because the regulators might assume that they're not really independent contractors for you--they're your agents," McGraw says.

Her advice is to avoid micromanagement. "Give them some degree of freedom to perform the service that you hired them to perform, and that includes the basic responsibilities of complying with HIPAA."

➔18 identity of patients. "So that business associate agreement may say: 'You give us permission to de-identify the data.' That's all that is needed." (See "Address data mining up front," page 18).

The business associates agreement, Greene says, should bind the vendor to use or disclose data only in the same manner as the healthcare provider can under HIPAA (see "Dispersing responsibility, page 20), in addition to these two provisions:

- Permitting the vendor to perform data aggregation to look at data across different covered entities and combine it for analysis for the benefit of healthcare providers;
- Allowing the vendor to use or disclose information for the vendor's own proper management and administration and to perform its legal responsibilities. For example, a vendor might have to report to the Food and Drug Administration, or have an auditor review live data to determine security practices.

MAKING THE SWITCH

While haggling over the initial contract, make sure terms are in place to protect your practice if you decide to terminate the relationship and switch to a different EHR vendor.

Physician dissatisfaction with EHRs is at an all-time high, and many physicians are looking to change systems. Yet questions about migrating data hang over these transactions, often making physicians leery about jumping ship even when it's the best decision for their practice.

"A pretty significant number of practices either had to dump their own EHR or are planning on doing it," says Robert Tennant, senior policy adviser at the Medical Group Management Association (MGMA). "So the question becomes, boy, what do you do then? Yes, they own the record, but it's not in a format that easily translates over to the new one."

Making matters worse, the situation calls for the loser of a customer to cooperate with the winner. "There's not much incentive for EHR vendors to make it easy for their customers to take their business elsewhere," Greene says. ➔22

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That possible scenario heightens the need to review the contract at the signing, says Pritts. One part of thinking through the agreement is "to identify these issues about what happens if they want to leave a specific vendor; and that should be, as a practical matter, in the contract." If that day arrives, the responsibilities are already spelled out.

It may not seem like the best environment to bring up the breakup, but think of it like a prenuptial agreement for this business relationship. Remember that it's much more difficult to accomplish once the ink is dry and, years later, the contract drives the separation, Griskewicz says.

Consider, though, that a vendor may reserve continuous rights to a departing provider's data, McGraw says. The return-or-destroy requirement applies only to patient health information, and "it doesn't necessarily cut off the business associate from being able to continue to use the de-identified data that they may have created from the identifiable data when they had it," she explains.

> "More often than not [data rights] are not addressed up front. You have pretty generic language, and oftentimes that can come back to haunt the physician."
>
> —ADAM H. GREENE, JD, PARTNER, DAVIS WRIGHT TREMAINE

Beyond data ownership questions, switching vendors requires a challenging feat: migrating data that's formatted and optimized for one proprietary system into a new system. "A particular vendor has designed software, and the data are created in that software, for that software, not created in a manner that can be used by other vendors' software," Greene says. (See "The interoperability problem," page 23.)

SURVIVING THE SWITCH

If your practice is contemplating an EHR switch, remember that it will be expensive, disruptive and riddled with technical issues related to data conversion. Yet it could still be the best decision your practice ever makes.

Five years ago, a 10-provider practice based in Independence, Missouri became an early case of converting its data to another EHR, at a cost of $65,000 above the purchase price of software and implementation, says Bryan Wood, practice administrator of Cockerell & McIntosh Pediatrics. Starting over without the data from the old system was never considered.

"So we just did it and we just planned on that extra cost," Wood says.

The practice received its raw data, written on "one compact disc, it didn't include much technical detail, or clues as to what the elements represent." With a background in IT, Wood had to use a computer tool to extract the data into a more beneficial form. Then he worked closely with database experts from the new vendor to convert, test and refine the data' a process that took four months.

Wood says his experience with the new vendor's database technicians was positive, but not without hitches. For example, errors sprouted up because the new system was looking for data elements that the old EHR did not collect, such as additional immunization details. "They did as good a job as they could with the data we received, but there were issues that we couldn't solve," he says.

There is no recourse for the manner in which data transfer takes place if the original contract did not cover it, Griskewicz says. "Vendors actually make money off providing that as a service of the exit strategy," she says. "They can say that if it's not in the contract, 'Well, we can do this for X amount of dollars.'" The price "depends on the vendor, there's no standard fee. It depends on the volume of the data that you're trying to

migrate."

It may also depend on the new vendor, she adds. "You bring them in, have them look at the file formats, the data--how it was stored. Can they take that information and help you with the migration? Because they're going to be much more motivated to help you down that road."

Jernigan Surgery Clinic, a small practice in Union City, Tennessee, went live with a new EHR in April. "They do everything they say; it pulls everything exactly how you have it," says Samantha Jernigan, practice administrator.

A vendor database specialist went through the previous EHR's data step by step with her, asking whether a certain data set should be pulled in or not. That allowed the practice to cull some information fields with little use, such as a second phone number or the third line of an address, which was rarely needed in the town of 11,000. Her master's degree in IT helped.

In the search for a replacement vendor, "other vendors would tell me, 'If anyone's offering you data migration for free, it's a trick. No one can do that for free.' And that's not true, they can. And you keep waiting for the, 'Okay, yeah, we can do that, but it's an extra charge.' No, it's really free."

And that could be the competitive spark for a reasonable solution to what happens to data in EHR vendors that go out of business. "I can't imagine there would be a system out there that you just couldn't convert into a format that you needed," says Jernigan. "They might say, 'Oh, we can't do that, it's not in the right format.' Well let's figure out how we can."

Practice and technical progress are lowering the conversion bar even for small practices, says Justin Barnes, formerly a healthcare IT executive and now a consultant. "Due to unified standards, innovative tools and the need for consolidated data and quality reporting, these migrations have become much less cumbersome than in the past." ◻

UP NEXT

Switching EHRs: Why it may be the best decision for your practice
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THE INTEROPERABILITY PROBLEM

Thousands of independent decisions on how to represent each and every clinical element in computer code have resulted over the years in a myriad of ways to record and share the same types of billing, demographic, lab value, diagnostic and other patient care details.

This variability is the root of healthcare's continuing problem in making EHRs interoperable, and full conversion of EHR data suffers from this state of affairs.

"Traditionally, migrating data from other EHRs has been a very expensive proposition," says Sam Bhat, vice president of sales and cofounder of the EHR vendor eClinicalWorks. "It is time-consuming, and end-user satisfaction from going through the process was not really good."

Pressure on vendors to improve data portability is increasing. The Electronic Health Record Association, a trade group of major IT vendors, recently created a developer code of conduct that has interoperability and portability as one of the tenets.

"It's in recognition that this is a critical issue," says Robert Tennant with MGMA. "I have heard horror stories of practices having to print and scan, because that's the only way they could get the records out. That's just terrible. That's not in the spirit of what we're trying to do with HIT."

In addition, companies seeing a business opening in the EHR replacement market are innovating in the area of data conversion, making it quicker, comprehensive and cheaper, sometimes at no additional cost.

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HEART FAILURE SHATTERS MILLIONS OF LIVES

HEART FAILURE PATIENTS: "STABLE" OR SILENTLY PROGRESSING?

Heart failure is a progressive disease that is characterized by frequent hospital admissions and high mortality rates:

>1 MILLION
HEART FAILURE HOSPITALIZATIONS OCCUR EVERY YEAR[1]
and rehospitalization continues to be an issue[2]

≥24%
OF HEART FAILURE PATIENTS DIE WITHIN 1 YEAR OF DIAGNOSIS[3,4]
this increases to ~50% within 5 years[3,4]

The neurohormonal imbalance associated with chronic heart failure is a contributing pathophysiological factor to the progression of the disease. Overactivation of the RAAS and SNS lead to decline in heart function, and cardiac remodeling; and the normal counterregulatory beneficial effects of the natriuretic peptide system (ANP/BNP) are diminished in heart failure.[5-7]

LET'S WORK TOGETHER TO CHANGE THAT

RAAS=renin-angiotensin-aldosterone system; SNS=sympathetic nervous system; ANP=atrial natriuretic peptide; BNP=brain natriuretic peptide.

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The EHR switch

Why it may be the best change your practice ever makes

Changing electronic health record vendors can be a costly process that drains productivity, but it still may be the right thing to do

by **GEORGE G. ELLIS JR., MD, FACP** *Chief medical adviser*

HIGHLIGHTS

01 Build a wish list of essential features for your practice's next system, and then compare your list with each vendor's offerings.

02 Prepare your practice financially for the decrease in productivity when switching EHR systems.

Switching your electronic health record (EHR) system is expensive, time-consuming, and disruptive to your practice. But if, as a physician, you are stuck with a system that has become unmanageable or negatively impacting your operations, converting could be the right solution no matter the cost.

With the conversion to the International Classification of Diseases-10th Revision, meaningful use 2 (MU2), and pay for performance on the horizon, you need an EHR system that works for you and makes your life easier, not harder.

My solo internal medicine practice in Boardman, Ohio has switched systems three times. I wanted to share some of the insights our team learned about this process.

In 2007, I purchased my second server-based system, after seeing a demonstration of the system's features by a salesman. During the pitch, he made big promises about the system's functionality, yet few were realized over the next five years of use. Upgrades were delayed; users were on different platforms; I was unable to attest to MU1 in 2011, and there was no Physician Quality Reporting System registry. The costs for fixes and hardware kept mounting.

Despite various problems, I liked some of the core features and functions of the system. I built and customized templates; I could easily navigate through notes, orders and prescribing. With training, my staff became adept at using the system. I really didn't want to switch, but the system could not get the practice to attest to meaningful use without additional costs. So the decision was made.

As part of the search for a new system, I started to investigate system features, review customer feedback, examine the track record of vendors, and, very importantly, consider the financial stability of the company. Also, I didn't want to rely just on demos from vendor sales people, so I decided to examine the published white papers about various systems. However, when I completed a form, the phone calls started, and I received literally hundreds of e-mails from overly aggressive salespeople.

Instead of vendors telling me what I wanted, I decided to build a wish list of essential features for my practice's next system. While there is no perfect system, I felt we could get closer to identifying the right system to meet my practice's needs. I received input from my office manager and key staff members. Here is my list:

Cloud-based practice management system

I no longer wanted the responsibility and expense of keeping and maintaining a server

on my premises. All of the practice's other systems were server-based, requiring expensive upgrades or replacement. The practice also had to contract with an information technology professional to maintain and manage the servers.

Pain-free upgrades

While upgrades are a natural part of software development, we looked for a system that would have significantly fewer disruptions to our practice operations.

Revenue-cycle management

I had talked to quite a few doctors about their experiences with revenue-cycle management (RCM) and decided that I was ready to adopt this kind of service.

Some of RCM's advantages are that it enables the seamless transition of coding and the submission of claims, thereby reducing the number of errors transferring billing information from one system to another. Also, if my biller quit, where would I be?

Once we got the hang of it, RCM sped up the "normal" billing process. The practice reduced rejected claims by 85% using RCM because of the scrubbing mechanisms in the system. I've seen a dramatic decrease in my accounts receivables, improved claims submission time and dramatically reduced the remittance time of submitted claims.

I get live eligibility at the time an appointment is scheduled, one week prior and the day of the visit. The practice can immediately access copay and deductible information. Claims go out on the day of the visit and payment reminders to patients go out automatically.

Meaningful use certification and PQRS registries

Although the cost of using an EHR far exceeds the $44,000 reimbursement we get for meaningful use, the ability to integrate and share data with other entities improves the delivery of patient care. We may feel forced to be part of MU2, but I really think that interoperability (when functional) will vastly improve continuity and transition of care by speeding communication among facilities and other providers.

> "The biggest lesson of all is, don't live with a system that doesn't work for you."

> I was one of the 50 physicians in the U.S. to attest to meaningful use 2 in the first quarter of the year. I call my dashboard 'meaningful use for dummies' because it has simplified the process for me."

The net effect will be to reduce redundant testing, improve treatment, and produce better overall patient care.

Quality metric dashboard with ticklers for preventative medicine

Quality metrics help guide the practice and improve the quality of care that I provide patients. And the ticklers warn and advise me on the need for vaccines, colonoscopies, and mammograms that are often overlooked.

As a result of the quality dashboard, which was high on my priority list, our practice attested to MU1 in 2012 and 2013. In 2014, I was one of 50 physicians in the U.S. to attest to MU2 in the first quarter of the year. I call my dashboard "meaningful use for dummies" because it has simplified the process for me.

Ability to interface with labs, imaging and other point-of-care tools

I wanted a system that would drop lab results directly into a patient's chart to avoid data entry errors and speed our accessibility to diagnostic information. I also wanted the system to upload directly into a dashboard to make tracking of practice guideline metrics accurate.

Onshore customer service and support that is focused on our practice needs

When I have a problem or an issue, it is important to have support from someone who understands the U.S. healthcare system and the unique needs of U.S.-based physicians.

Strong patient portal

I wanted the system to enable patients to request online appointments, prescription refills and to pay bills without involving additional staff time. I wanted my patients to be able to access the portal easily and maneuver through the portal without a lot of difficulty. I wanted to enhance the productivity of office staff; reducing the number of phone calls and amount of note-taking by receptionists saves time. It allows patients to communicate health measures such as blood sugars and blood pressures accurately and directly to the healthcare team.

Automated appointment reminders for patients

I also wanted to decrease the number of no-shows and increase adherence to follow-up visits for chronic conditions.

Reasonable outlay of costs

I wanted a system that would require a minimal investment in hardware and software.

Viable company that would be around in 20 years

I was looking for an EHR company with a strong financial track record and one that invests in research and development, because it decreases the risks of a company going out of business.

LESSONS LEARNED

Once we had our criteria, it helped our search efforts. But the process still took months to complete.

After we made the selection, the real work began. We began training; I started customizing templates. We prepared the practice financially for an anticipated loss in productivity and cash flow. And while the go-live stage remained a challenge, each day became easier. Ultimately, it took the practice four months for patient visits to return to pre-switch levels.

It's not easy to make the switch no matter how much the practice prepares, but it was worth the effort. Sticking to these 12 criteria allowed us to make the right choice. Although our current system is not without issues, we have a solid system on a solid platform that more than meets my needs.

Here are eight lessons our practice learned when switching systems.

It all starts with the end-user license agreement

First, have a lawyer review your old contract, and review the new end-user license agreement (EULA) before you sign. Make sure you have a EULA signed and training completed before notifying your current EHR vendor of the switch. Consider converting your records from your old system into the new system and explore the cost associated with the change. Make sure:

- you have an out clause;
- you understand the terms of the out clause, and that the separation is acceptable to your practice and the vendor; and
- the features, training and support promised in the sales process are actually referenced in the

contract, at the agreed-upon price.

The data: to convert or not?

Is it worth converting information that may be full of errors and that may cost a small fortune to convert? Data mapping and data conversion are costly. Think through these issues before you sign a final contract. Every time I have switched systems, we had a system in place to re-enter the data. This may seem like a lot of work, but for our practice it was an easier way to manage the conversion.

Build a cash reserve

I built up a cash reserve to cover two months of operating costs, so we didn't have to take out a line of credit. I did not draw a paycheck during this time period. I knew from my prior experiences of converting systems that there would be a drop in revenue due to productivity loss and the delay in billing through a new system.

Prepare financially for the decrease in productivity the practice will experience. Your income will drop. The conversion will also cause a delay in submitting claims—another problem to consider.

Should you jump in or ease in slowly?

Although I have talked to people who have tried a slow migration between EHR systems, I feel the best strategy is to transition all at once. Jump in and hold on! It feels like you are whitewater rafting during the go-live phase, and you will be paddling against the current for the next three months.

Don't believe the sales pitch

Would you buy a used car without checking collision reports or getting an independent assessment? Insist that your vendor give you the names of doctors who are using the system. Ask them for a list of 20-25 doctors so that you can pick physicians to contact. Often the vendor will try and persuade you to talk to customers who they know will give them excellent ratings.

Look at the October 10, 2014, issue of *Medical Economics* to see where doctors rated these systems in an unbiased and unsolicited study.

Learn and understand the system

Know the functionalities and capabilities of your EHR system.

Don't depend on your staff to be the sole power user. Learn the system, so that you can teach your team. It will help build efficiencies. Also, most solo practitioners don't have the luxury of a full-time, designated information technology person, so it's important for the practice leader to truly understand the capabilities of the system.

Prepare for the loss of productivity and the frustration that goes with it

Preparing yourself, your staff and your patients for the change is half the battle. Expect a decrease in productivity of 30%-50%. Prepare your staff with intense training.

Take steps to boost their morale, because they will probably become frustrated easily. Be ready to communicate to patients the reasons for changing systems and the benefits of the change, including access to a patient portal, improved quality of care with practice guidelines, ticklers for preventive care, e-prescribing, drug interaction checking and drug allergy warnings.

Don't change your workflow to adapt to the system. Adapt the system to enhance your workflow.

I have been using an EHR since 1992, when I started in practice. The market for EHRs is a dynamic place, undergoing great change. Many systems are inadequate, with too few users and the costs to constantly upgrade to maintain certification will drive many vendors out of business.

It might be time to switch when your EHR lacks support, is not MU2 certified, is inefficient or not user-friendly, offers multiple platforms and all users are not on the same version, if you want to add a practice management system with integrated scheduling and revenue cycle management, or when your practice has simply outgrown the EHR's usefulness.

The biggest lesson of all is, don't live with a system that doesn't work for you. You can make the switch, and now might be the right time to do it. ◘

George G. Ellis, Jr., MD, FACP, is a board certified internist who operates a solo practice in Boardman, Ohio. He is the chief medical adviser for Medical Economics.

> "Preparing yourself, your staff and your patients for the change is half the battle. Expect a decrease in productivity of 30% to 50%."

ROUNDTABLE

The future of interoperability

Three experts from different parts of the health IT arena discuss the barriers to achieving interoperability

by **MEDICAL ECONOMICS STAFF**

The ability of electronic health record systems (EHRs) to communicate with one another, known as "interoperability," has become a hot-button topic for physicians. One reason for this heightened interest is the requirement in meaningful use stage 2 (MU2) that eligible professionals exchange clinical summaries online in at least 10% of transitions of care, such as referrals to specialists and hospitals. In addition, accountable care organizations (ACOs) and patient-centered medical homes require physicians and other providers to exchange information more routinely than they do now to improve care coordination.

In this roundtable discussion, three panelists from different parts of the health IT arena discuss key barriers to interoperability and what the realities are for overcoming them. The panelists are: Doug Fridsma, MD, PhD, chief scientist of the Office of the National Coordinator for Health IT (ONC); Dan Haley, vice president of government and regulatory affairs for athenahealth, an EHR vendor; and Keith Hepp, senior vice president of business development at HealthBridge, a health information exchange (HIE) in Cincinnati. The exchange was moderated by Ken Terry, contributing editor for *Medical Economics*.

INTEROPERABILITY PROGRESS

"To start, how much progress do you think we've made so far on interoperability and what has been the impact of meaningful use on that?" asked Terry.

"First, we need to make sure that we are all talking about the same thing," said Fridsma. "There are clearly two components of interoperability: the ability to exchange information and then

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ROUNDTABLE PANELISTS

Doug Fridsma, MD, PhD,
is chief scientist of the Office of the National Coordinator for Health IT (ONC).

Dan Haley
is vice president of government and regulatory affairs for athenahealth, an EHR vendor.

Keith Hepp
is senior vice president of business development at HealthBridge, a health information exchange (HIE) in Cincinnati, Ohio.

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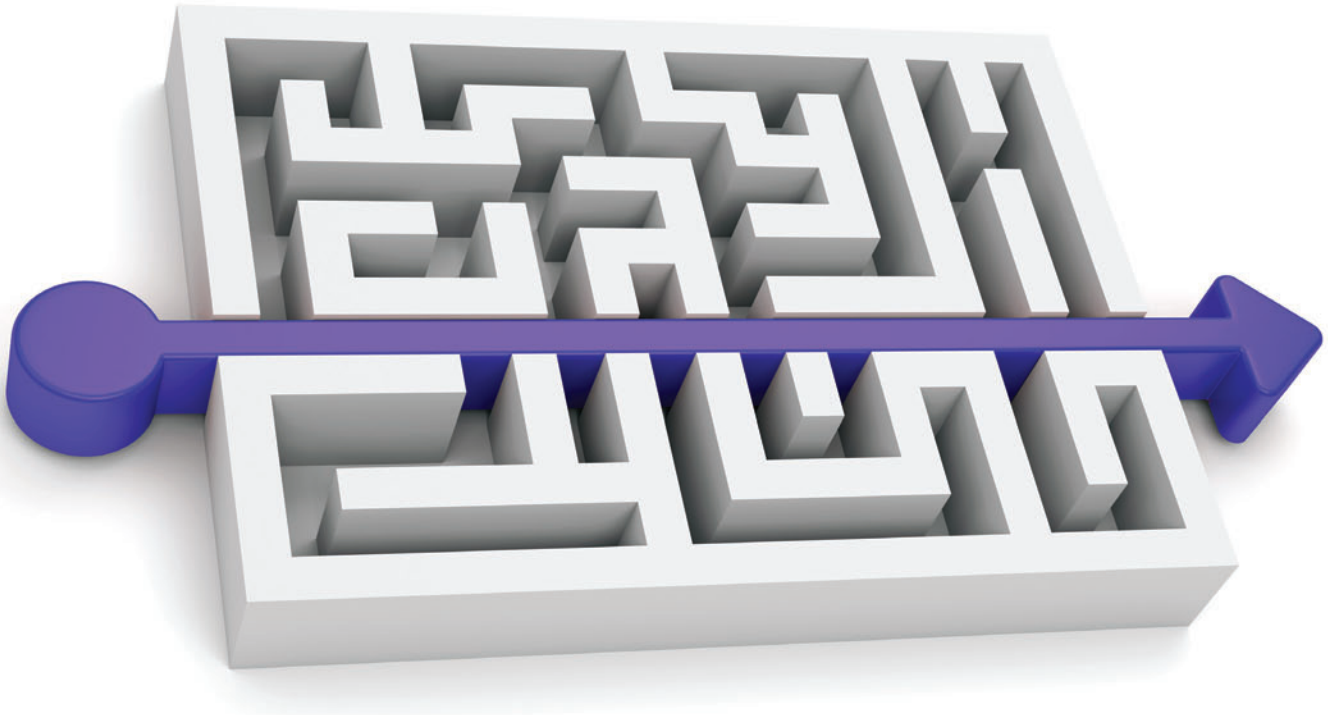

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> Providers and patients need to start demanding of health information technology the same level of functionality that we demand from information technology everywhere else." – DAN HALEY, VICE PRESIDENT, ATHENAHEALTH

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the ability to use the information that has been exchanged. So whenever someone says, are these systems interoperable or complains that they are not, I always ask what is it that they are trying to accomplish and to what degree does the technology help?"

"It's the distinction between interoperability and interoperation," agreed Haley. "It's not just a semantic distinction. Interoperability describes a capability and interoperation describes an activity."

"With that as a background, I think we have made some progress," noted Fridsma. "Largely because of the meaningful use incentive program, the majority of providers are now using EHRs. Without that, online exchange of health information would be impossible. Meaningful use stage 2 raises the bar for interoperability among these systems."

Haley countered that the Meaningful Use program has made the situation worse by subsidizing the purchase of non-interoperable EHRs. "Right now we have an awful lot of systems out there that are capable of interoperability but don't interoperate due to structural, technological, or financial reasons," he said.

"As you know, there are two parts to the meaningful use program," said Fridsma. "One is the certification criteria that are established though the ONC, and then there are the incentives and attestation that occurs through a separate process through CMS [the Centers for Medicare and Medicaid Services]. I think people have had technical challenges with attestation and meeting the requirements."

Hepp criticized the Continuity of Care Document (CCD) that is used as the standard format for the required summaries of care. (ONC mandates a variant of the CCD called the Consolidated Clinical Data Architecture, or C-CDA, but some providers are still using CCDs).

"There is too much variability in the specified elements of the CCD, making it difficult to extract usable data from the document," Hepp said. "Part of the challenge is getting everybody to agree on 'semantic normalization,' or the mapping of medical terms to a common nomenclature."

Fridsma agreed on the need for a more uniform CDA to promote interoperability. "However, this is not something the government can do on its own," he stressed. "It requires what I call open consensus-based, industry-engaged, standard development processes. The standard that comes out of those processes, however, is the starting point, not the end, because I don't believe that we can truly achieve interoperability in a committee."

"Committees in Washington, D.C. cannot establish interoperability," emphasized Haley. "Mandates won't do it. Federal dollars won't do it. We live in a world where we carry around a little supercomputer in our pocket that we use to interoperate, to share, and receive incredibly complex information with people all over the world. Providers and patients need to start demanding of health information technology the same level of functionality that we demand from information technology everywhere else."

"In one sense, this is a chicken and egg problem," responded Fridsma, "because you need both the policies to drive adoption and the technology to support those policies. ONC can devise policy drivers for interoperability, but it's up to the industry to develop the technology and the standards to implement those policies."

Fridsma believes that meaningful use has been able to "prime the pump" by helping to define technical specifications. He hopes that the industry, in conjunction with the

ONC and the standards development organizations, can help to overcome the challenges within the consolidated CDA.

Haley agreed that meaningful use has helped this collaborative process to an extent. "If you prime the pump too long, you will flood the engine," he said, "and what we are seeing now, in a sense, is the Meaningful Use program consuming itself."

Haley believes the government program has distorted the health IT market in ways that have impeded interoperability. For example, he said, the delays in the MU2 deadline, including the hardship exception for providers who lack 2014-certified EHRs, have locked many providers into 2011-certified products that the more advanced products can't communicate with.

"So the federal government is now defining as a hardship the very technologies they subsidized on behalf of those providers," Haley said. "You also get a chain of events where vendors tell their clients that they cannot meet their compliance deadlines and these care providers turn to the government and say it's not fair to punish them for the failing of their vendors. The government responds the only way they can by delaying the next stage, which has the effect of locking thousands and thousands and thousands of providers into the use of systems that do not interoperate." Moreover, he said, this policy has given vendors of non-interoperable EHRs another year to sell their systems.

Haley admitted, however, that the interoperability requirements of MU2 have encouraged many providers to start exchanging data with each other.

DIRECT MESSAGING

An important branch of policy-driven interoperability is secure messaging, using the Direct protocol that the public and private sectors agreed on recently. Direct messaging allows physicians and other providers to exchange secure messages using a protocol similar to e-mail. These messages may have attachments, such as CCDAs containing care summaries.

Like faxes, Direct can be used to "push"

> "The industry needs to be patient while the pieces fall into place."
>
> – KEITH HEPP, SENIOR VICE PRESIDENT, HEALTHBRIDGE

data from one point to another, but not to search for and "pull" data from disparate EHRs.

About half of the nation's physicians have Direct addresses supplied by three dozen "health information service providers," or HISPs. But that doesn't mean that all of those doctors are using Direct. DirectTrust, a trade association that accredits HISPs, says about 7.7 million Direct messages were exchanged from January through July of this year.

"Do you believe Direct messaging is becoming a major mode of communication among providers and will it help meaningful use?" asked Terry. The panelists lauded the Direct trend, but pointed out that it is a very limited form of interoperability.

"Direct is only part of the portfolio of solutions required to provide interoperability in all situations," Fridsma responded. "If you think about how we communicate with people in our family, we use our cellphone, text messages, email, or postings on Facebook. So Direct is an important part of the portfolio that will serve the needs of some specific kinds of information exchange, but we shouldn't expect it to be the end-all and be-all."

Haley agreed, but added that Direct is just one technological step up from fax. "We need to be careful not to lock ourselves into the use of inferior technologies in perpetuity in the name of making progress over the sad state of affairs we find ourselves in now, where doctors are still communicating by fax," he cautioned.

"I believe Direct will become a permanent part of the interoperability ecosystem," noted Hepp. "At HealthBridge we use different technologies based on what the problem is. For instance, we have hundreds of EHRs connected to our health systems, and we use HL7 and SSL [secure socket layer] technology. We don't see any reason to rip that out with Direct." Hepp emphasized that it depends upon the business problem being solved. "Direct is not the best, most efficient way to solve every problem," he added.

HEALTH INFORMATION EXCHANGES

Health information exchanges (HIEs), which can be used for both "push" and "pull" functions, enable providers to exchange data in some areas of the country. These organizations include public HIEs, and private HIEs that healthcare organizations use for communications among their affiliated hospitals, physicians, and ancillary providers.

Private exchanges have grown faster than public HIEs, partly because the latter have had difficulty finding a viable business model. In 2012, there were 119 operational public HIEs, with just 30% of hospitals and 10% of physicians participating in them.

Haley took a dim view of HIEs, saying he'd like to cut out "the middleman" entirely in data exchanges between EHRs. "When I communicate with a retail outlet electronically," he said, "I don't have to send my financial information to a government intermediary to translate it to the retailer, who then pushes information back through the intermediary to me."

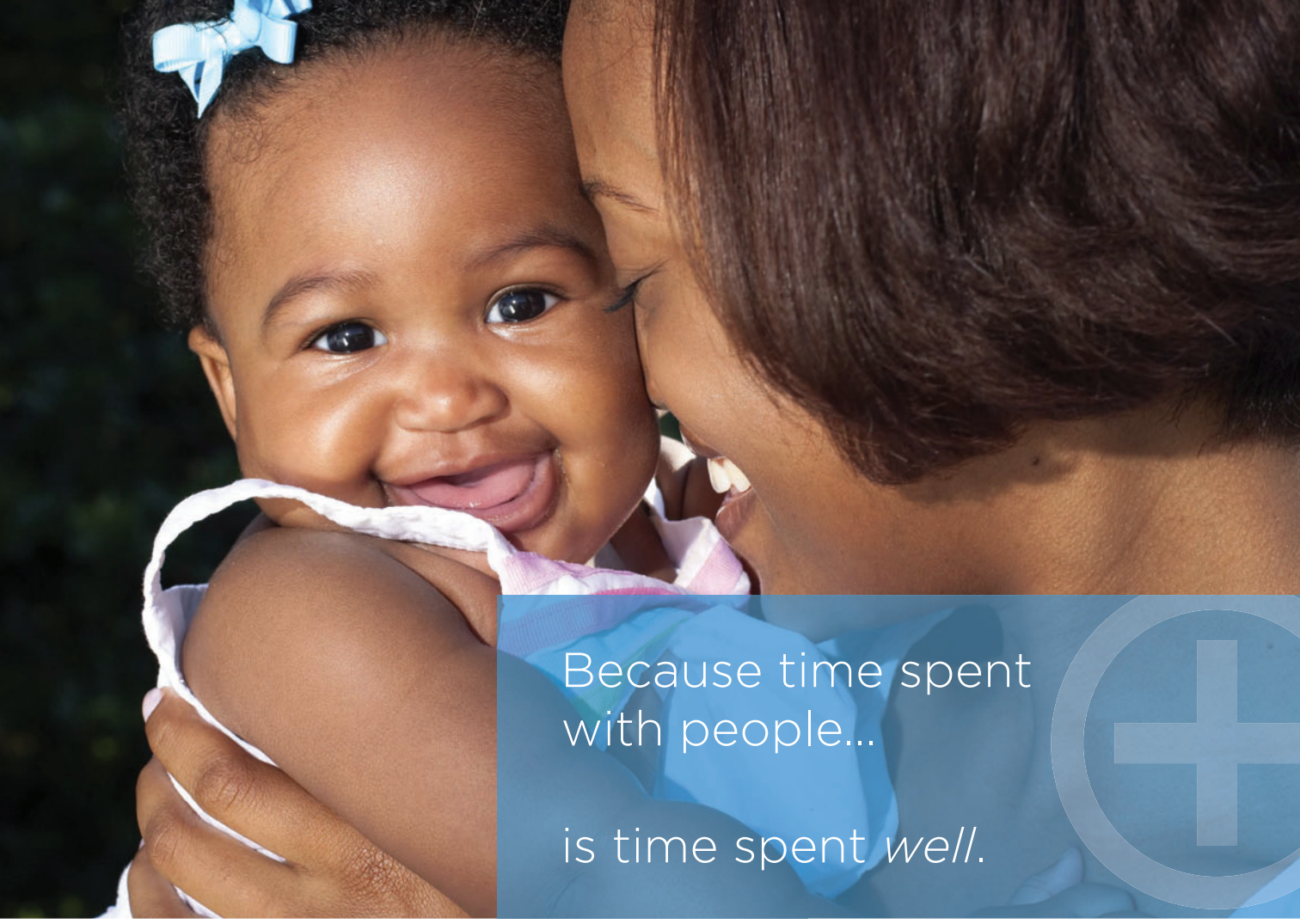
"The financial industry isn't the best analogy," responded Fridsma. "Certainly I interact with a retailer, but when I swipe my credit card, it goes to a clearinghouse that manages that transaction on behalf of that retailer. So there are intermediaries we currently use to help provide seamless transactions." He believes that HIEs can be useful and noted that successful HIEs don't just move information around, but also provide analytics and integrate data for their customers.

HealthBridge has been a great success story among HIEs. According to Hepp, it has been profitable for 10 years. "The basic value proposition for our hospital customers is cost savings," Hepp noted. It costs them $1.12 to mail a lab result to a physician, versus 12 cents to send it electronically via HealthBridge. We also provide the data that our participants need as they move into ACOs and other value-based payment models."

DATA LIQUIDITY

With most providers still in a very early stage of interoperabil-

➔ 36



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➔34 ity, the current emphasis is on exchanging documents, such as the CCDA care summaries attached to Direct messages. However, the data in these documents cannot flow automatically into the appropriate fields of receiving EHRs if those fields are different from the EHR that generated that data.

It's also difficult to search for data in disparate EHR databases. Both ONC and private organizations such as CommonWell, Healtheway, and the EHR/HIE Interoperability Workgroup are trying to solve these problems.

"ONC's long-term goal is to move from a document-centric to a data-centric HIE," Fridsma said. "We are seeking APIs, or plug-ins, that can help move this process along, and working on a structured data capture initiative to devise a syntax to describe granular data." He noted the ONC is continuing its work to standardize the meaning of medical terms, database structures, and the mechanisms of data transport and exchange.

Haley noted that CommonWell, an initiative started by several health IT vendors, including athenahealth, has been making progress. CommonWell is still focused on document exchange and accurate patient matching. Haley said the group is "excited" about a new HL7 specification, Fast Healthcare Interoperability Resources (FHIR), which defines a set of resources that represent granular clinical concepts.

Fridsma confirmed that FHIR has generated a lot of industry excitement. "Using modern standards like JSON and XML, FHIR is modular, data-centric, and developer-friendly," said Fridsma. "I think there is tremendous interest in this as an evolving standard that might support interoperability."

Although Haley expressed admiration for the FHIR approach, he cautioned the government against mandating it. "The reason we worry about that is precisely because FHIR is so cool and so promising," he said. "We know full well, as people who work in technology, that right around the corner there will be something that makes FHIR look like a fax machine. So we want government to resist the impulse to mandate use of a standard or some set of standards that could very well be obsolete before they are even universally adopted."

Hepp reiterated that semantic normalization must be accomplished before there can be true, data-centric interoperability. On the other hand, he noted, "We want to make sure we don't make the perfect the enemy of the good. If the results of the 250 most common tests can be exchanged accurately between disparate EHRs, that would provide 95% of the results that physicians need, even if the results of many other tests cannot be easily exchanged."

CONCLUSION

Terry asked each panelist for their final take-away messages. "The industry needs to be patient while the pieces fall into place," said Hepp. Looking back over the 15 years of HealthBridge's experience, he noted there have been many changes in health IT, business models and expectations in that period. "While healthcare has not moved as fast as other industries, I think the technology standards will get there. Healthcare as a whole is being transformed right now and interoperability is one piece in that major transformation."

"We will achieve interoperation when the consumers of health information technology demand interoperation, particularly care providers," said Haley. "There is no reason that care providers in this country should not expect of health information technology every bit of the capability and functionality that they expect of information technology everywhere else in their lives. And there is no reason that care providers should count on vendors who tell them they cannot prepare them to meet reasonable requirements that are intended to improve the sorry state of health information technology in this country. If a doctor's vendor is telling them that they can't meet the meaningful use deadlines, then they have to get a new vendor."

Fridsma re-emphasized the need to find multiple solutions to meet the interoperability challenge. "I think what we'll have in the future is not going to be a singular architecture, but a portfolio of different capabilities that will be applied to solving the problems and helping to incentivize things. Just as the analogy was made to how we manage the rest of our information needs, success in getting to an interoperable healthcare system is when we stop talking about interoperability; it actually works, and people aren't worried because the information is flowing at the right level of granularity and supporting the right usage," he said. ◘

Meaningful Use 2
A work in progress for physicians

Despite software and patient outreach challenges, many physicians are still determined to attest to stage 2

by **KEN TERRY** *Contributing editor*

From January through August of this year, just 3,152 eligible professionals (EPs) and 143 hospitals attested to Meaningful Use stage 2. Some critics of the EHR incentive program have said the slow rate of attestation shows that the program should be revamped or dropped. But physicians interviewed by *Medical Economics* say that they're soldiering on to meet the stage 2 requirements, despite difficult challenges in some areas.

The government has attributed the slow progress of stage 2 partly to the tardiness of many EHR vendors in meeting the 2014 certification criteria of the Office of the National Coordinator for Health IT (ONC). In response to this challenge, the Centers for Medicare and Medicaid Services (CMS) has decided to allow physicians who have not received or fully implemented 2014-certified EHRs to postpone stage 2 attestation until 2015 without facing a Medicare payment penalty. This year, they can use 2011-certified EHRs or a combination of 2011 and 2014 models to satisfy stage 1 or stage 2 requirements.

But even doctors who have upgraded their software and who have considerable EHR experience are finding stage 2 an arduous slog. For one thing, they and their staffs have to motivate patients to view their electronic records and communicate with their providers online. Moreover, the infrastructure for exchanging health information with other providers, as required, is not fully in place yet.

The financial incentives for showing Meaningful Use are front-loaded in stage 1 and diminish quickly in stages 2 and 3. So at this point, the primary motivation for physicians to continue with the program is their desire to avoid the back-end penalties for not attesting.

Some doctors have decided it's not worthwhile to go on. Michelle Holmes, a Seattle-based principal with ECG Management Consultants, says that several of her clients have chosen to budget for the Medicare penalties and the loss of the remaining incentives rather than continue. One of the reasons why they're giving up: "The technology hasn't caught up with the criteria," she says.

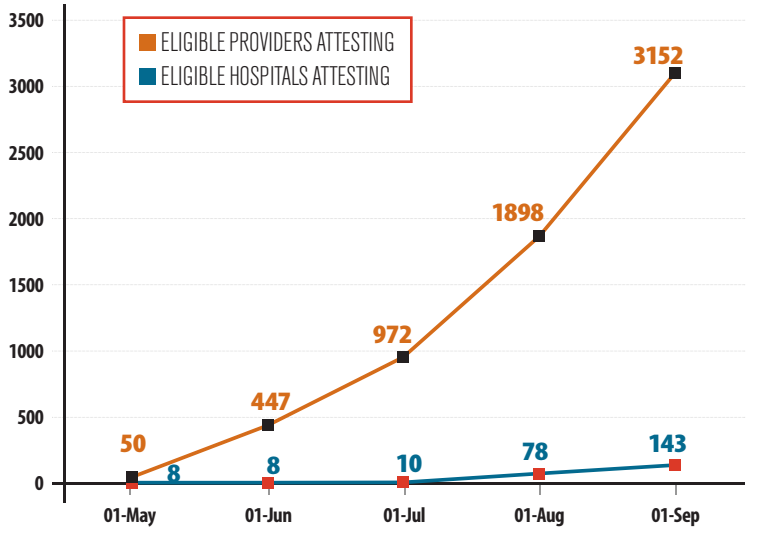
But other physicians are trying their best to comply with the MU stage 2 criteria. Some hope to attest this year. Here's what

HIGHLIGHTS

01 The financial incentives for attesting to Meaningful Use are front-loaded in stage 1 and diminish quickly in stages 2 and 3.

02 Consultants say that practices can increase the percentage of patients using their portals if they stress the value that patients can get from a portal.

MEANINGFUL USE 2 ATTESTATION NUMBERS, 2014



they're doing, and what you can do to make attestation easier.

PATIENT ENGAGEMENT

Few of the stage 2 requirements present serious challenges, but doctors must attest to all of them to achieve Meaningful Use. Among the most difficult areas are the transition-of-care and patient engagement requirements.

To meet the patient engagement criteria, practices typically use patient portals that interface or are integrated with their EHRs. According to the regulations, EPs must:

- provide at least 50% of patients seen within the MU reporting period with updated health records in four business days after the information becomes available to the EP,
- ensure that 5% of patients seen within the reporting period "view, download or transmit to a third party their health information,"
- provide 50% or more of their patients with a clinical summary within one business day after their office visit,
- ensure that 5% of patients seen during the reporting period communicate with them online,
- supply preventive and/or chronic care reminders to 10% of the patients who made two or more visits to the doctor in the prior 24 months, and
- provide patient-specific educational resources identified by the EHR to 10% of the patients seen during the reporting period.

Edward Gold, MD, an internist in a large primary care group based in Emerson, N.J., says that, while he is able to meet most of the stage 2 criteria, he is having trouble getting enough patients to communicate with him on his patient portal. Only 3% of his patients have done so to date, and he needs 5%.

Kenneth Kubitschek, MD, who practices in an internal medicine group in Asheville, North Carolina, says engaging patients electronically requires constant effort, including asking patients to "please send us a message."

"We don't necessarily need to, but we want them to do it, because we want to meet our 5%," he says.

Jennifer Brull, MD, a family physician in Plainville, Kansas, says that she and her colleagues, who have had a patient portal for nearly five years, have enrolled 60% of their patients on it. Earlier this year, just 39% of patients were using the site, but the practice has made a point of contacting non-participants and signing them up. Brull expects to have no problem meeting the patient engagement requirements.

PORTAL BENEFITS

Consultants say that practices can increase the percentage of patients using their portals if they stress the value that patients can get from a portal. Among the benefits for patients are the ability to receive lab results, request prescription refills and appointments, see statements and pay bills, obtain education materials, communicate with providers, and view and correct health records.

Practices should approach the portal as a potential winner for themselves and their patients rather than as just another box to check off for Meaningful Use, experts say. For example, notes Rosemarie Nelson, a Syracuse, New York-based consultant with the Medical Group Management Association (MGMA), using a portal for patient communications can greatly reduce pressure on a practice's phones and free up front-desk staff for other duties. Improving patient engagement can also enhance patient satisfaction, she adds.

Practices that view the portal as a tool for patient engagement should have no difficulty getting 5% of their patients to use the portal for viewing records and communicat-

ing with providers, says Holmes. But Nelson points out that practices still must take certain steps to ensure that a large enough portion of their patients sign up to meet the MU stage 2 criteria.

To begin with, physicians should recognize that patients won't find the portal on their own, even if it's linked to their practice site. Boris Rachev, senior principal and global health economist in CSC's global healthcare group, agrees that many patients are unaware of portal technology and what it's used for.

Another mistake that some practices make, Nelson says, is asking for patients' e-mail addresses when they register with the practice. Patients often decline because they think it will lead to them getting junk mail, even though the practice just wants to notify them when they have new messages on the portal.

It's more effective to have doctors or nurses urge patients to use the portal and explain why the practice wants their e-mail address, she says. A new study in the *Annals of Family Medicine* confirms this insight, although the study finds that involving the entire staff in the portal promotion effort gets the best results.

REMINDERS AND EDUCATION

Physicians can choose whether to use patient portals to meet two other MU stage 2 criteria. The first is the requirement that practices send preventive and chronic care reminders to 10% of the patients they see, and the other requires them to provide 10% of patients who visit them with educational materials. Their EHR has to generate the reminders and identify the patient-specific educational content, but how practices transfer these items to patients is up to them.

To send reminders, Holmes notes, a practice may be able to use its EHR to create and address letters to patients, but staff members still have to insert letters in envelopes and meter and mail them. While the same activities could be done more easily and cheaply online, many practices haven't acti-

> "The technology hasn't caught up with the [meaningful use 2] criteria."
>
> —MICHELLE HOLMES, PRINCIPAL,ECG MANAGEMENT CONSULTANTS, SEATTLE, WASHINGTON

MEANINGFUL USE 2 BASICS

Stage 2 of the meaningful use program focuses on:

1. More rigorous health information exchange
2. Increased requirements for e-prescribing and incorporating lab results
3. Electronic transmission of patient care summaries across multiple settings
4. More patient-controlled data

Source: ONC

vated that part of their portal, she says.

Brull's practice uses a combination of methods to alert patients that they're due for preventive or chronic care. She prefers to use the portal because it doesn't cost anything. But the practice phones or mails reminders to patients who aren't portal users.

Kagan says that the accountable care organization (ACO) to which his practice belongs identifies his patients' care gaps, using claims data and EHR reports. When he's ready to start his reporting period for stage 2, he says, his practice will probably mail reminders to patients.

One further point about portals: they're not all created equal. Particularly if your portal is not integrated with your EHR, using the portal to send care reminders to patients may require some manual data entry, Nelson observes.

But the physicians interviewed by *Medical Economics* say that it was fairly simple to transfer EHR updates or lab results to their portals. "Everything we do on the portal is completely automated," notes Gold.

TRANSITIONS OF CARE

To exchange care summaries at transitions of care, physicians may be able to use a regional health information exchange, but those are still not widespread. The other major approach is to use Direct messaging, which is similar to but more secure than regular e-mail.

According to DirectTrust, a trade association that accredits the entities that exchange Direct messages, about half of the nation's physicians have Direct addresses. In many cases, these addresses have been provided to the doctors by the healthcare systems that employ them or the hospitals with which they're affiliated. But a minority of physicians use Direct today, making it difficult for some doctors to reach the 10% threshold for MU stage 2, says Holmes.

Gold says that only two or three practices in his area are using Direct, although he thinks that will be enough for him to meet the stage 2 requirement. Kagan has started using Direct messaging to send clinical summaries to consultants when he refers patients to them. All of the local specialists have gotten Direct addresses from the hospital, but he doesn't know whether they're opening the electronic messages, so he continues to fax the same materials to them.

Brull has received three Direct addresses—only one of which she signed up for—from the facilities where she's on staff. She's afraid that she'll miss messages that were sent to the wrong address, but that's not an issue now.

"Nobody's using Direct anyway, so it doesn't matter too much at this point. But it's frustrating, because it could be very good. It hasn't lived up to its potential yet."

Kubitschek has a different problem with Direct. He knows that doctors in a hospital-owned group are receiving his Direct messages, because the count in his EHR keeps rising, he says. But they can't open the messages because they're on a 2011-certified EHR that doesn't have Direct capabilities. So this group and others with 2011-certified products have asked his practice to stop sending them Direct messages.

TECHNOLOGY AND CULTURE

It's apparent from these reports that the infrastructure for health information exchange at even the most basic level is still largely missing in many areas of the country. Where electronic data exchange does work, it can have wonderful results. Nelson cites a hospital in Syracuse that Direct-messages discharge summaries to its doctors before recently-discharged patients show up in their offices. But that won't help the many other physicians who can't exchange enough care summaries to show Meaningful Use.

Similarly, many doctors will find it hard to meet the MU patient engagement requirements. But here the problem is not technological, but cultural and administrative, says Rachev. While granting that some practices—particularly smaller ones—lack the in-house IT resources they need to make complex systems work smoothly, he also stresses the need for practices to redesign their workflow to take advantage of portals and other new technologies.

But that's easier said than done. Nelson notes that a physician in a small practice may not have the time to figure out all of the new EHR features and how to use them to show Meaningful Use.

"He or she is trying to see patients to keep revenue coming in and meet payroll and keep the lights on," she says. "But you need somebody to think about this stuff."

FIGHTING BACK SERIES WINNER

On the front lines of diabetes care

by **JOSE F. PENA, MD** *Contributing author*

How an accountable care organization (ACO) in one of the nation's poorest regions is improving diabetes care for its patients on a pay-for-performance model.

IN OCTOBER 2013, the *Los Angeles Times* reported that the Rio Grande Valley in Texas has two of the three poorest metropolitan areas in the nation. A month later, the *Texas Medical Observer* announced the release of a documentary called "Diabetesville USA," filmed in Cameron and Hidalgo counties, in the Rio Grande Valley, where it is estimated that more than 29% of the population lives with Diabetes Mellitus (DM). Poverty and disease are intimately connected.

The Rio Grande Valley ACO (RGV ACO)is one of the first Medicare ACOs in the country. We serve the communities in Hidalgo and Cameron counties and have a first-hand view of the problem.

RGV ACO adopted the Center for Medicare and Medicaid Services (CMS) vision of better care for individuals, better health for the population, and slower growth in Medicare expenditures, and since our inception in 2012 we have been committed to being part of the solution. Studies show that improving the quality of healthcare delivered to patient's leads to decreases in the costs of care.

As a participant in the Medicare Share Savings Program (MSSP) with a dual-eligible Medicare-Medicaid patient population penetration of 40%, RGV ACO is in a unique position to reduce the human and healthcare costs associated with DM and other chronic diseases.

DM is one of the most dangerous chronic diseases of our time. Forty-two percent of RGV ACO's Medicare beneficiaries live with this disease.

The stakes are high in terms of both comorbidities and mortality. DM is one of the leading causes of blindness, end-stage renal disease (ESRD) and cardiovascular disease. Renal failure occurs more often when uncontrolled DM is combined with uncontrolled hypertension.

The incidence of atherosclerosis increases significantly when dyslipidemia, tobacco smoking and hypertension are

Medical Economics FIGHTING BACK 2014 PHYSICIAN WRITING CONTEST

Physicians are operating their practices amidst monumental change. And it signals the need for useful, practical and thoughtful solutions. The winners and honorable mentions in this year's writing contest delivered just that. *Medical Economics* unveiled the first two winners in the August 25 and September 25 issues, and will unveil two other winning entries in the November 25 and December 25 issues. As a finale in late December, many of the entries in this year's contest will be featured on medicaleconomics.com.

> Everyone on the team clearly understood that it was unacceptable for a patient with poorly managed HbA1c, blood pressure and high cholesterol to leave the office without addressing the problems and adjusting the medications."

added to the equation, resulting in a high incidence of coronary artery disease, stroke and peripheral vascular disease. These can, in turn, lead to costly interventions, such as stenting of coronary arteries, bypass surgery and lower-extremity amputations.

A multidimensional approach to diabetes care that emphasizes blood pressure, lipids, glucose, aspirin use and tobacco avoidance maximizes health outcomes more than a strategy limited to one or two of those clinical domains. Indeed, the CMS grouped these five domains in the MSSP final rule, which defines the DM composite measures with which ACOs must be compliant.

It is an "All-or-Nothing" method of scoring: If a patient fails to be compliant with one quality measure (QM), the ACO is deemed to have failed in all five measures for that patient.

In 2012, RGV ACO's first year, we were achieving 70% to 80% patient compliance on individual's DM quality measures. However, controlling at goal all measures combined on every patient across our entire diabetic population turned out to be difficult, and our compliance rate was 23%, similar to the national average. Therein lay the challenge.

THE SOLUTION AND RESULTS

Improving the quality of care for our patients and improving our "quality scores" became our motivating factors.

To meet the challenge, we deployed a full care coordination model and initiated a strong team-based, patient-centered care approach. We created a diabetes education center, where a DM educator trained a team of medical assistants and licensed vocational nurses. They were also trained as care coordinators, and at least one was added to each clinic.

In some clinics, health coaches joined the team and we established a call center targeting uncontrolled DM patients. We made routine calls to survey blood sugar levels, and remind patients to take their cholesterol and blood pressure medications. Self-management education was in full force.

We optimized the use of our electronic health records (EHR) system to enable the team to use pop-up reminders to track each patient's HbA1c, low-density lipoprotein cholesterol, blood pressure, smoking status and the use of anti-platelet therapy.

Everyone on the team clearly understood that it was unacceptable for a patient with poorly managed HbA1c, blood pressure and high cholesterol to leave the office without addressing the problems and adjusting the medications. We impressed upon the providers the need to take extra time to figure out what patients require.

As a result, our compliance rate began to shift upward. The 2013 QM samples we submitted to CMS demonstrate that an encouraging 75% to 90% of patients are at goal on individual DM QMs, and 48% of patients are compliant with all DM clinical measures at once ("all-or-nothing" scoring). We achieved a better than 100% improvement on the combined measures in one year, which places us in a very high percentile.

PROMISE FOR THE FUTURE

Uncontrolled DM and its comorbidities lead to staggering economic challenges for insurance companies and taxpayers.

These include more frequent hospitalizations (at an average cost of more than $17,000 per episode), more expensive laser treatment for DM retinopathy, coronary artery bypass surgery (at around $50,000 to $60,000 per episode) and other expensive procedures. A patient with DM and ESRD costs Medicare an annual average of $75,000.

By implementing aggressive primary and secondary prevention, in a patient–centered environment, with EHR optimization, focus on high-risk patients and adding a care coordinator to each office, RGV ACO has saved Medicare several million dollars.

If the various care coordination and quality improvement programs followed by many ACOs and other programs across the country become more widely adopted, the potential for Medicare and healthcare providers to improve the care of our patients and save billions of dollars is within reach.

With patients and physician's engagement, access to cost of care data and a focused leadership team, it can be done. ■

Jose F. Pena, MD, is the chief executive officer and chief medical director for the Rio Grande Valley Accountable Care Organization in Rio Grande Valley, Texas.

Coding Insights

HOW TO AVOID MODIFIER 25 DENIALS

Q Please explain modifier 25 and it's proper use. Can you present some scenarios for how to use the modifier when providing various services during one encounter, including visits, vaccines and other services?

A: MODIFIER 25 is defined as a "significant, separately identifiable Evaluation and Management Service by the same physician or other qualified healthcare professional on the same day of the procedure or other service." As the definition indicates, modifier 25 should always be appended to an Evaluation and Management (E/M) code.

I'll address three scenarios using modifier 25.

They are:

- **a physical, a sick visit and vaccines done on the same day,**
- **a sick visit and vaccine done the same day, and**
- **a sick visit and a precure, such as a nebulizer, ear lavage, or rapid strep screen, done on the same day.**

Scenario 1

First, a physical/preventive visit (99381-99387, 99391-99397), a sick visit E/M (99211-99215) and vaccines (vaccine and administration code) performed on the same date of service should be coded with the 25 modifier appended to the sick visit E/M code.

For example:

- **99385**
- **99212—25**
- **90741 (or G0008 for Medicare patients)**
- **90688**

Keep in mind that, when billing a preventive visit code with an E/M, the E/M code should be an established-patient code.

This is because most insurance payers won't pay for two new-patient codes on the same date.

Secondly, the documentation for these combination visits isn't going to support a new-patient code. The documentation elements (for example, review of systems, past family and social history, exam) are credited for the preventive code and can't be additionally counted for the E/M.

Scenario 2 and 3

Scenarios two and three include a sick visit E/M (i.e., 99201-99215) and vaccine or lab performed on the same date.

For most payers, modifier 25 is not required on the E/M code when billed in conjunction with a lab service(s), immunization(s), or x-ray(s). I will caution again that you need to check with each payer to ensure this is the practice they want followed.

For the last scenario – a sick visit and a procedure (i.e., a nebulizer or ear lavage) performed on the same date, modifier 25 would need to be appended to the E/M code, such as:

- **99213—25**
- **69210 (Removal impact cerumen requiring instrumentation, unilateral)**

The use of modifier 25 does vary by payer, so be sure you check your remittance advice to ensure that you don't have to deal with any unexpected claim denials. ◘

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

Legally Speaking

CREATING YOUR PRACTICE'S 'BRING YOUR OWN DEVICE' POLICY

by **LAUREN RIEDERS, JD** *and* **MARIANNE MONROY, JD** *Contributing authors*

More healthcare employees are using personal smartphones and tablets for work-related purposes.

There are advantages to employees being able to use a device of their choice to communicate with other employees, remain accessible, and work remotely.

But bring your own device (BYOD) also poses legal concerns and the potential for data breaches.

In particular, one concern employers must keep in mind is overtime issues under the U.S. Fair Labor Standards Act. When non-exempt employees are given access to company e-mail and other data outside on their personal devices outside of their regular working hours, employers should be aware that this time may constitute additional working hours, and thus potentially overtime, for which the employee must be compensated.

Minimizing risk

A well-drafted BYOD policy minimizes these risks by outlining preventative controls, emphasizing security, and informing employees of their responsibilities for keeping data safe. In addition to a written policy, employers are frequently employing mobile device management (MDM) service providers for security tools to protect devices and data. This software addresses many of the risks associated with personal mobile devices. For example, most MDM software has the capability to encrypt data on mobile devices and remotely lock and wipe out the devices in the event they are lost or stolen.

Accessing employing devices

Employees should be

Device policies

Employers should use tools for the greatest protection of sensitive company information and create or revise existing BYOD policies. Some important considerations to incorporate into such policies:

Acceptable use terms

Employers should indicate the business purposes for which the device may be used, and any limitations to that use.

Ownership/Control

Employers should clearly define who owns the data stored on the device. Employers should also indicate that the company is not responsible for employees' lost or stolen personal data on the device.

Protocols for handling lost or stolen device, including remote-wipe capability

Employees should immediately notify designated personnel of theft or loss of device. The employer should also have mechanisms in place to remotely wipe either the entire device or only a folder of the device containing company information, thereby protecting the employee's personal data. Healthcare institutions face an extra layer of concern over security and privacy associated with personal health information (PHI) being transmitted and the potential for Health Insurance Portability and Accountability Act (HIPAA) violations. In the event of a data breach containing PHI, potential HIPAA breaches must be reported to the employer.

Multiple levels of security

Employers should consider requiring two passwords as an extra layer of security. Employers may also require antivirus or protective software on the employee's device.

Prevent local storage of sensitive information on device

The employer should implement measures to prevent sensitive information from being stored locally and/or without password protection.

Cloud storage prohibitions/ limitations

Employers should identify which cloud storage and file sharing services have known risks and are too risky to permit

warned if there is a situation where the organization may need to access personal information on the employee's device. In this regard, the employer should explain what information is being tracked and how that information is being used and stored. Finally, employers should remind employees of their duty to comply with legal and ethical regulations, including intellectual property laws and laws governing proprietary or trade secret information. The policy should also prohibit the use of devices for harassment or discrimination.

The importance of training

As with any new policy or procedure, employers should consider instituting a training program to educate employees on the importance of compliance with BYOD policies and being careful with the access and transmission of confidential information. While there is certainly a temptation for employers to prohibit the use of personal devices to access company information, employers should recognize that the trend towards BYOD is likely to stay. A strong BYOD policy and an informed staff are the surest ways to prevent security breaches.

Lauren Rieders, JD, is an associate and Marianne Monroy, JD, is a partner at Garfunkel Wild, P.C., in Great Neck, New York. Send your legal questions to medec@advanstar.com.

employees to use to transmit confidential information.

Payment/ Reimbursement

If the employer requires the employee to pay for a service plan, the employer should indicate that it is not responsible for payment. However, if the employer is responsible for paying for certain charges, the BYOD policy should clearly spell out the payment structure.

Termination

Employers should address what happens to the cell phone number and company data in the event an employee's employment is terminated.

Abuse of policy

Employers should indicate the consequences for violating the BYOD policy, such as the loss of privileges to access company data remotely.

Obtain written consent

Employees should attest in writing to receiving the BYOD policy.

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14. **Issue Date for Circulation Data Below:** **August 25 2014**
15. **Extent and Nature of Circulation**

	Average No. Copies Each Issue During Preceding 24 Months	No. Copies of Single Issue Published Nearest to Filing Date
A. Total Number of Copies	**180,627**	**170,212**
B. Legitimate Paid and/or Requested Distribution		
1. Outside County Paid/Requested Mail Subscriptions Stated on PS Form 3541	**86,276**	**83,938**
2. In-County Paid/Requested Mail Subscriptions Stated on PS Form 3541	**0**	**0**
3. Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid or Requested Distribution Outside USPS	**10**	**15**
4. Requested Copies Distributed by Other Mail Classes Through the USPS	**0**	**0**
C. Total Paid and /or Requested Circulation (Sum of 15b (1), (2), (3), and (4))	**86,286**	**83,953**
D. Non-requested Distribution		
1. Outside County Non-requested Copies Stated on PS Form 3541	**93,508**	**85,933**
2. In-County Non-requested Copies Stated on PS Form 3541	**0**	**0**
3. Non-requested Copies Distributed Through the USPS by Other Classes of Mail	**0**	**0**
4. Non-requested Copies Distributed Outside the Mail	**391**	**138**
E. Total Non-requested Distribution (Sum of 15d (1), (2), (3) and (4))	**93,899**	**86,071**
F. Total Distribution (Sum of 15c and e)	**180,185**	**170,024**
G. Copies not Distributed	**442**	**188**
H. Total (Sum of 15f and g)	**180,627**	**170,212**
I. Percent Paid and/or Requested Circulation	**47.89%**	**49.38%**
16. Electronic Copy Circulation		
*If you are not claiming electronic copies, skip to line 17		
a. Requested and Paid Electronic Copies	**18805**	**18465**
b. Total Requested and Paid Print Copies (Line 15C) + Requested/Paid Electronic Copies	**105,091**	**102,418**
c. Total Requested Copy Distribution (Line 15F) + Requested/Paid Electronic Copies	**198,990**	**188,489**
d. Percent Paid and/or Requested Circulation (Both Print & Electronic Copies)	**52.81%**	**54.34%**

☑ **I certify that 50% of all my distributed copies (electronic and print) are legitimate requests or paid copies.**

17. **Publication of Statement of Ownership for a Requester Publication is required and will be printed in the October 15 issue of this publication.**
    Name and Title of Editor, Publisher, Business Manager, or Owner: Christine Shappell, Audience Development Director
    Signature: Christine Shappell
    Date: 9/30/14

I certify that the statements made by me above are correct and complete.

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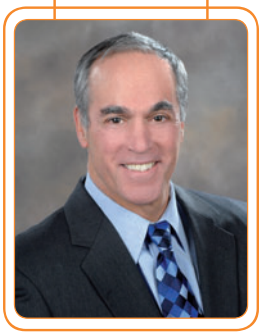

Mark J. Nelson MD
FACC, MPH

E-mail:
mjnelsonmd7@gmail.com

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The Last Word

CMS LAUNCHES 'OPEN PAYMENTS' SITE DESPITE PHYSICIAN CONCERNS

by **ALISON RITCHIE** *Content specialist*

The Centers for Medicare and Medicaid Services (CMS) has released 4.4 million payment records, totaling nearly $3.5 billion, made from drug and device manufacturers to physicians and teaching hospitals during the last five months of 2013.

AS REQUIRED by the Affordable Care Act, CMS has launched its Open Payments website. For now, it contains payment records for 546,000 physicians and 1,360 teaching hospitals, including gifts, meals, travel expenses, and teaching fees.

While CMS argues that the data promotes transparency, physician advocate groups argue that releasing the data without context may confuse consumers.

"Financial ties among medical manufacturers' payments and health care providers do not necessarily signal wrongdoing," CMS said in a statement. "Given the importance of discouraging inappropriate relationships without harming beneficial ones, CMS is working closely with stakeholders to better understand the current scope of the interactions among physicians, teaching hospitals, and industry manufacturers."

The American Medical Association (AMA) has long voiced concerns over the release, questioning the data's accuracy and whether the data is misleading.

"Publicly reporting industry payments to individual physicians can imply, wrongly, that such payments are always inappropriate," the AMA said in a statement. "Some may be, but to be able to make an informed judgment, it is vital to be able to set the financial information in context. Just because a physician has a relationship with industry does not automatically mean that his or her professional judgment has been influenced inappropriately."

Beginning June 2015, the website will be updated annually and contain a year's worth of data. CMS plans to issue new tools to make the data more searchable.

The initial launch of the Open Payments website has not been without glitches.

Although physicians were given 45 days to review their information and dispute any claims, those days were not consecutive. After a large discrepancy in data was revealed CMS temporarily disabled the Open Payments website for nearly two weeks, and pushed back the review deadline.

More than 26,000 physicians and 400 teaching hospitals registered to review their data before it was made public. But the AMA argues that physicians were not given adequate notice when the review website was taken offline.

"Many physicians reported making numerous calls to the CMS Help Desk for assistance in registering," the AMA said in a written statement. "A 360-page guidance document that CMS originally provided to help physicians through the process failed to detail all the steps involved to register with the system, review personal reports, and seek correction of any inaccurate data."

Due to reported inaccuracies in the review period, CMS de-identified about 33% of the payment records in the first release, so payment recipients' names are not listed.

The American Osteopathic Association (AOA) has voiced concerns over whether physicians will be able to review those de-identified records before they are eventually made public.

"This could negatively affect physicians who have previously registered for the Open Payments System and did not locate and identify a payment report in their name and, therefore, did not have the opportunity to review and dispute any potential discrepancies," the AOA said in a written statement.

CMS has withheld an additional 199,000 records from the first release. The agency said that 190,000 of those records were withheld because they were subject to a pending U.S. Food and Drug Administration approval of trade secrets. The remaining 9,000 records were withheld due to ongoing disputes.