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APRIL 25, 2013

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ADVANSTAR MEDICAL COMMUNICATIONS GROUP

VOL. 90 NO. 8

While there are many diabetes complications,

PAINFUL DPN IS ONE THEY CAN'T IGNORE

Help manage your patients' painful Diabetic Peripheral Neuropathy with LYRICA

ONLY LYRICA IS RECOMMENDED AS LEVEL A by AAN evidence-based guideline for the treatment of painful diabetic neuropathy (PDN)[1]

LYRICA® PREGABALIN Ⓒ capsules

"If clinically appropriate, pregabalin should be offered for the treatment of PDN (Level A)."[1]

The medical organizations that developed this guideline (the AAN, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation) recognize that specific care decisions are the prerogative of the patient and physician caring for the patient, based on all of the circumstances involved.

For full guideline, visit www.aan.com/guidelines.

Level A=Established as effective, based on at least 2 Class I studies.

Class I level evidence includes a randomized, controlled clinical trial of the intervention of interest with masked or objective outcome assessment, in a representative population, and other specified criteria.

AAN=American Academy of Neurology.

For Full Prescribing Information and Medication Guide, please visit www.LyricaHCP.com.

Please see the Brief Summary of Prescribing Information on adjacent pages.

Reference: 1. Bril V, England JD, Franklin GM, et al. Evidence-based guideline: treatment of painful diabetic neuropathy. Report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. *Neurology*. 2011;76:1758-1765.

LYRICA is indicated for the management of neuropathic pain associated with Diabetic Peripheral Neuropathy.

Selected safety information:

LYRICA is contraindicated in patients with known hypersensitivity to pregabalin or any of its other components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy.

There have been postmarketing reports of hypersensitivity in patients shortly after initiation of treatment with LYRICA. Adverse reactions included skin redness, blisters, hives, rash, dyspnea, and wheezing. Discontinue LYRICA immediately in patients with these symptoms.

There have been postmarketing reports of angioedema in patients during initial and chronic treatment with LYRICA. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. Discontinue LYRICA immediately in patients with these symptoms.

Antiepileptic drugs (AEDs) including LYRICA increase the risk of suicidal thoughts or behavior in patients taking AEDs for any indication. Monitor patients treated with any AED for any indication for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Pooled analyses showed clinical trial patients taking an AED had approximately twice the risk of suicidal thoughts or behavior than placebo-treated patients. The estimated incidence rate of suicidal behavior or ideation among 27,683 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one patient for every 530 patients treated with an AED.

The most common adverse reactions across all LYRICA clinical trials are dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, constipation, euphoric mood, balance disorder, increased appetite, and thinking abnormal (primarily difficulty with concentration/attention).

Inform patients taking LYRICA that dizziness and somnolence may impair their ability to perform potentially hazardous tasks such as driving or operating complex machinery until they have sufficient experience with LYRICA to determine its effect on cognitive and motor function.

Higher frequency of weight gain and edema was observed in patients taking both LYRICA and thiazolidinedione antidiabetic drugs. Exercise caution when coadministering these drugs. Patients who are taking other drugs associated with angioedema such as angiotensin-converting enzyme inhibitors (ACE inhibitors) may be at increased risk of developing angioedema. Exercise caution when using LYRICA in patients who have had a previous episode of angioedema.

PBP531004-01

February 2013

Pfizer Working together for a healthier world™

LYRICA® (pregabalin) CAPSULES Ⓒ

BRIEF SUMMARY: For full prescribing information, see package insert.

INDICATION AND USAGE

LYRICA is indicated for:

- Management of neuropathic pain associated with diabetic peripheral neuropathy

DOSAGE AND ADMINISTRATION

LYRICA is given orally with or without food. When discontinuing LYRICA, taper gradually over a minimum of 1 week.

Neuropathic Pain Associated with Diabetic Peripheral Neuropathy:

- Administer in 3 divided doses per day
- Begin dosing at 150 mg/day
- May be increased to a maximum of 300 mg/day within 1 week
- Dose should be adjusted for patients with reduced renal function

Patients with Renal Impairment

In view of dose-dependent adverse reactions and since LYRICA is eliminated primarily by renal excretion, adjust the dose in patients with reduced renal function. Base the dose adjustment in patients with renal impairment on creatinine clearance (CLcr), as indicated in Table 1. To use this dosing table, an estimate of the patient's CLcr in mL/min is needed. CLcr in mL/min may be estimated from serum creatinine (mg/dL) determination using the Cockcroft and Gault equation:

$$\text{CLCr} = \frac{[140 - \text{age (years)}] \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dL)}} \quad (\times 0.85 \text{ for female patients})$$

Next, refer to the Dosage and Administration section to determine the recommended total daily dose based on indication, for a patient with normal renal function (CLcr ≥60 mL/min). Then refer to Table 1 to determine the corresponding renal adjusted dose.

(For example: A patient initiating LYRICA therapy for postherpetic neuralgia with normal renal function (CLcr ≥60 mL/min), receives a total daily dose of 150 mg/day pregabalin. Therefore, a renal impaired patient with a CLcr of 50 mL/min would receive a total daily dose of 75 mg/day pregabalin administered in two or three divided doses.)

For patients undergoing hemodialysis, adjust the pregabalin daily dose based on renal function. In addition to the daily dose adjustment, administer a supplemental dose immediately following every 4-hour hemodialysis treatment (see Table 1).

Table 1. Pregabalin Dosage Adjustment Based on Renal Function

Creatinine Clearance (CLcr) (mL/min)	Total Pregabalin Daily Dose (mg/day)*				Dose Regimen
≥60	150	300	450	600	BID or TID
30–60	75	150	225	300	BID or TID
15–30	25–50	75	100–150	150	QD or BID
<15	25	25–50	50–75	75	QD
Supplementary dosage following hemodialysis (mg)†					
Patients on the 25 mg QD regimen: take one supplemental dose of 25 mg or 50 mg					
Patients on the 25–50 mg QD regimen: take one supplemental dose of 50 mg or 75 mg					
Patients on the 50–75 mg QD regimen: take one supplemental dose of 75 mg or 100 mg					
Patients on the 75 mg QD regimen: take one supplemental dose of 100 mg or 150 mg					

TID = Three divided doses; BID = Two divided doses; QD = Single daily dose.

*Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.

†Supplementary dose is a single additional dose.

CONTRAINDICATIONS

LYRICA is contraindicated in patients with known hypersensitivity to pregabalin or any of its components. Angioedema and hypersensitivity reactions have occurred in patients receiving pregabalin therapy.

WARNINGS AND PRECAUTIONS

Angioedema There have been postmarketing reports of angioedema in patients during initial and chronic treatment with LYRICA. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. Discontinue LYRICA immediately in patients with these symptoms. Exercise caution when prescribing LYRICA to patients who have had a previous episode of angioedema. In addition, patients who are taking other drugs associated with angioedema (e.g., angiotensin converting enzyme inhibitors [ACE-inhibitors]) may be at increased risk of developing angioedema. **Hypersensitivity** There have been postmarketing reports of hypersensitivity in patients shortly after initiation of treatment with LYRICA. Adverse reactions included skin redness, blisters, hives, rash, dyspnea, and wheezing. Discontinue LYRICA immediately in patients with these symptoms. **Withdrawal of Antiepileptic Drugs (AEDs)** As with all AEDs, withdraw LYRICA gradually to minimize the potential of increased seizure frequency in patients with seizure disorders. If LYRICA is discontinued, taper the drug gradually over a minimum of 1 week. **Suicidal Behavior and Ideation** Antiepileptic drugs (AEDs), including LYRICA, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Monitor patients treated with any AED for any indication for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI: 1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence rate of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebo-treated patients, but the number is too small to allow any conclusion about drug effect on suicide. The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed. The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed. Table 2 shows absolute and relative risk by indication for all evaluated AEDs.

Table 2. Risk by indication for antiepileptic drugs in the pooled analysis

Indication	Placebo Patients with Events Per 1000 Patients	Drug Patients with Events Per 1000 Patients	Relative Risk: Incidence of Events in Drug Patients/Incidence in Placebo Patients	Risk Difference: Additional Drug Patients with Events Per 1000 Patients
Epilepsy	1.0	3.4	3.5	2.4
Psychiatric	5.7	8.5	1.5	2.9
Other	1.0	1.8	1.9	0.9
Total	2.4	4.3	1.8	1.9

The relative risk for suicidal thoughts or behavior was higher in clinical trials for epilepsy than in clinical trials for psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications. Anyone considering prescribing LYRICA or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated. Inform patients, their caregivers, and families that LYRICA and other AEDs increase the risk of suicidal thoughts and behavior and advise them of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Report behaviors of concern immediately to healthcare providers. **Peripheral Edema** LYRICA treatment may cause peripheral edema. In short-term trials of patients without clinically significant heart or peripheral vascular disease, there was no apparent association between peripheral edema and cardiovascular complications such as hypertension or congestive heart failure. Peripheral edema was not associated with laboratory changes suggestive of deterioration in renal or hepatic function. In controlled clinical trials the incidence of peripheral edema was 6% in the LYRICA group compared with 2% in the placebo group. In controlled clinical trials, 0.5% of LYRICA patients and 0.2% placebo patients withdrew due to peripheral edema. Higher frequencies of weight gain and peripheral edema were observed in patients taking both LYRICA and a thiazolidinedione antidiabetic agent compared to patients taking either drug alone. The majority of patients using thiazolidinedione antidiabetic agents in the overall safety database were participants in studies of pain associated with diabetic peripheral neuropathy. In this population, peripheral edema was reported in 3% (2/60) of patients who were using thiazolidinedione antidiabetic agents only, 8% (69/859) of patients who were treated with LYRICA only, and 19% (23/120) of patients who were on both LYRICA and thiazolidinedione antidiabetic agents. Similarly, weight gain was reported in 0% (0/60) of patients on thiazolidinediones only; 4% (35/859) of patients on LYRICA only; and 7.5% (9/120) of patients on both drugs. As the thiazolidinedione class of antidiabetic drugs can cause weight gain and/or fluid retention, possibly exacerbating or leading to heart failure, exercise caution when co-administering LYRICA and these agents. Because there are limited data on congestive heart failure patients with New York Heart Association (NYHA) Class III or IV cardiac status, exercise caution when using LYRICA in these patients. **Dizziness and Somnolence** LYRICA may cause dizziness and somnolence. Inform patients that LYRICA-related dizziness and somnolence may impair their ability to perform tasks such as driving or operating machinery. In the LYRICA controlled trials, dizziness was experienced by 30% of LYRICA-treated patients compared to 8% of placebo-treated patients; somnolence was experienced by 23% of LYRICA-treated patients compared to 8% of placebo-treated patients. Dizziness and somnolence generally began shortly after the initiation of LYRICA therapy and occurred more frequently at higher doses. Dizziness and somnolence were the adverse reactions most frequently leading to withdrawal (4% each) from controlled studies. In LYRICA-treated patients reporting these adverse reactions in short-term, controlled studies, dizziness persisted until the last dose in 30% and somnolence persisted until the last dose in 42% of patients. **Weight Gain** LYRICA treatment may cause weight gain. In LYRICA controlled clinical trials of up to 14 weeks, a gain of 7% or more over baseline weight was observed in 9% of LYRICA-treated patients and 2% of placebo-treated patients. Few patients treated with LYRICA (0.3%) withdrew from controlled trials due to weight gain. LYRICA associated weight gain was related to dose and duration of exposure, but did not appear to be associated with baseline BMI, gender, or age. Weight gain was not limited to patients with edema *[see Warnings and Precautions, Peripheral Edema]*. Although weight gain was not associated with clinically important changes in blood pressure in short-term controlled studies, the long-term cardiovascular effects of LYRICA-associated weight gain are unknown. Among diabetic patients, LYRICA-treated patients gained an average of 1.6 kg (range: -16 to 16 kg), compared to an average 0.3 kg (range: -10 to 9 kg) weight gain in placebo patients. In a cohort of 333 diabetic patients who received LYRICA for at least 2 years, the average weight gain was 5.2 kg. While the effects of LYRICA-associated weight gain on glycemic control have not been systematically assessed, in controlled and longer-term open label clinical trials with diabetic patients, LYRICA treatment did not appear to be associated with loss of glycemic control (as measured by HbA_{1C}). **Abrupt or Rapid Discontinuation** Following abrupt or rapid discontinuation of LYRICA, some patients reported symptoms including insomnia, nausea, headache, anxiety, hyperhidrosis, and diarrhea. Taper LYRICA gradually over a minimum of 1 week rather than discontinuing the drug abruptly. **Tumorigenic Potential** In standard preclinical *in vivo* lifetime carcinogenicity studies of LYRICA, an unexpectedly high incidence of hemangiosarcoma was identified in two different strains of mice *[see Nonclinical Toxicology, Carcinogenesis, Mutagenesis, Impairment of Fertility]*. The clinical significance of this finding is unknown. Clinical experience during LYRICA's premarketing development provides no direct means to assess its potential for inducing tumors in humans. In clinical studies across various patient populations, comprising 6396 patient-years of exposure in patients >12 years of age, new or worsening-preexisting tumors were reported in 57 patients. Without knowledge of the background incidence and recurrence in similar populations not treated with LYRICA, it is impossible to know whether the incidence seen in these cohorts is or is not affected by treatment. **Ophthalmological Effects** In controlled studies, a higher proportion of patients treated with LYRICA reported blurred vision (7%) than did patients treated with placebo (2%), which resolved in a majority of cases with continued dosing. Less than 1% of patients discontinued LYRICA treatment due to vision-related events (primarily blurred vision). Prospectively planned ophthalmologic testing, including visual acuity testing, formal visual field testing and dilated funduscopic examination, was performed in over 3600 patients. In these patients, visual acuity was reduced in 7% of patients treated with LYRICA, and 5% of placebo-treated patients. Visual field changes were detected in 13% of LYRICA-treated, and 12% of placebo-treated patients. Funduscopic changes were observed in 2% of LYRICA-treated and 2% of placebo-treated patients. Although the clinical significance of the ophthalmologic findings is unknown, inform patients to notify their physician if changes in vision occur. If visual disturbance persists, consider further assessment. Consider more frequent assessment for patients who are already routinely monitored for ocular conditions. **Creatine Kinase Elevations** LYRICA treatment was associated with creatine kinase elevations. Mean changes in creatine kinase from baseline to the maximum value were 60 U/L for LYRICA-treated patients and 28 U/L for the placebo patients. In all controlled trials across multiple patient populations, 1.5% of patients on LYRICA and 0.7% of placebo patients had a value of creatine kinase at least three times the upper limit of normal. Three LYRICA-treated subjects had events reported as rhabdomyolysis in premarketing clinical trials. The relationship between these myopathy events and LYRICA is not completely understood because the cases had documented factors that may have caused or contributed to these events. Instruct patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if these muscle symptoms are accompanied by malaise or fever. Discontinue treatment with LYRICA if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur. **Decreased Platelet Count** LYRICA treatment was associated with a decrease in platelet count. LYRICA-treated subjects experienced a mean maximal decrease in platelet count of 20 x 10^3/µL, compared to 11 x 10^3/µL in placebo patients. In the overall database of controlled trials, 2% of placebo patients and 3% of LYRICA patients experienced a potentially clinically significant decrease in platelets, defined as 20% below baseline value and <150 x 10^3/µL. A single LYRICA treated subject developed severe thrombocytopenia with a platelet count less than 20 x 10^3/µL. In randomized controlled trials, LYRICA was not associated with an increase in bleeding-related adverse reactions. **PR Interval Prolongation** LYRICA treatment was associated with PR interval prolongation. In analyses of clinical trial ECG data, the mean PR interval increase was 3–6 msec at LYRICA doses ≥300 mg/day. This mean change difference was not associated with an increased risk of PR increase ≥25% from baseline, an increased percentage of subjects with on-treatment PR >200 msec, or an increased risk of adverse reactions of second or third degree AV block. Subgroup analyses did not identify an increased risk of PR prolongation in patients with baseline PR prolongation or in patients taking other PR prolonging medications. However, these analyses cannot be considered definitive because of the limited number of patients in these categories.

ADVERSE REACTIONS

Clinical Trials 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. In all controlled and uncontrolled trials across various patient populations during the premarketing development of LYRICA, more than 10,000 patients have received LYRICA. Approximately 5000 patients were treated for 6 months or more, over 3100 patients were treated for 1 year or longer, and over 1400 patients were treated for at least 2 years.

Adverse Reactions Most Commonly Leading to Discontinuation in All Premarketing Controlled Clinical Studies In premarketing controlled trials of all populations combined, 14% of patients treated with LYRICA and 7% of patients treated with placebo discontinued prematurely due to adverse reactions. In the LYRICA treatment group, the adverse reactions most frequently leading to discontinuation were dizziness (4%) and somnolence (4%). In the placebo group, 1% of patients withdrew due to dizziness and <1% withdrew due to somnolence. Other adverse reactions that led to discontinuation from controlled trials more frequently in the LYRICA group compared to the placebo group were ataxia, confusion, asthenia, thinking abnormal, blurred vision, incoordination, and peripheral edema (1% each).

Most Common Adverse Reactions in All Premarketing Controlled Clinical Studies In premarketing controlled trials of all patient populations combined, dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, and "thinking abnormal" (primarily difficulty with concentration/attention) were more commonly reported by subjects treated with LYRICA than by subjects treated with placebo (≥5% and twice the rate of that seen in placebo).

Controlled Studies with Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

Adverse Reactions Leading to Discontinuation In clinical trials in patients with neuropathic pain associated with diabetic peripheral neuropathy, 9% of patients treated with LYRICA and 4% of patients treated with placebo discontinued prematurely due to adverse reactions. In the LYRICA treatment group, the most common reasons for discontinuation due to adverse reactions were dizziness (3%) and somnolence (2%). In comparison, <1% of placebo patients withdrew due to dizziness and somnolence. Other reasons for discontinuation from the trials, occurring with greater frequency in the LYRICA group than in the placebo group, were asthenia, confusion, and peripheral edema. Each of these events led to withdrawal in approximately 1% of patients.

Most Common Adverse Reactions Table 3 lists all adverse reactions, regardless of causality, occurring in ≥1% of patients with neuropathic pain associated with diabetic neuropathy in the combined LYRICA group for which the incidence was greater in this combined LYRICA group than in the placebo group. A majority of pregabalin-treated patients in clinical studies had adverse reactions with a maximum intensity of "mild" or "moderate".

Table 3. Treatment-emergent adverse reaction incidence in controlled trials in neuropathic pain associated with Diabetic Peripheral Neuropathy (events in at least 1% of all LYRICA-treated patients and at least numerically more in all LYRICA than in the placebo group)

Body System - Preferred term	75 mg/d [N=77] %	150 mg/d [N=212] %	300 mg/d [N=321] %	600 mg/d [N=369] %	All PGB* [N=979] %	Placebo [N=459] %
Body as a whole						
Asthenia	4	2	4	7	5	2
Accidental injury	5	2	2	6	4	3
Back pain	0	2	1	2	2	0
Chest pain	4	1	1	2	2	1
Face edema	0	1	1	2	1	0
Digestive system						
Dry mouth	3	2	5	7	5	1
Constipation	0	2	4	6	4	2
Flatulence	3	0	2	3	2	1
Metabolic and nutritional disorders						
Peripheral edema	4	6	9	12	9	2
Weight gain	0	4	4	6	4	0
Edema	0	2	4	2	2	0
Hypoglycemia	1	3	2	1	2	1
Nervous system						
Dizziness	8	9	23	29	21	5
Somnolence	4	6	13	16	12	3
Neuropathy	9	2	2	5	4	3
Ataxia	6	1	2	4	3	1
Vertigo	1	2	2	4	3	1
Confusion	0	1	2	3	2	1
Euphoria	0	0	3	2	2	0
Incoordination	1	0	2	2	2	0
Thinking abnormal†	1	0	1	3	2	0
Tremor	1	1	1	2	1	0
Abnormal gait	1	0	1	3	1	0
Amnesia	3	1	0	2	1	0
Nervousness	0	1	1	1	1	0
Respiratory system						
Dyspnea	3	0	2	2	2	1
Special senses						
Blurry vision‡	3	1	3	6	4	2
Abnormal vision	1	0	1	1	1	0

*PGB: pregabalin

† Thinking abnormal primarily consists of events related to difficulty with concentration/attention but also includes events related to cognition and language problems and slowed thinking.

‡ Investigator term; summary level term is amblyopia.

Other Adverse Reactions Observed During the Clinical Studies of LYRICA Following is a list of treatment-emergent adverse reactions reported by patients treated with LYRICA during all clinical trials. The listing does not include those events already listed in the previous tables or elsewhere in labeling, those events for which a drug cause was remote, those events which were so general as to be uninformative, and those events reported only once which did not have a substantial probability of being acutely life-threatening. Events are categorized by body system and listed in order of decreasing frequency according to the following definitions: *frequent* adverse reactions are those occurring on one or more occasions in at least 1/100 patients; *infrequent* adverse reactions are those occurring in 1/100 to 1/1000 patients; *rare* reactions are those occurring in fewer than 1/1000 patients. Events of major clinical importance are described in the Warnings and Precautions section. Body as a Whole – *Frequent:* Abdominal pain, Allergic reaction, Fever; *Infrequent:* Abscess, Cellulitis, Chills, Malaise, Neck rigidity, Overdose, Pelvic pain, Photosensitivity reaction; *Rare:* Anaphylactoid reaction, Ascites, Granuloma, Hangover effect, Intentional Injury, Retroperitoneal Fibrosis, Shock. Cardiovascular System – *Infrequent:* Deep thrombophlebitis, Heart failure, Hypotension, Postural hypotension, Retinal vascular disorder, Syncope; *Rare:* ST Depressed, Ventricular Fibrillation. Digestive System – *Frequent:* Gastroenteritis, Increased appetite; *Infrequent:* Cholecystitis, Cholelithiasis, Colitis, Dysphagia, Esophagitis, Gastritis, Gastrointestinal hemorrhage, Melena, Mouth ulceration, Pancreatitis, Rectal hemorrhage, Tongue edema; *Rare:* Aphthous stomatitis, Esophageal Ulcer, Periodontal abscess. Hemic and Lymphatic System – *Frequent:* Ecchymosis; *Infrequent:* Anemia, Eosinophilia, Hypochromic anemia, Leukocytosis, Leukopenia, Lymphadenopathy, Thrombocytopenia; *Rare:* Myelofibrosis, Polycythemia, Prothrombin decreased, Purpura, Thrombocythemia. Metabolic and Nutritional Disorders – *Rare:* Glucose Tolerance Decreased, Urate Crystalluria. Musculoskeletal System – *Frequent:* Arthralgia, Leg cramps, Myalgia, Myasthenia; *Infrequent:* Arthrosis; *Rare:* Chondrodystrophy. Generalized Spasm. Nervous System – *Frequent:* Anxiety, Depersonalization, Hypertonia, Hypesthesia, Libido decreased, Nystagmus, Paresthesia, Sedation, Stupor, Twitching; *Infrequent:* Abnormal dreams, Agitation, Apathy, Aphasia, Circumoral paresthesia, Dysarthria, Hallucinations, Hostility, Hyperalgesia, Hyperesthesia, Hyperkinesia, Hypokinesia, Hypotonia, Libido increased, Myoclonus, Neuralgia; *Rare:* Addiction, Cerebellar syndrome, Cogwheel rigidity, Coma, Delirium, Delusions, Dysautonomia, Dyskinesia, Dystonia, Encephalopathy, Extrapyramidal syndrome, Guillain-Barré syndrome, Hypalgesia, Intracranial hypertension, Manic reaction, Paranoid reaction, Peripheral neuritis, Personality disorder, Psychotic depression, Schizophrenic reaction, Sleep disorder, Torticollis, Trismus. Respiratory System – *Rare:* Apnea, Atelectasis, Bronchiolitis, Hiccup, Laryngismus, Lung edema, Lung fibrosis, Yawn. Skin and Appendages – *Frequent:* Pruritus; *Infrequent:* Alopecia, Dry skin, Eczema, Hirsutism, Skin ulcer, Urticaria, Vesiculobullous rash; *Rare:* Angioedema, Exfoliative dermatitis, Lichenoid dermatitis, Melanosis, Nail Disorder, Petechial rash, Purpuric rash, Pustular rash, Skin atrophy, Skin necrosis, Skin nodule, Stevens-Johnson syndrome, Subcutaneous nodule. Special senses – *Frequent:* Conjunctivitis, Diplopia, Otitis media, Tinnitus; *Infrequent:* Abnormality of accommodation, Blepharitis, Dry eyes, Eye hemorrhage, Hyperacusis, Photophobia, Retinal edema, Taste loss, Taste perversion; *Rare:* Anisocoria, Blindness, Corneal ulcer, Exophthalmos, Extraocular palsy, Iritis, Keratitis, Keratoconjunctivitis, Miosis, Mydriasis, Night blindness, Ophthalmoplegia, Optic atrophy, Papilledema, Parosmia, Ptosis, Uveitis. Urogenital System – *Frequent:* Anorgasmia, Impotence, Urinary frequency, Urinary incontinence; *Infrequent:* Abnormal ejaculation, Albuminuria, Amenorrhea, Dysmenorrhea, Dysuria, Hematuria, Kidney calculus, Leukorrhea, Menorrhagia, Metrorrhagia, Nephritis, Oliguria, Urinary retention, Urine abnormality; *Rare:* Acute kidney failure, Balanitis, Bladder Neoplasm, Cervicitis, Dyspareunia, Epididymitis, Female lactation, Glomerulitis, Ovarian disorder, Pyelonephritis.

Comparison of Gender and Race The overall adverse event profile of pregabalin was similar between women and men. There are insufficient data to support a statement regarding the distribution of adverse experience reports by race.

Post-marketing Experience The following adverse reactions have been identified during postapproval use of LYRICA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Nervous System Disorders – Headache. Gastrointestinal Disorders – Nausea, Diarrhea. Reproductive System and Breast Disorders – Gynecomastia, Breast Enlargement.

In addition, there are post-marketing reports of events related to reduced lower gastrointestinal tract function (e.g., intestinal obstruction, paralytic ileus, constipation) when LYRICA was co-administered with medications that have the potential to produce constipation, such as opioid analgesics. There are also post-marketing reports of respiratory failure and coma in patients taking pregabalin and other CNS depressant medications.

DRUG INTERACTIONS

Since LYRICA is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (<2% of a dose recovered in urine as metabolites), and does not bind to plasma proteins, its pharmacokinetics are unlikely to be affected by other agents through metabolic interactions or protein binding displacement. *In vitro* and *in vivo* studies showed that LYRICA is unlikely to be involved in significant pharmacokinetic drug interactions. Specifically, there are no pharmacokinetic interactions between pregabalin and the following antiepileptic drugs: carbamazepine, valproic acid, lamotrigine, phenytoin, phenobarbital, and topiramate. Important pharmacokinetic interactions would also not be expected to occur between LYRICA and commonly used antiepileptic drugs. Pharmacodynamics Multiple oral doses of LYRICA were co-administered with oxycodone, lorazepam, or ethanol. Although no pharmacokinetic interactions were seen, additive effects on cognitive and gross motor functioning were seen when LYRICA was co-administered with these drugs. No clinically important effects on respiration were seen.

USE IN SPECIFIC POPULATIONS

Pregnancy Pregnancy Category C. Increased incidences of fetal structural abnormalities and other manifestations of developmental toxicity, including lethality, growth retardation, and nervous and reproductive system functional impairment, were observed in the offspring of rats and rabbits given pregabalin during pregnancy, at doses that produced plasma pregabalin exposures (AUC) ≥5 times human exposure at the maximum recommended dose (MRD) of 600 mg/day. When pregnant rats were given pregabalin (500, 1250, or 2500 mg/kg) orally throughout the period of organogenesis, incidences of specific skull alterations attributed to abnormally advanced ossification (premature fusion of the jugal and nasal sutures) were increased at ≥1250 mg/kg, and incidences of skeletal variations and retarded ossification were increased at all doses. Fetal body weights were decreased at the highest dose. The low dose in this study was associated with a plasma exposure (AUC) approximately 17 times human exposure at the MRD of 600 mg/day. A no-effect dose for rat embryo-fetal developmental toxicity was not established. When pregnant rabbits were given LYRICA (250, 500, or 1250 mg/kg) orally throughout the period of organogenesis, decreased fetal body weight and increased incidences of skeletal malformations, visceral variations, and retarded ossification were observed at the highest dose. The no-effect dose for developmental toxicity in rabbits (500 mg/kg) was associated with a plasma exposure approximately 16 times human exposure at the MRD. In a study in which female rats were dosed with LYRICA (50, 100, 250, 1250, or 2500 mg/kg) throughout gestation and lactation, offspring growth was reduced at ≥100 mg/kg and offspring survival was decreased at ≥250 mg/kg. The effect on offspring survival was pronounced at doses ≥1250 mg/kg, with 100% mortality in high-dose litters. When offspring were tested as adults, neurobehavioral abnormalities (decreased auditory startle responding) were observed at ≥250 mg/kg and reproductive impairment (decreased fertility and litter size) was seen at 1250 mg/kg. The no-effect dose for pre- and postnatal developmental toxicity in rats (50 mg/kg) produced a plasma exposure approximately 2 times human exposure at the MRD. There are no adequate and well-controlled studies in pregnant women. Use LYRICA during pregnancy only if the potential benefit justifies the potential risk to the fetus. To provide information regarding the effects of in utero exposure to LYRICA, physicians are advised to recommend that pregnant patients taking LYRICA enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. This can be done by calling the toll free number 1-888-233-2334, and must be done by patients themselves. Information on the registry can also be found at the website http://www.aedpregnancyregistry.org/. **Labor and Delivery** The effects of LYRICA on labor and delivery in pregnant women are unknown. In the prenatal-postnatal study in rats, pregabalin prolonged gestation and induced dystocia at exposures ≥50 times the mean human exposure (AUC$_{(0-24)}$ of 123 µg•hr/mL) at the maximum recommended clinical dose of 600 mg/day. **Nursing Mothers** It is not known if pregabalin is excreted in human milk; it is, however, present in the milk of rats. Because many drugs are excreted in human milk, and because of the potential for tumorigenicity shown for pregabalin in animal studies, decide whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use** The safety and efficacy of pregabalin in pediatric patients have not been established. In studies in which pregabalin (50 to 500 mg/kg) was orally administered to young rats from early in the postnatal period (Postnatal Day 7) through sexual maturity, neurobehavioral abnormalities (deficits in learning and memory, altered locomotor activity, decreased auditory startle responding and habituation) and reproductive impairment (delayed sexual maturation and decreased fertility in males and females) were observed at doses ≥50 mg/kg. The neurobehavioral changes of acoustic startle persisted at ≥250 mg/kg and locomotor activity and water maze performance at ≥500 mg/kg in animals tested after cessation of dosing and, thus, were considered to represent long-term effects. The low effect dose for developmental neurotoxicity and reproductive impairment in juvenile rats (50 mg/kg) was associated with a plasma pregabalin exposure (AUC) approximately equal to human exposure at the maximum recommended dose of 600 mg/day. A no-effect dose was not established. **Geriatric Use** In controlled clinical studies of LYRICA in neuropathic pain associated with diabetic peripheral neuropathy, 246 patients were 65 to 74 years of age, and 73 patients were 75 years of age or older. In controlled clinical studies of LYRICA in neuropathic pain associated with postherpetic neuralgia, 282 patients were 65 to 74 years of age, and 379 patients were 75 years of age or older. No overall differences in safety and efficacy were observed between these patients and younger patients. In controlled clinical studies of LYRICA in fibromyalgia, 106 patients were 65 years of age or older. Although the adverse reaction profile was similar between the two age groups, the following neurological adverse reactions were more frequent in patients 65 years of age or older: dizziness, vision blurred, balance disorder, tremor, confusional state, coordination abnormal, and lethargy. LYRICA is known to be substantially excreted by the kidney, and the risk of toxic reactions to LYRICA may be greater in patients with impaired renal function. Because LYRICA is eliminated primarily by renal excretion, adjust the dose for elderly patients with renal impairment.

DRUG ABUSE AND DEPENDENCE

Controlled Substance LYRICA is a Schedule V controlled substance. LYRICA is not known to be active at receptor sites associated with drugs of abuse. As with any CNS active drug, carefully evaluate patients for history of drug abuse and observe them for signs of LYRICA misuse or abuse (e.g., development of tolerance, dose escalation, drug-seeking behavior). **Abuse** In a study of recreational users (N=15) of sedative/hypnotic drugs, including alcohol, LYRICA (450 mg, single dose) received subjective ratings of "good drug effect," "high" and "liking" to a degree that was similar to diazepam (30 mg, single dose). In controlled clinical studies in over 5500 patients, 4% of LYRICA-treated patients and 1% of placebo-treated patients overall reported euphoria as an adverse reaction, though in some patient populations studied, this reporting rate was higher and ranged from 1 to 12%. **Dependence** In clinical studies, following abrupt or rapid discontinuation of LYRICA, some patients reported symptoms including insomnia, nausea, headache or diarrhea *[see Warnings and Precautions, Abrupt or Rapid Discontinuation]*, consistent with physical dependence. In the postmarketing experience, in addition to these reported symptoms there have also been reported cases of anxiety and hyperhidrosis.

OVERDOSAGE

Signs, Symptoms and Laboratory Findings of Acute Overdosage in Humans There is limited experience with overdose of LYRICA. The highest reported accidental overdose of LYRICA during the clinical development program was 8000 mg, and there were no notable clinical consequences. Treatment or Management of Overdose There is no specific antidote for overdose with LYRICA. If indicated, elimination of unabsorbed drug may be attempted by emesis or gastric lavage; observe usual precautions to maintain the airway. General supportive care of the patient is indicated including monitoring of vital signs and observation of the clinical status of the patient. Contact a Certified Poison Control Center for up-to-date information on the management of overdose with LYRICA. Although hemodialysis has not been performed in the few known cases of overdose, it may be indicated by the patient's clinical state or in patients with significant renal impairment. Standard hemodialysis procedures result in significant clearance of pregabalin (approximately 50% in 4 hours).

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility Carcinogenesis A dose-dependent increase in the incidence of malignant vascular tumors (hemangiosarcomas) was observed in two strains of mice (B6C3F1 and CD-1) given pregabalin (200, 1000, or 5000 mg/kg) in the diet for two years. Plasma pregabalin exposure (AUC) in mice receiving the lowest dose that increased hemangiosarcomas was approximately equal to the human exposure at the maximum recommended dose (MRD) of 600 mg/day. A no-effect dose for induction of hemangiosarcomas in mice was not established. No evidence of carcinogenicity was seen in two studies in Wistar rats following dietary administration of pregabalin for two years at doses (50, 150, or 450 mg/kg in males and 100, 300, or 900 mg/kg in females) that were associated with plasma exposures in males and females up to approximately 14 and 24 times, respectively, human exposure at the MRD. Mutagenesis Pregabalin was not mutagenic in bacteria or in mammalian cells *in vitro*, was not clastogenic in mammalian systems *in vitro* and *in vivo*, and did not induce unscheduled DNA synthesis in mouse or rat hepatocytes. Impairment of Fertility In fertility studies in which male rats were orally administered pregabalin (50 to 2500 mg/kg) prior to and during mating with untreated females, a number of adverse reproductive and developmental effects were observed. These included decreased sperm counts and sperm motility, increased sperm abnormalities, reduced fertility, increased preimplantation embryo loss, decreased litter size, decreased fetal body weights, and an increased incidence of fetal abnormalities. Effects on sperm and fertility parameters were reversible in studies of this duration (3–4 months). The no-effect dose for male reproductive toxicity in these studies (100 mg/kg) was associated with a plasma pregabalin exposure (AUC) approximately 3 times human exposure at the maximum recommended dose (MRD) of 600 mg/day. In addition, adverse reactions on reproductive organ (testes, epididymides) histopathology were observed in male rats exposed to pregabalin (500 to 1250 mg/kg) in general toxicology studies of four weeks or greater duration. The no-effect dose for male reproductive organ histopathology in rats (250 mg/kg) was associated with a plasma exposure approximately 8 times human exposure at the MRD. In a fertility study in which female rats were given pregabalin (500, 1250, or 2500 mg/kg) orally prior to and during mating and early gestation, disrupted estrous cyclicity and an increased number of days to mating were seen at all doses, and embryolethality occurred at the highest dose. The low dose in this study produced a plasma exposure approximately 9 times that in humans receiving the MRD. A no-effect dose for female reproductive toxicity in rats was not established. Human Data In a double-blind, placebo-controlled clinical trial to assess the effect of pregabalin on sperm motility, 30 healthy male subjects were exposed to pregabalin at a dose of 600 mg/day. After 3 months of treatment (one complete sperm cycle), the difference between placebo- and pregabalin-treated subjects in mean percent sperm with normal motility was <4% and neither group had a mean change from baseline of more than 2%. Effects on other male reproductive parameters in humans have not been adequately studied.

Animal Toxicology and/or Pharmacology Dermatopathy Skin lesions ranging from erythema to necrosis were seen in repeated-dose toxicology studies in both rats and monkeys. The etiology of these skin lesions is unknown. At the maximum recommended human dose (MRD) of 600 mg/day, there is a 2-fold safety margin for the dermatological lesions. The more severe dermatopathies involving necrosis were associated with pregabalin exposures (as expressed by plasma AUCs) of approximately 3 to 8 times those achieved in humans given the MRD. No increase in incidence of skin lesions was observed in clinical studies. Ocular Lesions Ocular lesions (characterized by retinal atrophy [including loss of photoreceptor cells] and/or corneal inflammation/mineralization) were observed in two lifetime carcinogenicity studies in Wistar rats. These findings were observed at plasma pregabalin exposures (AUC) ≥2 times those achieved in humans given the maximum recommended dose of 600 mg/day. A no-effect dose for ocular lesions was not established. Similar lesions were not observed in lifetime carcinogenicity studies in two strains of mice or in monkeys treated for 1 year.

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June 2012

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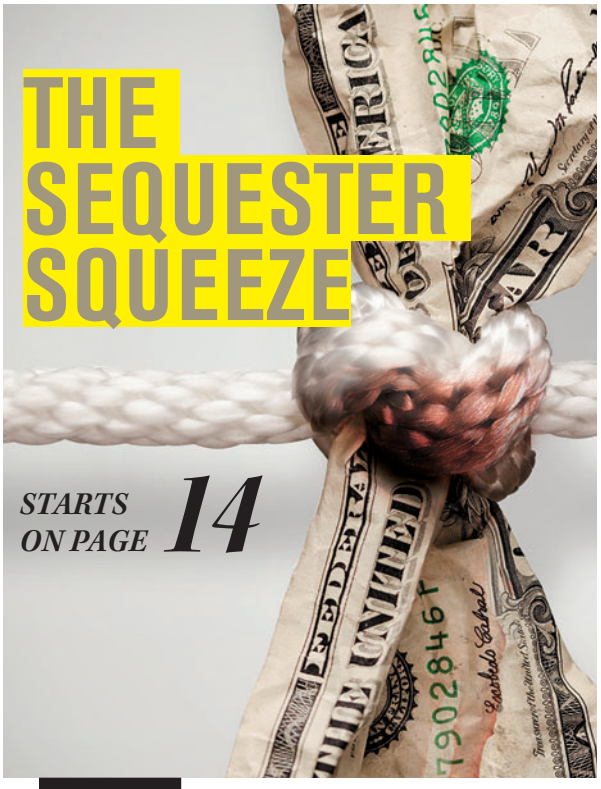

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When to bill using the facility rate instead of the provider office rate.

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ONLINE EXCLUSIVE

INSIDE THE AMBULATORY PRACTICE OF THE FUTURE

Patient engagement is the guiding principle behind the Ambulatory Practice of the Future, which was built to test new business and clinical care models that will redefine the rules of patient engagement. Practice founder David Judge, MD, speaks with *Medical Economics* about building a care team, adopting technology to improve communication among patients and staff, and what it really means to be patient-centered.

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"One of the solutions to finding the right staffing balance is to establish a staffing budget."

—Keith Borglum, CHBC

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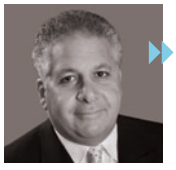

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from the Trenches

> "Taking needed medications diligently, reducing stress, having hobbies that are creative and active, keeping regular doctor appointments—these behaviors lead to success in health for patients of all shapes, sizes, cultures, and ethnicities."
>
> **Lenny Husen, MD,** ANTIOCH, CALIFORNIA

DON'T NEGLECT REFERRALS TO WEIGHT SPECIALISTS

Regarding your article, "The obesity epidemic" (February 25, 2013): A common complaint of my patients is, "Why didn't my family doctor tell me about you sooner?" It is reasonable to refer to a specialist if everything you've tried isn't working or if the patient has a problem that you'd rather not manage.

Don't think you should refer only "extreme cases" to a specialist. If you have a patient whose heart problem warrants a specialist in your mind, then apply the same logic to a patient with a weight problem.

Thomas Marlowe, MD
CHARLOTTE, NORTH CAROLINA

FOCUS ON HELPING LARGE-SIZED PATIENTS

Regarding the article, "The obesity epidemic," the trend to obesity in the United States has leveled off since 1999. The average weight of all developed countries has increased with better nutrition, as has the average height.

Second, although correlations exist between obesity and certain health conditions, your article implies that obesity causes diabetes, cancer, hypertension, and heart disease. The Framingham Risk Score does not use obesity. It uses cholesterol, blood pressure, sex, and age, not body mass index (BMI).

Third, the healthiest BMI is actually 25 to 30. This statistic frequently is ignored. Because of cognitive dissonance, many Americans, including physicians, simply want to believe that thinner is better, because thinner is seen as more attractive. A range of healthy BMI probably extends from 18 to 32, depending on the individual's level of activity, body fat and muscle composition, and genetic background.

Fourth, at least 30% of all people with BMI less than 25 are unhealthy. Being thin does not mean being healthy, just as fat does not mean being "morbid" automatically.

Unfortunately, no good treatments for obesity exist. Only a small percentage of people can lose substantial amounts of weight by calorie restriction and keep it off for 5 years.

Exercising leads to better health, at any size. Quitting smoking and not using mind-altering recreational substances to excess are vital. Most Americans could eat more healthfully. Taking needed medications, reducing stress, having hobbies that are creative and active, keeping regular doctor appointments—these behaviors lead to success in health for patients of all shapes, sizes, cultures, and ethnicities. This success then translates to our success in the economics of medicine and success in addressing the needs of our obese patients.

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ACP UNVEILS NEW APP FOR CLINICAL GUIDELINES

Internal medicine physicians and other clinicians now can access evidence-based clinical recommendations from the American College of Physicians (ACP) through a new mobile app.

Available for free for the iPhone, iPad, and Android, the app includes recommendations from ACP's clinical practice guidelines and guidance statements. Users can access clinical recommendations and rationale, summary tables, algorithms, and high-value care advice for all currently active guidelines in a mobile format designed to be easy to read and interactive.

"The ACP clinical guidelines app continues ACP's goal to improve healthcare quality by disseminating evidence-based clinical recommendations through innovative Web and mobile applications," says Amir Qaseem, MD, PhD, MHA, FACP, the ACP's director of clinical policy. "And the app will help save busy clinicians one of their most valued assets: time."

Getty Images/Photodisc/ Nick Koudis

PROPOSED FEDERAL BUDGET DRAWS MIXED REVIEWS FROM MEDICAL GROUPS

Medical organizations representing primary care physicians (PCPs) and other doctors offered mixed reactions to President Barack Obama's 2014 budget proposal.

If approved the budget could reduce federal spending by $400 billion over 10 years through changes to Medicare and other healthcare programs; reform the sustainable growth rate, although a replacement model is not detailed; and reduce funding for graduate medical education (GME), which groups say would threaten the future supply of PCPs in the healthcare system.

The American Academy of Family Physicians (AAFP) says it was pleased with the budget's commitment to reforms to improve patient health and quality of care as well as address health service costs. Specifically, the AAFP applauds the proposed increase on federal taxes on tobacco and provisions that would improve access for low-income families through Medicaid expansion, support of the Patient-Centered Medical Home (PCMH) model, and assistance to the elderly and disabled through Medicare physician payment reform. The organization also says it is "troubled" that the proposed budget would cut funding for GME for teaching hospitals, however.

The American Medical Association (AMA) expresses similar reactions to the proposed budget. For more details about the budget and medical organizations' reactions to it, see www.MedicalEconomics.com/2014budget.

WALGREENS SET TO OFFER CHRONIC CARE

Walgreens is ready to take retail clinics a step further, with a recent announcement that the pharmacy chain will begin offering chronic care in addition to immunizations and acute care.

Walgreens will offer chronic care at its more than 330 Take Care locations, excluding clinics in Missouri, the company says. The chronic care services will include assessment, treatment, and management of conditions such as hypertension, diabetes, high cholesterol, and asthma, in addition to preventive health services.

The company cites physician shortages, the expected flood of newly-insured Americans in 2014 created by the Affordable Care Act, and the growing patronage of retail clinics as reasons for its decision to expand.

"With this service expansion, Take Care clinics now provide the most comprehensive service offering within the retail clinic industry, and can play an even more valuable role in helping patients get, stay, and live well," says Jeffrey Kang, MD, MPH, senior vice president of health and wellness services and solutions for Walgreens.

Despite news report, reliable data on physician bankruptcies lacking

IT'S A scary headline, one that screams for physicians' attention: "Doctors driven to bankruptcy." A recent CNN.com article told the tale of unfortunate and hardworking physicians, who, through no fault of their own, were being forced to shut down their businesses by familiar health industry bogeymen such as malpractice costs, declining reimbursements, and excessive compliance costs.

"It's a trend that's accelerated in recent years, industry experts say, with potentially serious consequences for doctors and patients," the article states.

Facilitated by its accompanying #bankruptdoctors hashtag, the article sparked indignation on Twitter. "Great article by @CNNMoney!" said the American Academy of Family Physicians. "We need fundamental changes in how physicians are paid."

The physician-practice bankruptcy "problem" makes for a volatile headline and sparks an emotional response. After all, with a supposed looming doctor shortage, doesn't the United States need all the physicians it can muster?

The only problem with the article: We have no idea whether its basic premise is true. It's built on one piece of data from Bobby Guy, co-chairman of the American Bankruptcy Institute's (ABI) health committee, who told CNN that he noticed eight physician-practice bankruptcy filings in March, which he said is a "very unusual" number.

So how many physician practices filed for bankruptcy in February? What about last March, or March 2011? If physician bankruptcies have "accelerated in recent years," then don't we need some historical comparison data to verify that statement?

You'd think so, but that's not likely to happen.

Nobody can say for sure because no official source of physician-practice bankruptcy filings exists, Guy said in a phone interview with *Medical Economics*.

"The evidence is anecdotal, not statistical," says Guy, who tracks Chapter 11 filings as part of his job. "We tend to watch the trends, and to us that seems high."

Statistics published on the ABI's Web site break down bankruptcies into broad categories, reporting the numbers by filing location or chapter number, for example. It's impossible, it seems, to obtain a breakdown by industry.

Guy and his colleagues obtained the March number by combing through individual bankruptcy filings. It's possible more than eight occurred, but Guy can't say for sure.

To be clear, Guy is just doing his job, but for CNN it's another story. Should Guy's admittedly anecdotal evidence be enough of a foundation for CNN to base a report on?

It certainly seems logical that physicians practices could be filing for bankruptcies more often than they were previously. Reimbursements are down. Some patients are foregoing necessary care. Government-mandated electronic health record systems are expensive. Physician burnout is up, and job satisfaction is down.

"My experience is that there are heavy economic pressures on the medical community, and that is driving a trend of financial distress," Guy said.

But without any solid historical data to back it up, the "physician-practice-bankruptcy-is-accelerating" idea is only a theory that may or may not have any basis in reality.

The sequester squeeze

Already-fragile practices brace for its effects

BY JEFFREY BENDIX, MA, *Senior Editor*

HIGHLIGHTS

01 The budget sequestration that took effect March 1 includes a 2% reduction in reimbursements to physicians for Part B Medicare claims and electronic health records meaningful use attestation.

02 Funding for federal health and safety programs has been cut under the sequestration, which could lead to greater demand for the services of primary care physicians.

As budget talks continue, you may well be looking for additional expenses to trim and new sources of practice revenue as a result of the $85 billion in federal spending cuts that went into effect March 1.

FOR PRIMARY CARE PHYSICIANS (PCPs) the most immediate impact of the cuts—known as the sequester—will be a 2% reduction in reimbursements for Part B Medicare claims. Those cuts include reimbursements to practices that have successfully attested to meaningful use of electronic health record (EHR) systems.

"Many of the practices I see are already running on razor-thin margins, so these (cuts) are a real concern for them," says Mark Master, CPA, a partner in the healthcare services group of EisnerAmper, an accounting and consulting firm in Jenkintown, Pennsylvania, and a member of the Medical Group Management Association (MGMA). "To take 2% away from their Medicare payments comes right out of doctors' pockets."

That is the case with Patricia Roy, DO, a family practitioner in Muskegon, Michigan, and a member of *Medical Economics*' editorial board.

"At this point, I don't see changing staffing or hiring, but it will definitely reduce my take-home pay," she says.

The same is true for Sal Volpe, MD, a solo internal medicine practitioner in New York, New York, and *Medical Economics* editorial board member. "I couldn't say to the people who work for me, 'You're all going to make less money for the next year so I can make [the cuts] back,' " Volpe explains. Moreover, he notes, about half of his practice's gross revenue pays for overhead costs, thus doubling the impact of the cuts. "I'm just going to take the hit and shop a little more intelligently for my family," he says.

Volpe thinks that some practices will deal with the cuts by limiting or eliminating year-end staff bonuses. "Those are easier to manage because you don't promise a fixed amount," he notes.

"This kind of uncertainty may force doctors with large Medicare populations to say, 'Maybe I can't take on more Medicare; maybe I shouldn't hire that extra person because

Suggestions for absorbing the Medicare sequester cuts

Apart from cutting your own pay, what steps can you take to make up for lost Medicare revenue?

Here are suggestions from the experts:

☑ REDUCE NON-VITAL SERVICES

"You can't change the direction of the wind, but you can trim your sales," says Judy Bee, principal with Practice Performance Group in La Jolla, California. Bee, a *Medical Economics* editorial consultant, advises starting by looking at reducing services that won't affect billing or the quality of patient care, such as appointment-scheduling. "Maybe people will have a harder time getting in to see you, but you want to be sure they will get good care once they do," she says.

☑ PAY ATTENTION TO DETAIL

Bill Lewis, CPA, a partner in the medical industry practice of the accounting and consulting firm CohnReznik LLP, advises his clients to question every product and service their practice purchases. "Is it something you really need for your business, or is it just force of habit that makes you continue buying it?" he says. For example, physicians in group practices could belong to different medical societies and brief each other on the societies' activities, rather than everyone in the practice belonging (and paying dues to) the same groups. "If you're a small practice, you really have to pay attention to detail," he says.

☑ GET THE RIGHT PEOPLE IN PLACE

Practice owners need to be sure staff members have the proper training and temperament for the jobs they are doing, Lewis says. A front-office person may be hardworking and loyal, but those qualities do not always qualify someone to be an office manager, he points out. "You want to make sure your engine is working properly, but if you have the wrong person at the wrong task, you're not being wise with your dollars," he says.

☑ CHANGE YOUR PATIENT MIX

Another possible strategy is to reduce the number of non-emergent Medicare patients your practice sees—provided you have enough patients covered by insurance that reimburses at Medicare rates or better. The way to do that, Bee says, is by limiting the number of appointments each day for non-emergent Medicare patients. Alternatively, more care of Medicare patients can be handed off to midlevels. "The doctor makes the diagnosis and says, 'Here's the treatment plan,' and all the follow-up is done by the midlevel, who is a cheaper provider," she says. "It has the additional advantage of keeping the doctor's schedule open while still providing good care to the patient."

☑ ADD AN ANCILLARY SERVICE

Yet another option for mitigating the impact of the Medicare cuts is to add an ancillary service for which patients are willing to pay cash, such as weight-loss products, sleep testing, or onabotulinumtoxinA injections.

"AT THIS POINT, I DON'T SEE CHANGING STAFFING OR HIRING, BUT IT WILL DEFINITELY REDUCE MY TAKE-HOME PAY."

PATRICIA ROY, DO

next year it'll be another 2% and now it really starts to affect my ability to meet payroll,'" says Volpe.

(Because Medicare reimburses for 80% of most claims, the net reduction to doctors' fee payments will be 2% x 80%, or 1.6%.)

MOOD OF FRUSTRATION, PESSIMISM

As unwelcome as the Medicare cuts are, most primary care practices probably can absorb them if they are a one-time event. (See "Suggestions for absorbing the Medicare sequester cuts" on page 15.) Unless Congress and the White House can agree on other ways to reduce the nation's budget deficits, however, the cuts are scheduled to continue through 2021 at an annual pace of 2%, with effects that will be felt throughout the healthcare industry and beyond. (See "Annual impacts of federal Medicare funding cutbacks" and "Top 10 employment segments affected by Medicare funding cuts in 2013" on page 20.)

That prospect, combined with the ever-present possibility of far larger Medicare cuts called for under the sustainable growth rate (SGR) funding formula, creates a mood of frustration and pessimism among many doctors.

"When I meet with our members, they roll their eyes and say they're tired of what seems like another 'ask' and another hit from Medicare every few months," says Jeffrey Cain, MD, FAAFP, president of the American Academy of Family Physicians. "They see these things as part of what they call 'the hassle of Medicare.' Family medicine is not as profitable as other specialties, so when they hear '2% here, SGR there, invest in this, start using EHRs,' they get frustrated with the multiple demands."

Anders Gilberg, senior vice president for government affairs with the MGMA, says, "It's the threat of always looking on the horizon and seeing a cliff there. That's what's causing our members to make the biggest adjustments in their practices, like holding off investing in new technology or opening satellite offices. It's a complete erosion in the trust they have in Congress and the government to provide any stability for physicians."

The fact that the cuts extend to reimbursements for attesting to meaningful

MEDICAL ECONOMICS POLL

Q: Will the budget sequestration affect your practice?

COMMENTS

"But we have already been 'hit' by not seeing enough Medicare patients in a year to e-prescribe. I love to do that, but more of my patients are on Advantage plans, and they don't count."

MARILYN HUHEEY, MD, COLUMBUS, OHIO

"Any kind of fee we try to pass on to the patient will be viewed by the trial lawyer-controlled media and government as just another way for greedy doctors to try to pay for their Ferraris."

DENIS SCONZO, MD, YONKERS, NEW YORK

"How exactly does it get passed on when payment is either from Medicare or insurance—both contract-based and not alterable? I know we can't pass it on! It's either cut overhead or take the hit!"

JIM LOG, MD, PADUCAH, KENTUCKY

"My practice will certainly see a difference, as 95% of my patients are either Medicaid or Medicare. If we can get any increase from Medicaid payments, then it may be neutral."

JACKIE BEENE, MD, SACVILLE, MISSOURI

How will budget sequestration affect your practice?
Comment today @ https://www.facebook.com/questions/608698099158863/

To view the poll and other responses, visit https://www.facebook.com/questions/608698099158863/

> WHEN I MEET WITH OUR MEMBERS, THEY ROLL THEIR EYES AND SAY THEY'RE TIRED OF WHAT SEEMS LIKE ANOTHER...HIT FROM MEDICARE EVERY FEW MONTHS."
>
> JEFFREY CAIN, MD, FAAFP, PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS

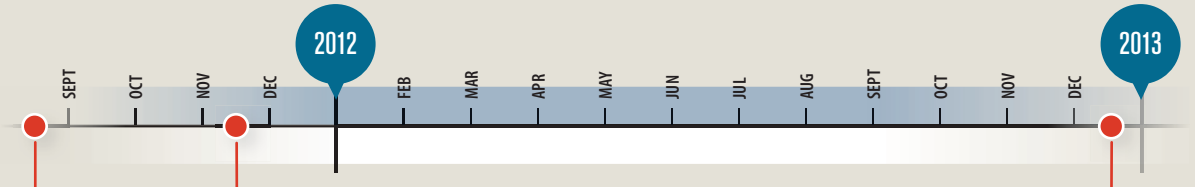
use is another cause of frustration. Meg McElroy, MBA, RHIA, consumer engagement subject matter specialist with the American Health Information Management Association, notes that under the meaningful use regulations, eligible providers who waited until 2013 to start the attestation process already were receiving less in reimbursement than those who started earlier ($39,000 versus $44,000). "Now, on top of that, you're going to be receiving 2% less. That doesn't sit well, especially with eligible providers in small- to medium-sized practices who don't have a cushion to fall back on," she says. "It's disheartening."

Roy adds: "Many smaller practices like mine invested heavily to adopt EHR technology and did so with the promise of a certain payback for achieving meaningful use. To reduce that now is really a dishonorable move."

Adding to the uncertainty is the possibility that commercial insurers will follow Medicare's lead and reduce their payments when they renew their contracts with physicians. "Since Medicare tends to be the benchmark for so many of these contracts, it would probably follow that there will be a corresponding impact on the private payers," says Bill Lewis, CPA, a partner in the medical industry practice of the accounting and consulting firm CohnReznick LLP.

➔ 18

THE BUDGET SEQUESTRATION: A TIMELINE



August 2011

As part of an agreement to raise the nation's debt ceiling, Congress passes the Budget Control Act (BCA) of 2011. The BCA establishes a joint House/Senate Committee, the Joint Select Committee on Deficit Reduction, (also called the "Supercommittee") to find $1.5 trillion in federal spending cuts between 2013 and 2021. If it doesn't do so, then the BCA mandates automatic cuts of $1.2 trillion to begin taking effect January 1, 2013. The cuts are to be split equally between defense and non-defense programs, with some non-defense programs, such as Medicaid and the Department of Veterans Affairs, exempted.

November 2011

The Supercommittee announces that it is unable to agree on spending reductions.

December 2012

Congress delays start of the sequester until March 1, 2013, so that it does not take effect at the same time as the expiration of the Bush tax cuts for wealthy Americans and the end of the payroll tax cut for wage-earners (the "fiscal cliff").

The budget sequester's impact on key federal health and safety programs, fiscal year 2013

Department/program	Base funding (in millions)	Sequestration (in millions)
Centers for Medicare and Medicaid Services	$577,439	$11,851 (2.0%)
National Institutes of Health	$ 31,049	$ 1,553 (5.0%)
Administration for Children and Families	$ 19,689	$ 982 (4.9%)
Environmental Protection Agency	$ 9,418	$ 472 (5.0%)
Global Health Programs	$ 8,218	$ 411 (5.0%)
Health Resources and Services Administration	$ 8,109	$ 365 (4.5%)
Supplemental Nutrition for Women, Infants, and Children	$ 6,660	$ 333 (5%)
Centers for Disease Control and Prevention	$ 6,019	$ 303 (5.03%)
Indian Health Services	$ 4,483	$ 220 (4.9%)
Food and Drug Administration	$ 4,168	$ 209 (5.0%)
Substance Abuse and Mental Health Services Administration	$ 3,368	$ 168 (4.9%)
Animal and Plant Health Inspection Service	$ 1,106	$ 56 (5.0%)
Food and Safety Inspection Service	$ 1,055	$ 53 (5.0%)
Prevention and Public Health Fund	$ 1,000	$ 51 (.5%)
Occupational Safety and Health Administration	$ 568	$ 28 (4.9%)
Patient-Centered Outcomes Research Institute	$ 390	$ 20 (5.1%)
Mine Safety and Health Administration	$ 377	$ 19 (5.0%)
Federal Drug Control Program	$ 341	$ 17 (4.9%)
National Highway Traffic Safety Administration	$ 141	$ 7 (4.9%)
Office of Healthy Homes and Lead Hazard Control	$ 121	$ 6 (4.9%)
Office of the National Coordinator for Health Information Technology	$ 17	$ 1 (5.8%)
Totals	**$ 683,736**	**$17,225 (2.52%)**

Source: U.S. Office of Budget and Management

➔17 EFFECTS EXTEND BEYOND PHYSICIANS

Physicians are by no means the only ones to feel the effects of the budget sequester. Large swaths of the nation's healthcare infrastructure, including the Food and Drug Administration, National Institutes of Health, and the Centers for Disease Control and Prevention (CDC), also are seeing their funding reduced. (See "The budget sequester's impact on key federal health and safety programs, fiscal year 2013," left.)

It's still too early to say with certainty how these funding reductions will affect PCPs. It's noteworthy, however, that the American Public Health Association predicts that reductions in CDC funding will lead to 30,000 fewer children and 20,000 fewer adults receiving immunizations, as well as a decreased ability for the agency to investigate multi-state disease outbreaks. It's reasonable to assume that at least some of the resulting treatment burden will fall on PCPs, especially with more people having access to health insurance under the Affordable Care Act.

Funding for programs designed to increase the supply of future physicians, such as the National Health Service Corps, Title VII of the Public Health Service Act (the only federal program providing dollars specifically to academic departments and programs to increase the number of PCPs), and graduate medical education generally, also is being cut. "The cuts are hitting practicing physicians, research that is important to medicine in general, and programs for training physicians, so it's really impacting the healthcare industry from all angles," says Ray Quintero, director of government relations for the American Osteopathic Association.

Quintero adds that he sees little prospect of Congress reversing the first round of sequester cuts. Longer-term, however, he holds out hope of greater stability for Medicare funding, particularly with regard to the SGR. He points to the Congressional Budget Office's recent downward revision—from $243 billion to $138 billion—of its estimated

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EQUAL HOUSING LENDER

Top 10 employment segments affected by Medicare funding cuts

Segment	Negative employment impact
Hospitals	92,984
Physician, dental, and other health practitioner offices	40,220
Nursing and residential care facilities	38,115
Medical and diagnostic labs / other ambulatory services	38,350
Home healthcare services	25,547
Real estate establishments	22,705
Food services and drinking establishments	21,865
Employment services	15,356
Wholesale trade businesses	8,424
Insurance carriers	7,472
Total	**311,038**

Source: Tripp Umbach

Annual impacts of federal Medicare funding cutbacks

Year	Funding cuts
2013	$10.7 billion
2014	$11.2 billion
2015	$11.6 billion
2016	$12.5 billion
2017	$12.9 billion
2018	$13.5 billion
2019	$14.5 billion
2020	$15.5 billion
2021	$16.4 billion
Total:	**$108.1 billion**

Source: Tripp Umbach

"IT'S THE THREAT OF ALWAYS LOOKING ON THE HORIZON AND SEEING A CLIFF THERE."

ANDERS GILBERG, SENIOR VICE PRESIDENT, MEDICAL GROUP MANAGEMENT ASSOCIATION

cost for scrapping the SGR, and the introduction in the House of Representatives of the Medicare Physician Innovation Act of 2013, which would repeal the SGR. In addition, he says, the Energy and Commerce and Ways and Means committees of the U.S. House of Representatives are developing a joint proposal for repealing the SGR and moving Medicare away from the fee-for-service model.

"All these proposals are largely consistent with one another, which means everyone is at least speaking the same language, something we haven't seen in recent years," he says. "Also, the fact that we're talking about [the SGR] early in the year, rather than in November or December right before cuts are due to take effect, is a hopeful sign."

Legally Speaking

YOU CAN HELP SET EXPECTATIONS ON ELECTRONIC HEALTH RECORDS LIABILITY

By **GORDON OWNBY, JD**

A TOURIST from Arizona suddenly collapses while visiting a boardwalk in New Jersey. The young woman's friends rush her to a local hospital, but she cannot communicate with the medical personnel. Her companions provide the woman's identification, but they cannot offer any relevant medical history.

Fortunately, under a national system for shared electronic health records (EHRs) now being developed, the physician uses an online portal that provides access to her new patient's medical file.

As EHRs move toward a system of national access, questions inevitably arise as to the medical liability implications of having access to all records, all the time.

The benefits of national EHR access are too numerous to keep privacy and security concerns from being resolved. As is often the case, however, the law needs to catch up to the technology. More specifically, courts will have to weigh how to treat healthcare providers who have access to data unlike anything previously available.

Unfortunately, medical records sometimes contain lab values and x-rays that were not acted on, even by the doctors who ordered them. Will our New Jersey physician be faulted for not following up on those items herself? Even with perfectly maintained files, what kind of duty will be imposed on a clinician when a mass of raw information from primary care practitioners, specialists, clinics, and other sources is imbedded many screens deep for a patient who is a complete stranger?

Ultimately, the law—and the medical profession itself—will have to answer these and similar questions so that a national EHR system can achieve its full potential to save lives while protecting providers from "gotcha" litigation. Fortunately, ways exist for both—plus technology itself—to move us forward.

In the law, the fundamental principle of duty requires all persons to use ordinary care to prevent others from being injured as a result of their conduct. Any departure from this principle requires balancing certain considerations. Among those factors are the burdens on a defendant and the consequences to the community of imposing a duty.

When a national EHR system emerges, you will need to be confident in your decisions as you navigate through data collected over vast expanses of time and geography. And communities will need to decide whether a more realistic standard exists than requiring physicians to have absolute command of even the most minute entries in these new super-records.

You and your fellow physicians must help the courts reach those destinations through ongoing dialogue and other activities. It will be easy to blame attorneys or the courts if a national system creates a new level of litigation risk, but medical professional liability trials are not lost on the testimony of attorneys. That's not how it works: Jurors can find against a physician for professional negligence only if another physician says they should.

With a national EHR system, you can seize the opportunity to help establish the appropriate standard of care, one that opens up a new era of patient care while also setting reasonable parameters on what a healthcare provider should be responsible for when an errant entry lurks in the medical file.

Welcome medical record technology as warmly as computerized imaging and pulse oximetry. In fact, a primary benefit of EHRs is not merely the display of information, but also the building of systems of alerts and prompts so that orphaned lab reports and x-rays cannot go unaddressed by the appropriate care providers.

Ultimately, avoiding litigation stemming from shared medical records will take contributions from the law, medicine, and technology itself.

With all three forces going in the right direction, chances will be excellent for our traveler's safe return home.

The author is general counsel for the Cooperative of American Physicians Inc. Send your primary care-related health law questions to ***medec@advanstar.com.***

CODING INSIGHTS
RACs reviewing place of service coding [32]

Operations

6 steps you can take to remain independent—for now

Evolution is necessary, but it is still possible to survive in solo or small practice if that is your wish

by **LISA ZAMOSKY**

HIGHLIGHTS

01 The trend of hospitals acquiring physician practices will cool down, but it will not go away.

02 The impulse to stay independent, regardless of market trends, is still strong among a significant number of doctors in practice today.

03 To remain truly independent in the future, primary care practices will need to be set up as medical homes or using some other model that rewards coordinated and comprehensive care.

If Marcus Welby, MD, were in business today, he might have sold his medical practice to the local hospital.

PRACTICING SOLO, or even in very small groups, is becoming an increasingly difficult—although possible—proposition for many family and internal medicine physicians.

Growing regulatory pressures, privacy rules, the burdens of billing and collections, steep investments to incorporate electronic health record (EHR) systems, and onerous requirements of data collection are all difficult to manage on one's own. These forces, coupled with declining revenues, are causing more doctors in small practices to consider employment over independence.

"What you're seeing largely is that, as insurers continue to underpay providers, providers have no choice but to go into the arms of someone with more money," says Joseph Valenti, MD, board member of the nonprofit Physicians Foundation. "Physicians are being placed into an economic situation which is untenable."

Given that reality, it's little surprise that a recent survey conducted by the healthcare staffing firm Jackson Healthcare found that not only are hospital acquisitions of physician practices up (52% of hospitals plan to acquire practices in 2013 as compared with 44% in 2012), the majority of those deals—70%, in fact—are initiated by doctors looking to sell.

"We expected hospitals to be acquiring internal medicine and primary care practices, most probably, to develop [accountable care organization (ACOs)]. That's what we assumed. However, we're finding that it's more opportunistic than strategic at

this point," says Sheri Sorrell, market research manager with Jackson Healthcare. "Physicians are knocking on the door, and hospitals seem to be jumping at the opportunity."

That doesn't surprise American College of Physicians President David Bronson, MD, who says it makes perfect sense for doctors to approach their local hospitals or to listen when hospitals approach them. These days, doctors in private practices "are under more and more financial strain and don't have the capital to invest in things that would help them," he says.

Although recent acquisitions predominantly are about opportunity, hospitals also cite other reasons for the trend, the Jackson Healthcare survey finds:

- **58% of hospitals are scooping up physician practices to build a competitive advantage;**
- **57% say practice acquisition is a doctor recruitment strategy;**
- **55% say they want to maintain a competitive advantage; and**
- **30% are acquiring practices as part of an ACO formation strategy.**

CHARACTERISTICS OF THE SALE

Given the Affordable Care Act's (ACA's) emphasis on primary care, it's not surprising to see that among the practices most desired by hospitals are those focused on general internal medicine and family medicine (see the tables on pages 30 and 31). In time, however, that scenario is likely to change.

According to Lou Goodman, PhD, president of the Physicians Foundation, several specialties, including colorectal surgery, ob/gyn, plastic surgery, anesthesiology, and radiology, thus far have been able to successfully maintain their independence. But in time, he adds, "specialists will be at the mercy of the hospitals. So the trend is [for doctors] to group together and get as large as they can."

Another interesting aspect to the current acquisition trend is that selling seems to make the most sense for physicians who have been in business for a long time. "A lot of the older doctors are saying, 'I can't deal with it—EHR, administration, everything else. I think I'll sell,' " Sorrell says.

Generally, she says, older doctors are finding compliance with the health reform law to be much more difficult than they anticipated—and a lot more expensive. And, of course, longer-practicing physicians are most likely to have well-established practices, which will be of greater value to hospitals.

But a generational mind-set also is at play here, experts say. Newer doctors—those in their 40s and younger—tend to be much more comfortable with the idea of employment than their older colleagues.

"We find that physicians under 40 are, by and large, employed," Bronson says.

One reason for that situation is the high cost of medical education. "With medical students coming out [of school] with $300,000 of debt per individual, and then marrying another medical student whose story is the same…they're in a financial situation where they're not able to capitalize a practice by themselves," Bronson says.

Industry surveys also indicate that newer doctors want to be in a system that offers health insurance coverage and doesn't require them to put in the same hours as was once expected of physicians. "They want to raise their families. For them, employment is attractive," Bronson says.

The Physicians Foundation has found the same thing in its surveys of doctors. Among the newer set, Goodman says, "the last choice is solo independent practice, which up until the last decade was the number one choice for doctors."

WILL THE TREND CONTINUE?

If trends continue the way they have been, more than 75% of newly hired physicians will be hospital employees within the next few years, according to a survey conducted last year by the physician search and consulting firm Merritt Hawkins.

The question is, can this spree of physician practice purchases continue?

"It will cool down, but it won't go away," Bronson says. "It's not going to do what it did in the 1990s, where everybody bought everything and then they sold everything," he adds.

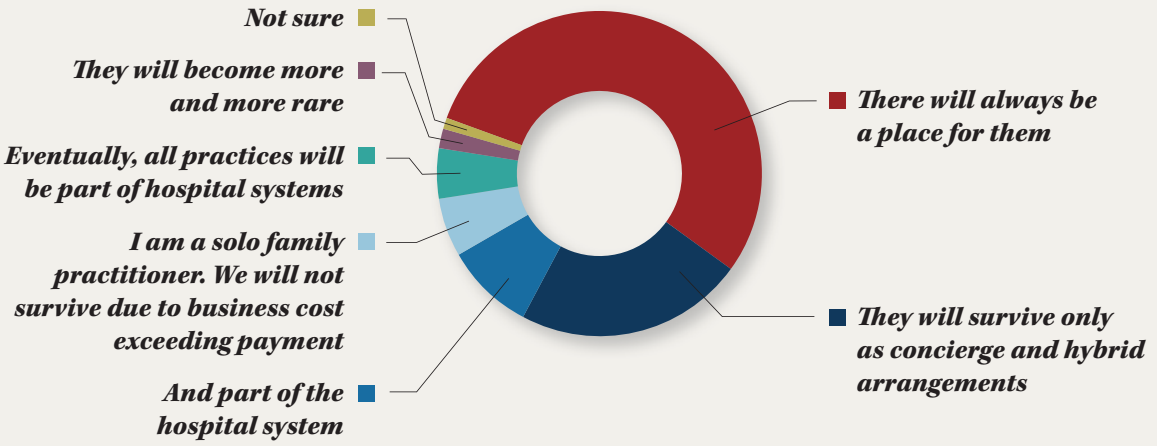
Things are different this time around because market forces, coupled with provisions of the ACA, are forcing more fundamental changes, including clinical integration models and a greater focus on population health. Hospitals may become more selective over time, however, weeding out those practices that are less efficient.

"WE EXPECTED HOSPITALS TO BE ACQUIRING INTERNAL MEDICINE AND PRIMARY CARE PRACTICES, MOST PROBABLY, TO DEVELOP ACOS. . . .[BUT] WE'RE FINDING THAT IT'S MORE OPPORTUNISTIC THAN STRATEGIC AT THIS POINT."

SHERI SORRELL, MARKET RESEARCH MANAGER, JACKSON HEALTHCARE

MEDICAL ECONOMICS POLL

What is the future of independent small and solo practices in primary care?



COMMENTS

"Not looking good under Obama care! Too many taxes passed on for new equipment."

"Surprised they have survived this long."

"They're the backbone of medicine to us all!"

"The control of overhead and provider lifestyle is best accomplished by well-run independents; however, it takes entrepreneurial guts and attention to details. I suspect it pays better, too, at least in my experience (did both)."

"Primary care is a must. Before specialists, they are the first physicians in society, although it so sad that they are looked down on in the United States. It is all about who makes the most money. They forgot the basic medicine."

"ICD10 will cost a solo physician $80,000. If ObamaCare doesn't break me by then, ICD10 certainly will. I'm just glad that I am nearer the end of my career than at the beginning."

"I'm leaving private solo practice after 10 years. My business is successful despite many bumps in the road. I just can't see myself staying in medicine for much longer where the responsibility for the patient's illness is placed squarely and only on the physician with no responsibility to fall on the patient or the insurance companies. I don't see solo or small groups making it unless they want to sell supplements or some ancillary service. It's sad, because I think the kind of medicine I practice is really what patients want: personalized service that is available, real, and interactive."

What do you think the future holds for small and independent solo practices in primary care? Comment today @https://www.facebook.com/questions/613846655310674

To view the poll and other responses, visit https://www.facebook.com/questions/613846655310674

Valenti also points to a tendency on the part of hospitals to buy practices that they feel very little commitment toward, creating a high degree of churn in many markets. "One of the trends we're going to start seeing is all these doctors finding out that it's not as great as they thought and leaving the hospitals and going back out [to private practice]."

STAYING SOMEWHAT SOLO

The impulse to stay independent, regardless of market trends, is still strong among a significant number of doctors in practice today. A survey of more than 5,000 physicians conducted last year by malpractice insurer The Doctors Company found that 56% of respondents believed they were unlikely to change practice models over the next 5 years.

Regardless, it's clear many will continue to feel the pressure to partner. "Physicians are being forced to look for ancillary sources of income because they just can't make it on their practices anymore. That's why you saw physician-owned hospitals open. And then the moratorium came out and made those illegal," Valenti says.

Still, some options are available to doctors interested in remaining independent in today's changing environment:

- **Focus on value.** According to Bronson, it's important for doctors to look for opportunities to provide higher-value care through value-based purchasing approaches, such as ACOs and Patient-Centered Medical Homes.

"To do that requires practicing in a clinically integrated system that's not necessarily financially integrated," Bronson says. "These clinical integration models can help doctors both improve quality and, hopefully, reward them financially so that they are in a more viable situation."

- **Gather together.** It's becoming much more difficult for a very small family or internal medicine practice to survive in many markets today. But physicians who shudder at the thought of selling their practices to become employees should at least look to partner with other practices. This strategy can be a way of increasing efficiencies, lowering overhead, and increasing negotiating power for higher reimbursement.

"ONE OF THE TRENDS WE'RE GOING TO START SEEING IS ALL THESE DOCTORS FINDING OUT THAT IT'S NOT AS GREAT AS THEY THOUGHT AND LEAVING THE HOSPITALS AND GOING BACK OUT [TO PRIVATE PRACTICE]."

JOSEPH VALENTI, MD, BOARD MEMBER, PHYSICIANS FOUNDATION

- **Take control.** "What I would like to see, if we're going to have consolidation, is that these consolidated groups at least be physician-led and physician-driven," Valenti says.

And just that sort of trend is under way, according to Sorrell. "Physician groups are trumping hospitals by developing their own ACOs and then pitting one hospital against another and saying, 'Okay, who wants to play?' " she says.

- **Explore new models.** Newer medical models, including concierge and micropractices, are working for a small minority of physicians, experts say, although currently they don't seem to be a remedy for what ails the masses. "Those are experiments right now, and they are interesting concepts, but there is very little of that actually going on at the moment," Goodman says.

- **Choose carefully.** If you do decide to sell your practice to a hospital, carefully evaluate your purchaser. If possible, avoid joining a hospital with a culture that is going to dictate how you practice medicine.

"You want to be able to add value to the system so that you are a partner with the hospital, even as you're employed," Bronson advises.

- **Look for experience.** Talk with others in the community to assess what kind of experience the hospital has with employed doctors. What's it like for other physicians working in that environment?

"You're going to find places that do it wonderfully well, and you're going to find places that are very inexperienced and haven't figured it out yet and make some mistakes," Bronson says. Learn ahead of time, if possible, which one you're dealing with.

A GLIMPSE INTO THE FUTURE

Will the market be full of independent primary care physicians in the years to come? Generally, the experts think not.

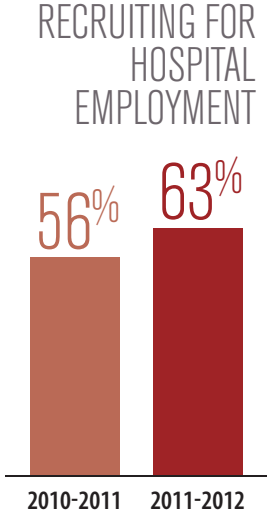
"Over the next 20 years, I would predict that we're going to see a substantial decline in the truly independent physicians," Bronson predicts.

As that decline occurs, however, both Valenti and Goodman see unintended consequences associated with widespread consolidation.

➔30

Practice setting trends

Healthcare search and consulting firm Merritt Hawkins, part of AMN Healthcare, reviewed the firms' permanent physician assignments to determine the types of medical settings into which physicians are being recruited. Family and general internal medicine physicians remain the most-sought doctors by medical groups, hospitals, and other healthcare organizations. Practice arrangements are changing, however.



Source: Merritt Hawkins

PRACTICE ACQUISITION TRENDS

Staffing firm Jackson Healthcare surveyed hospital chief executive officers, administrators, physician recruiters, chief operating officers and other leaders to determine their actual and planned recruiting as well as the thinking behind it.

2012 acquisitions by specialty (actual)

Specialty	Percent of total
Family practice	54
Internal medicine, general	26
Obstetrics/gynecology	24
Cardiology	18
Primary care	16
General surgery	12
Urology	10
Hospitalist and rheumatology	8*
Gastroenterology, Nurse practitioner, Oncology, Orthopedic surgery, Otolaryngology, Pediatrics, General	6*
Emergency medicine, Endocrinology, Diabetes and metabolism, Neurology	4*
Neurosurgery, Physical medicine and rehabilitation, Psychiatry (adult), Pulmonary medicine	4*
Allergy and immunology, Cardiothoracic surgery, Infectious diseases, Maternal and fetal medicine, Nephrology, Occupational medicine, Pathology, Pediatrics, Subspecialty, Radiation oncology, Radiology, Vascular surgery	2*

*The percentage represents each specialty individually, not as a group. For example, gastroenterology = 6% and nurse practitioner = 6%.

N=50

➔25

"Doctors and the health insurance companies seem to be fairly aligned on a lot of issues right now in that if physicians remain independent, the insurance business stays whole. If physicians don't stay independent and become employed by institutions, those institutions will become so vertically integrated that they will be able to self-insure and write their own insurance," Goodman says.

That's something to watch as markets shift around the country.

Still, Goodman acknowledges, true independent practice, if not set up as a medical home or some other model that rewards coordinated and comprehensive care, is just not going to be possible going forward.

2013 acquisitions by specialty (planned)

Specialty	Percent of total
None/not planning to acquire	48
Family practice	31
Internal medicine, general	22*
Primary care	13
Cardiology, Orthopedic surgery	10*
Gastroenterology, General surgery, Urology	8*
Obstetrics/gynecology, Oncology	7*
Otolaryngology	6
Neurology, Nurse practitioner, Pulmonary medicine	5*
Ambulatory care, Hospitalist, Infectious disease, Pediatrics, General	4*
Cardiothoracic surgery, Neurosurgery, Rheumatology, Endocrinology, Diabetes and metabolism, Geriatric medicine, Orthopedic (non-surgical), Pain medicine, Radiation oncology, Trauma, Vascular surgery	3*
Anesthesiology, Bariatrics, Emergency medicine, Ophthalmology, Plastic surgery, Psychiatry (adult)	2*
Colon and rectal surgery, Critical care medicine, Dermatology, Hematology, Maternal and fetal medicine, Nephrology, Occupational medicine, Podiatry, Radiology, Sleep medicine, Sports medicine	1*

*The percentage represents each listed specialty individually, not as a group. For example, Cardiology=10% and Orthopedic surgery=10%.

N=119

Reasons for practice acquisition

Physicians approach hospital/seek to sell their practices	70%
Build a competitive advantage	58%
Part of a physician recruitment strategy	57%
Maintain a competitive advantage	55%
Accountable care organization formation	30%
Improve patient safety	28%

Source: "Trend Watch: Physician Practice Acquisitions," Jackson Healthcare

N=69

"IF PHYSICIANS DON'T STAY INDEPENDENT AND BECOME EMPLOYED BY INSTITUTIONS, THOSE INSTITUTIONS WILL BECOME SO VERTICALLY INTEGRATED THAT THEY WILL BE ABLE TO SELF-INSURE AND WRITE THEIR OWN INSURANCE."

LOU GOODMAN, PHD, PRESIDENT, PHYSICIANS FOUNDATION

Coding Insights

RACs REVIEWING POS CODING FOR DOCTOR SERVICES IN AN OUTPATIENT SETTING

We have an office that is part of a hospital. We perform surgical procedures in the office and have been receiving denials for some of our claims. How do we bill these services and get paid appropriately for our work?

WHEN A physician furnishes services in an outpatient setting of a hospital, including a provider-based department of a hospital, payment is made under the Medicare Physician Fee Schedule at the facility rate. In these instances, the claim should be billed with place of service (POS) 22 (hospital outpatient), instead of POS 11 (physician office).

Recovery audit contractors (RACs) are looking at these types of scenarios to ensure that claims are being billed with the appropriate POS code, because they have found that doctors are incorrectly reporting office POS code of 11 when services are provided in an outpatient hospital setting, resulting in overpayments to the physicians.

Through data analysis (automated review) by the RACs, an outpatient claim is identified reporting the same surgical Current Procedural Terminology (CPT) code for the same patient and same date of service as a professional claim with a reported POS 11. To account for the increased expense that doctors incur by performing services in their offices, Medicare Part B reimburses physicians at a higher rate for surgical procedures performed in their offices.

When doctors perform these services in facility settings (for instance, outpatient facilities), Medicare reimburses the overhead expenses to the facility and the physician receives a lower reimbursement rate. An improper payment exists when physicians bill these services with an incorrect POS based on the setting in which the services were rendered.

Those CPT codes in the integumentary system (10000 series) have been found to have the greatest number of improper payments, but RACs are reviewing all surgical CPT codes (10000-60000).

Review your billing practices, paying special attention to POS coding, and ensure that your billing staff is using the correct POS code on professional claims to specify the entity where services were rendered. ◘

REVIEW YOUR BILLING PRACTICES, PAYING SPECIAL ATTENTION TO POS CODING, AND ENSURE THAT YOUR BILLING STAFF IS USING THE CORRECT POS CODE ON PROFESSIONAL CLAIMS TO SPECIFY THE ENTITY WHERE SERVICES WERE RENDERED.

*The answer to this question was provided by **Renee Stantz,** a billing and coding consultant for VEI Consulting Services, Indianapolis, Indiana. Send your primary care-related coding questions to **medec@advanstar.com***

Trends

Circulation education

Stressing smoking cessation, physical activity, portion control, and blood pressure management can help patients with multiple health issues

by **BETH THOMAS HERTZ**

HIGHLIGHTS

01 Circulatory system disorders have been the leading causes of death and major causes of disability in the United States for almost a century, even as overall mortality rates decline.

02 As the healthcare system moves from volume-based to value-based incentives, physicians improve patient outcomes by redoubling efforts to counsel patients to adopt good health habits at any age.

Diseases of the circulatory system are not just the domain of specialists. The 2010 National Ambulatory Medical Care Survey found that family physicians have more visits for circulatory problems (35% of visits) than cardiologists (19%) in the United States.

CIRCULATORY SYSTEM diseases accounted for about 7,500 office visits a year out of a little more than 1 million in the survey, which is a nationally representative sample survey of visits to nonfederal office-based patient-care physicians, excluding anesthesiologists, radiologists, and pathologists.

Circulatory system disorders such as heart disease and stroke have been the leading causes of death and major causes of disability in the United States for almost a century, even as mortality rates decline. They account for more than $200 billion in annual costs in the healthcare system and are the cause of more than one-third of the deaths in those aged at least 65 years. Also, circulatory disorders often signal other health problems.

Many circulatory problems can be improved with better lifestyle choices, however. As the U.S. healthcare system moves from volume-based to value-based incentives, primary care physicians (PCPs) and others have the opportunity to make major improvements in their patient outcomes by redoubling efforts to counsel patients to adopt good health habits at any age.

YOUR TOP ALLY: THE PATIENT

According to the American Heart Association, a physician's most valuable ally in stroke treatment and prevention is the patient.

Harlan M. Krumholz, MD, an internationally recognized heart disease specialist, believes that PCPs have a pivotal role in providing front-line care that can help patients lower their risk factors for circulatory system diseases, with smoking at the top of the list.

Krumholz is the Harold H. Hines Jr. Professor of Medicine (cardiology) and professor of investigative medicine and of public health (health policy) at the Yale University School of Medicine. He is also director of Yale-New Haven Hospital Center for Outcomes Research and Evaluation. He has authored more than 250 journal articles and chapters on cardiovascular care and serves on many national committees focused on improving the care of patients with heart disease.

"Every appointment needs to be seen as an opportunity to encourage and educate patients to stop smoking," he says. "Too often, this gets pushed aside by fancy risk assessments or lipid tests, but nothing beats making education a priority."

Education should not be limited to smoking cessation, however. Patients need to be informed about the importance of physical activity, meal portion control, blood pressure management, and more, he says.

"You need to let them know what they can do for themselves to improve their health without medications," he says. "Anything they can do to avoid having to take medication is worth it. Pills seem like a simple and easy answer, but all have risks and costs associated with them, for the patient and for society."

Helping a patient make significant lifestyle changes is powerful, he stresses. It offers the possibility of a cure that has no side effects and the opportunity to avoid many other problems, such as hypertension or osteoarthritis. "We just don't have enough respect for the power of lifestyle interventions," he says.

TIME CONSTRAINTS

With PCPs being pressed to see more patients than ever, taking the time to deliver lifestyle coaching can seem impossible. Krumholz suggests, however, that physicians use whatever time they do have in each visit to push the message. Even 20 seconds is worth it, he says.

"Patients hear you, even if it doesn't seem like it," he says. "Offer positive reinforcement of the benefits, and one day they will be ready to make changes."

Having a practice that is a medical home has helped Yul Ejnes, MD, immediate past chairman of the American College of Physicians Board of Regents and a practicing internist in Cranston, Rhode Island, reach out to patients with high-risk factors.

"Part of the solution is to use the clinical staff more efficiently," Ejnes says. "It does not all have to be on the doctor. There is not enough time in the exam room. At least some screening can be done by the staff, and the physician can train them to deliver a consistent message about these issues." The heart association, the American Stroke Association, and many other organizations also offer a wide range of patient information, tools, and resources online.

Although his office has a nurse care manager who can work closely with patients to schedule follow-up appointments for things such as a smoking cessation regimen, he says that even medical assistants can ask about smoking status, note excess weight or blood pressure readings, and give relevant printed materials to patients to take home and think about.

"Sometimes the best thing doctors can do is get out of the way and let the staff help," Ejnes says. "It's not something that only we can do."

Although some insurers now reimburse practices for the time spent on lifestyle education, even practices that are not compensated for it can make it at least somewhat profitable by identifying patients who could benefit from such services—possibly through an electronic health record system—and contacting them later to see how they are doing and encourage them to come back for a followup.

"Sometimes it is useful to uncouple some activities from a visit. Normally, if the patient doesn't come back in, nothing happens," he says.

The extra visits generated by such follow-up can be profitable, and they can help improve your scores on performance measures, which will be increasingly valuable in the future.

35%
OF VISITS
to family physicians are for circulatory problems

7,500
number of annual office visits for circulatory system diseases

$200 BILLION+
annual healthcare system costs related to circulatory system disorders

Source: National Ambulatory Medical Care Survey

AAFP programs

The American Academy of Family Physicians (AAFP) offers several programs to help physicians encourage wellness in the realm of circulatory disorders:

"ASK AND ACT"

The AAFP's tobacco cessation program "Ask and Act" encourages family physicians to ask all patients about tobacco use, then to act to help them quit.

According to the AAFP, strong evidence exists that advice from a healthcare professional can more than double smoking cessation success rates and that patients are more satisfied with their healthcare if their primary care provider offers smoking cessation interventions—even if a patient is not ready to quit.

@ For more information, visit www.aafp.org/online/en/home/clinical/publichealth/aim/about.html.

Resources on the AAFP Web site (www.aafp.org/online/en/home/clinical/publichealth/tobacco.html) are designed to make your interventions with your tobacco-using patients more effective. Information on maximizing billing for preventive services also is included, as well as many links to additional resources.

Materials to encourage patients to quit smoking, including posters, brochures, and pins encouraging them to ask for help, are offered for purchase. One example is packets of "prescription" pads that contain brief, specific patient tips on what to do before, during, and after their quit dates, so patients know exactly what steps to take as they go through their smoking cessation.

AMERICANS IN MOTION–HEALTHY INTERVENTIONS

Americans In Motion–Healthy Interventions (AIM-HI) is an AAFP initiative designed to improve the health of patients through a multifaceted fitness program addressing physical activity, nutrition, and emotional well-being in the individual, family, and community.

AIM-HI goals include encouraging family physicians to be fitness role models, improving family physicians' ability to positively affect the fitness of their patients, and enhancing awareness of the family physicians' unique ability to promote fitness within their communities.

AIM-HI presents fitness—physical activity, nutrition, and emotional well-being—as "the treatment of choice" for prevention and management of many chronic conditions. AIM-HI helps family medicine practices create a fitness focus through implementation of these critical strategies:

- raising awareness among clinicians and office staff regarding their own personal fitness,
- creating an office environment that is conducive to integrating AIM-HI concepts into everyday office routines, and
- using the AIM-HI philosophy and tools to help patients improve their fitness.

"NOTHING BEATS MAKING EDUCATION A PRIORITY."

HARLAN M. KRUMHOLZ, MD

1/3

deaths due to circulatory disease in adults aged at least 65 years as a fraction of total deaths in that age group

Source: National Ambulatory Medical Care Survey

CODING

The following Current Procedural Terminology codes can be reported when billing for smoking and tobacco-use cessation counseling services:

99406: Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes.

99407: Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes.

The Centers for Medicare and Medicaid Services also included these codes, as well as Healthcare Common Procedure Coding System (HCPCS) codes G0436 and G0437, on the list of services for which the use of a telecommunications system may substitute for an in-person encounter, effective January 1, 2012.

Effective January 1, 2013, the following HCPCS codes also are reimbursable for services provided via telecommunications systems:

G0446: Annual face-to-face intensive behavioral therapy of cardiovascular disease

G0447: Face-to-face behavioral counseling for obesity

Contact your payers to determine their criteria for billing for such services.

PERSISTENCE PAYS OFF

Both experts agree that although PCPs already know the value of counseling patients to help them make healthier choices, it is essential that they do not get discouraged if patients do not respond right away to their encouragement to stop smoking or take other steps.

"Many won't act on your advice, but there are enough success stories to show us that repetitive messaging is effective," Krumholz says. "Patients hear you, and your work really does pay off in the end."

Don't view patients' unsuccessful attempts at change as failures, Ejnes adds. Stay positive and open-minded.

"Reassure patients that many people do not succeed on their first attempt and that we can learn from what didn't work and change our approach next time," he says. "Scolding them is not terribly effective. Be positive and productive."

Another potential benefit of continuously repeating the message about healthier choices is that if you can change one patient's lifestyle choices, it can have a ripple effect on their social networks. Some of their friends will be influenced to make changes, a trend that is beneficial to the community far beyond your actual patient base, Krumholz says.

"New behaviors become normative and spread like healthy virus among a person's friends," he says. "We don't have to change everyone, but if we can prevail on some, it spreads.

"This type of work is not flashy, but it is worth it," he concludes. "Even if you just get one person to respond, it is a huge win."

WORKING WITH SPECIALISTS

Another aspect of improving circulatory health and the costs associated with it is not only your ability to know when to refer to a specialist but also how to manage that referral for maximum outcomes.

"Care coordination is something we need to do better," Ejnes says. "If a patient is seeing a [PCP] and a cardiologist, who is checking their lipids and managing their cholesterol?"

When you do refer a patient to a specialist, make communication a priority so that your patient's efforts at improving his or her health are maximized.

FOR MORE INFORMATION
See our circulatory disorder resource center at www.MedicalEconomics.com/circulatory-disorders.

Circulatory disease demographics

11%
OF ADULTS
aged at least 18 years have ever been told by a doctor or other health professional that they had heart disease

The 2011 National Health Interview Survey, a multipurpose health survey conducted by the Centers for Disease Control and Prevention's National Center for Health Statistics, provides insight into which patients are most likely to present with circulatory problems.

It found that 11% of adults aged at least 18 years had ever been told by a doctor or other health professional that they had heart disease, 6% had never been told they had coronary heart disease, 24% had been told on two or more visits that they had hypertension, and 3% had ever been told they had experienced a stroke.

Men were more likely than women to have ever been told they had coronary heart disease, but the prevalence of stroke in men and women was similar.

The survey found a positive relationship between age and the presence of heart disease (including coronary heart disease), hypertension, and stroke: As age increased, the percentages of adults with these conditions also increased.

Being educated mattered, but so did poverty. As educational levels increased, the percentages of adults with coronary heart disease, hypertension, and stroke decreased. Adults in families that were poor or near poor were more likely to have ever been told they had these types of conditions than were adults in families that were not poor.

The motivational interview

The American Heart Association recommends physicians use the following script of five Rs when interacting with patients who are not ready to quit smoking:

RELEVANCE
Personalize why quitting to relevant to them, such as the health benefits they will gain.

RISKS
Ask the patient to identify the negative consequences of tobacco use, such as stroke, heart attack, or shortness of breath.

REWARDS
Ask the patient to identify the rewards of stopping smoking, such as saving money or setting a good example for their children.

ROADBLOCKS
Ask the patient what are his or her barriers to quitting. Is the patient afraid of weight gain? Depression? Withdrawal symptoms?

REPETITION
Repeat these steps at each appointment. Remember that nearly half of all smokers try to quit each year, and most will make several attempts before they succeed.

Preventing death and disability from cardiovascular disease

Cardiovascular disease (CVD) is the number one and most costly killer in the United States and a major cause of disability. It cost the United States a projected $503 billion in medical expenses (direct costs) and lost productivity (indirect costs) in 2010.

According to the Centers for Disease Control and Prevention Heart Disease and Stroke Prevention Program, the past 50 years have seen significant progress in the battle against heart disease, stroke, and other forms of CVD.

According to the National Institutes of Health, 1.6 million lives have been saved since 1977 that otherwise would have been lost to heart disease and stroke. An estimated 44% of the decrease in heart disease deaths from 1980 to 2000 was a result of prevention through the reduction of risk factors.

According to the American Heart Association, avoiding key risk factors and receiving early diagnosis and correct treatment are essential to combating heart disease and stroke. Not smoking, maintaining a healthy weight, and controlling blood sugar, blood pressure, and cholesterol may add 10 years of life.

OTHER FACTS:

- An estimated 47% of U.S. adults at least 20 years have total cholesterol levels of 200 mg/dL or higher. A 10% decrease in these levels population-wide may result in about a 30% cut in the incidence of coronary heart disease.
- One in three U.S. adults has high blood pressure. About 69% of people who have a first heart attack, 77% who have a first stroke, and 74% with congestive heart failure have blood pressure above 140/90 mm Hg.
- Only 27% of respondents in a 2005 study knew heart attack signs and symptoms and would call 911 first if someone were having a heart attack or stroke.
- People free of risk factors have lower healthcare costs and are far less likely to develop CVD.

After 2 decades of progress, however, the percentage of Americans without major heart disease risk factors is dropping and now stands at less than 10%.

"AT LEAST SOME SCREENING CAN BE DONE BY THE STAFF, AND THE PHYSICIAN CAN TRAIN THEM TO DELIVER A CONSISTENT MESSAGE ABOUT THESE ISSUES."

YUL EJNES, MD

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

Financial Strategies

3 STEPS TO CONTROLLING STAFF COSTS

by **KEITH BORGLUM,** *CHBC*

After provider compensation, costs for support staff are the biggest expense of running a medical practice. Even with good practice management, you and your practice manager may feel that you never can get staffing levels just right, which is understandable. Too many variables are involved to achieve perfection.

BECAUSE WORK generally expands to fit the time available, excess staffing costs can result from employees being added during periods of high load—during flu season, or when converting to open-access scheduling, for example. Staff members then might be permanently retained even after work patterns change, seasonal impacts end, or short-term projects are completed.

On the other hand, understaffing may reduce costs over the short term, but it usually increases the emotional costs of physician stress and staff complaints of overwork, and it can reduce your efficiency to the point where costs increase as a percentage of collections.

Here are three steps to determining the appropriate staffing balance for your practice.

Establish a budget. One of the solutions to finding the right staffing balance is to establish a staffing budget. The first step to doing so is to look at benchmark data for practices that are similar to yours. The two best sources of staffing data:

- for small and solo practices—the National Society of Certified Healthcare Business Consultants (NSCHBC) Statistics Report for small and solo practices, and
- for large and multispeciality practices—the Medical Group Management Association Costs Survey.

Both organizations offer sample reports online, at www.nschbc.org and www.mgma.com, respectively.

According to the NSCHBC, median staffing for solo and small primary care practices is three to four full-time equivalent support staff per doctor, presuming no nonphysician providers or ancillary services and approximately 20 to 25 patient office visits per day. The budget for this level of staffing typically approaches 20 to 24% of gross collections.

Adjust for your practice's circumstances. The next step in determining the proper staff size is to adjust the benchmarks you find to account for the particular circumstances of your practice, such as staff productivity, payer mix, use of quality measures, and local wage levels. An older physician whose patients have aged with him or her will have different staffing needs than a newer doctor with a younger patient mix.

It also is important to consider the skill level of staff members. We all have observed those exceptional people who seem to effortlessly do twice as much work as their colleagues.

Once you have tailored the benchmarks to your circumstances, you will have a custom tool that you can use to evaluate staff costs and can easily update to compare with the national surveys. For example, if the surveys show that costs have increased 2% in a particular year, then you can apply that adjustment to your custom benchmark.

Obtain input from staff. The final step in the process is to discuss your findings with your staff members and solicit their input for staying within budget, then review the data monthly. First, all should read the book *The One Minute Manager* by Kenneth Blanchard, PhD, and Spencer Johnson, MD.

The bottom line to investing in budgeting, just as it is in investing in other good practice-management behavior, is a flowing, more profitable, and less stressful practice.

The author is a medical practice management consultant in Santa Rosa, California, and a Medical Economics *editorial consultant. Send your practice finance-related questions to* **medec@advanstar.com**.

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Technology

No pain, no gain

Medical Economics EHR Best Practices Study leader talks about his EHR implementation and vendor switch and shares tips for success

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

HIGHLIGHTS

01 Implementing an electronic health record system will negatively affect productivity at first, but the increased access to data ultimately will improve patient engagement, billing, and patient care.

02 Patient panel size, the number of new patients per week, and typical office visit length are considerations when assessing a particular system's appropriateness for your practice.

It was Friday—a morning that was the culmination of months of planning for the office-based physician and his staff of five employees.

FOR DR. George G. Ellis Jr., MD, who owns a busy solo internal medicine practice in Boardman, Ohio, this day was going to be challenging. He knew it, and so did his staff. Hundreds of hours had been invested in tutorials, and thousands of dollars in computer hardware, set up, logistics, health information technology (HIT) support, system preparation, connectivity, and readying for months of detailed patient data entry.

For Ellis, it was his "go-live" day. It's a day that is about as welcomed in a physician's practice as black Friday to a stockbroker.

There's going to be a downturn in productivity, Ellis says, and you can only hope there isn't a complete crash.

For any physician, office manager, and staffer experiencing the first day's use of a new electronic health record (EHR) system with active patients, it's an event as memorable as some of history's greatest tragedies.

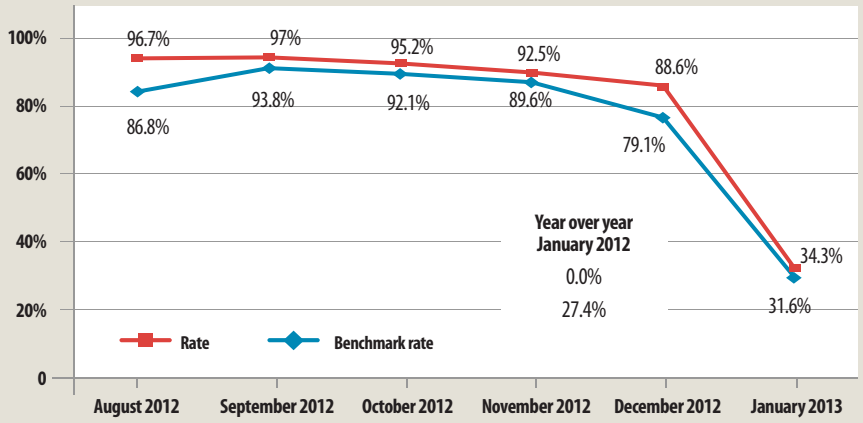
Why? Consider exactly what is happening during an EHR implementation. The practice and its team members not only are adopting an entirely new electronic means of data capture, they are reinventing and reimagining just about every process in the practice, from patient data entry, insurance eligibility, billing, coding, communication with patients and staff, all the way to follow-up appointment reminders.

And although Ellis clearly understood the pain associated with any EHR implementation, regardless of system, he also could see the long-term vision as it related to engaging patients in new ways, recording medical and billing data, and ultimately improving patient care with so much access to relevant data about the practice's patient panel, their health statuses, immunization rates, practice finances, denial rates, etc.

On this Friday, Ellis, who leads and par-

REVENUE REALIZATION RATE

This chart shows how well the practice of George G. Ellis Jr., MD, resolved claims through a revenue realization rate compared with the national benchmark. Ellis attributes it to more aggressive management of revenue cycle and claims processing. Ideally, after 6 months, at least 95% of a given month's changes should be fully adjudicated—either paid or adjusted. Other outstanding amounts are overdue to your practice and require additional work.



ticipates in the 2-year *Medical Economics* EHR Best Practices Study, implemented athenahealth's cloud-based service that has a comprehensive and integrated EHR with practice management, patient communications, and care coordination capabilities.

Although Ellis says it is a robust platform that takes time to learn and effectively use, it has incorporated some very useful tools related to its core functions. In this report, *Medical Economics* takes a closer look at Ellis' practice and his strategy for implementing the system, as well as his quest for achieving meaningful use, and we share some of his "best practices" after 9 months since first implementing athenahealth's system.

BACK TO THE BEGINNING

Ellis is no stranger to EHR systems. This is his fourth system, dating back to 1992. When he decided to switch from a server-based system to the athenahealth's cloud-based system in December 2011, he knew that he would leave a tremendous amount of historical patient data behind. The practice made the decision that they would not operate in parallel systems, which is a move most HIT experts laud.

"We did not transfer data from the old system," he says. "It just wasn't worth the effort to do it."

For most solo, office-based practices, the undertaking and expense to port over past medical records is nearly a deal-breaker when implementing these systems, Ellis adds.

When you work in a very busy practice with an open patient panel, the proposition is almost too much for a small staff. Ellis' practice has 4,800 to 4,900 patients in its panel. Located just outside of Youngstown, Ohio, in a largely blue-collar community with a higher-than-average Medicare base, the practice employs an office manager, two receptionists, a medical assistant, and a billing person.

The practice, Ellis says, typically sees 10 new patients a week and shuffles between a total panel of 120 to 160 patients a week. The pace of the practice is fast, and he relies heavily on his staff, notably his medical assistant (a trained paramedic), who helps set up patients before encounters.

Although the average office visit lasts about 15 minutes, new patients typically take longer—closer to 30 minutes. Acute problems can be addressed in about 10 minutes, he adds.

All of these elements also are important considerations in assessing the functionality and fit of an EHR system, Ellis adds. The practice's structure, Ellis explains, is important because the EHR system needs to help the practice maintain its pace and viability. Understanding an EHR's capabilities upfront, and evaluating the system based on the needs of the practice, is extremely important for every physician. He took the time, and he believes the homework paid off.

In fact, the integration of clinical, management, analytics, billing, patient commu-

5 TIPS for an EHR implementation

1/ Pick the right electronic health record (EHR) system for your office. Identify the needs of your practice, and then make certain the system can adapt to meet those needs.

2/ Be thorough in your due diligence when it comes to hardware and software selection.

3/ Train. Train some more.

4/ Educate your staff and patients about the need for the implementation. And be open with your staff and patients about the short-term realities and long-term improvements associated with it.

5/ Experiment with the functionality of your EHR to make certain you are getting the most benefit from its use. Appoint and train "super users" in the practice to help answer questions during the implementation.

Denial rates

The following table presents the denial rate information for your practice over the past 12 months. The numbers in the table represent the percentage of claims that scrub, receive a front-end denial, or receive a back-end denial. A "..." in a cell means there were no claims that month.

Year	Scrub rate	Front-end denial rate	Back-end denial rate
February 2012	...	...	...
March 2012	...	...	...
April 2012	...	...	...
May 2012	57.5	0.0	...
June 2012	10.3	0.9	4.2
July 2012	6.8	1.9	6.9
August 2012	4.8	0.6	2.5
September 2012	8.1	0.2	5.7
October 2012	7.5	0.0	6.9
November 2012	5.7	0.3	6.6
December 2012	5.1	0.5	5.0
January 2013	6.6	0.0	4.4
Annual	**7.9**	**0.5**	**5.2**

Monitoring accounts receivable

Year	Days	Benchmark rate
May 2012	55.9	33.2
June 2012	36.9	34
July 2012	32.6	34.6
August 2012	28.3	35.4
September 2012	35.3	34.9
October 2012	29.3	32.5
November 2012	32.1	32
December 2012	28.8	32.2
January 2013	33.6	33.2

nication, and care coordination capabilities made athenahealth's system attractive to his practice, and it helped streamline many of these core operational functions into one system.

MAKING PREPARATIONS

As part of his evaluation, Ellis wanted a vendor with a solid reputation and a system with low upfront costs, a growing base of users, and depth in clinical and practice management functionality. And he wanted a system that not only closely matched the workflow of his practice, but also could be customized to help him see the volume of patients typical for his practice. He also knew that he wanted the ability to streamline and improve communication with his patients electronically.

As part of the *Medical Economics* 2-year EHR Best Practices Study, which paired 29 physicians with nine EHR vendors, Ellis was offered athenahealth's service for 2 years as part of the joint agreement to participate in the study.

Once the end-user license agreement was signed, it triggered another very important, and often underused, aspect of implementatiog: training.

In fact, before the go live date, he and his staff performed online training tutorials during non-office hours. He paid them for the next 12 weeks of training. In fact, in the end, online tutorials helped, but working in the system before going live would have been a far stronger approach.

The practice had developed two "super users," and that was extremely helpful before the go-live date.

A DAY AT THE OFFICE

When a patient steps into the office, he or she is asked to complete demographic questionnaire that covers past medical problems, family history, social history, and everything relative to that visit. The office staff collects the patient's insurance information, collects a co-pay, and takes a photograph for the record. This begins the process of data entry into the system. And it remains one of the most time-consuming and important aspects to implementing an EHR, Ellis says. In essence, the practice is laying the foundation of data that will accompany all subsequent encounters. It's the piece of an implementation that takes the most time, but one

that pays dividends long-term.

During the go-live day, Ellis says, the productivity in his office slowed to a crawl as his patients supplied data and his staff entered them into the EHR and began to see patients and document the encounters. They were learning new aspects of the system not previously encountered, but they were trying to communicate with patients and practice an entirely new workflow as far as check-in, processing, performing the patient encounter, and check-out.

"We started putting every patient in the system as if it was the first time he or she was being seen," Ellis says. "It was very disruptive. I felt like the engine fell out. During that first day, we saw 10 patients in 10 hours." A typical day sees closer to 40 patients, and on some days, even more.

Not only was the first day taxing on the staff members, but they also had to explain to patients why they needed to re-enter demographic data in the system. "It was just a really slow process in the beginning," Ellis recalls.

Although improvement was noted during that first week, it took the practice's team close to 3 to 4 weeks to show noticeable speed at processing. During that first month of implementation, Ellis' practice was seeing less than half of his normal volume. Although physicians should anticipate a 30% drop in productivity, they also need to plan for it financially and its impact to the operation, Ellis says. And importantly, physicians should set a timeframe for the practice to bounce back to normal productivity levels. Note: Ellis didn't draw a paycheck for 3 months.

NO PAIN, NO GAIN

As the team improved its competency in using the system, and when Ellis began seeing a return to normalcy, the practice began implementing some of the advanced features of the system.

Data mining, denial reports, revenue metrics, patient portal establishment, email communication with patients, advanced callback features, appointment reminders, claims scrubbing, coding issues—all were features that began to offer insight into his practice and his patient panel.

Ultimately, Ellis attested for meaningful use in about 100 days after implementation. The process was made simpler by one of athenahealth system's features, he says.

Long-term, the practice has returned to normal volume, as shown in "Ellis appointment count" below. It's also important to note that his practice went live on May 18, 2012.

In terms of tracking accounts receivables, the practice had its worst showing during the first month and has since recovered.

The system's focus on revenue cycle management (see the related story beginning on page 44), Ellis says, has improved its cash flow, submission of claims, reduction in denials, and collecting from private and public payers.

MORE ON PATIENT COMMUNICATION

And, importantly, access to a secured online portal to communicate with patients via email and enabling patient access to health information including education materials is helping the practice engage patients in new ways and build efficiency. In fact, Ellis was surprised at the interest of his patients as it relates to accessing and engaging the practice in their care online. He communicates via email with patients every day and is actively using advanced features associated with the online portal that allow:

- message exchange,
- review and payment of billing statements,
- appointment requests,
- researching of health topics,
- review of personal health information,
- completion and updating of medical forms, and
- updating of a patient's profile and contact information.

When it comes to metrics, Ellis says the practice is moving forward and showing improvements in many of the core measures outlined the government's EHR incentive program for meaningful use 1 and 2.

He also looks forward to the day when physicians will have the ability to communicate with each other and share medical information in secured ways, all in an effort to create new efficiencies in the delivery of care.

"That's what this is all about—improving the health of patients and creating an efficient system that allows our practice to offer advanced care and further develop our services to remain economically viable," Ellis says.

Anatomy of the practice

Practice square feet: 3,000

Number of exam rooms: 4

Number of physicians: 1

Number of full-time equivalents: 5

Electronic health record (EHR) system provider: athenahealth

Billing/coding provider: athenahealth

Number of computer workstations:

- Front office: 2
- Back office: 5
- Exam rooms: 5
- Waiting room: 0

Connectivity: wireless, wired, WEP IIa

Hardware: HP Elite Desktops, custom-built PCs, 1 tablet, 2 wireless laptops for emergent use in case of workstation failure

Laboratory interfaces: Access to labs real-time

Telephone system: Voice-over internet protocol to integrate with the EHR system

Ellis appointment count

Year	Numbers of appointments
May 2012	172
June 2012	428
July 2012	474
August 2012	446
Sept. 2012	377
Oct. 2012	544
Nov. 2012	504
Dec. 2012	374
** Total **	**3,319**
Jan. 2013	469

Medical Economics' study enters second year; participants identify best practices

More than a year ago, *Medical Economics* connected 29 primary care physicians (PCPs) with nine electronic health record (EHR) system vendors to document best practices related to implementation.

The *Medical Economics* EHR Best Practices Study allows physicians time to gain experience and knowledge by working with an EHR system over 2 years. As the study moves into its second year, all of the participating physicians have implemented systems, and many already have attested to meaningful use.

The ultimate goal of the study is to gather real-world data and identify strategies to help solo and small office-based doctors in their quest to implement and use EHR systems. To accomplish this goal, the study has been segmented into four stages of an EHR implementation: pre-implementation, implementation, post-implementation, and EHR functionality. Study participants are asked to report on everything from vendor selection, data migration, connectivity, and assessing a practice's integration capabilities to developing a workflow and preparing for the unanticipated costs. Participants are reporting key benchmarks to help other physicians gain a realistic understanding of the process and identify creative ways to ease implementation in their practices.

Participating vendors include ABEL Medical Software, Amazing Charts, Aprima, athenahealth, CureMD, McKesson Physician Practice Group, MedNet Medical Solutions, Practice Fusion, and Vitera.

Examine your revenue cycle to keep pace with changing economic trends

New ways of paying for healthcare call for adjustments to billing, collections processes

by **GEORGE G. ELLIS JR.,** *MD*

REVENUE CYCLE MANAGEMENT (RCM) tools can drive healthcare reimbursement to higher levels. And tools to actively and accurately monitor your revenue cycle are becoming rapidly available in the form of robust electronic health record (EHR) systems that are consolidating functions to streamline the way revenue is we collect and process revenue.

Consider that RCM refers to an entire billing process. The cycle begins when a patient books an appointment, and it ends when remittance is received from the payer and the patient. It also includes multiple steps along the way, including eligibility checks (verifying insurance); capturing, entering, editing, or scrubbing a claim, collecting accurate information needed to create a medical billing claim to a third-party payer, Medicare, Medicaid, and so on.

And the revenue cycle is taking on greater significance because of a variety of financial trends affecting primary care physicians. A white paper published by Triple Tree Consulting says that the inefficiencies of redundant data collection, manual process, and repetitive rework of claims submissions are "all contributing to a diminishing bottom line." Sound familiar? And as the trend pushes payers (and many other businesses influencing our revenue cycle) to reduce healthcare costs, we physicians will need to become much more efficient in the way we manage and operate our practices.

Some of those efficiencies range from how we handle eligibility checks to the processes we have in place to scrub claims or investigate the reason for a denial. And there are just as many reasons to conduct a thorough examination of your revenue cycle.

Why? Not only are insurance deductibles increasing, so is the use of flexible spending accounts. More and more of our patients will be tied to costs associated with their healthcare. This trend has been called "consumer-driven health," and Triple Tree Consulting suggests that it will be the greatest driver to healthcare since the rise of managed care. It will have a direct effect on how we organize and collect for our services for patients and payers.

We also are seeing consolidation of services that traditionally have helped us manage this revenue cycle—from billers and coders, to billing processing companies, to payer adjudication, to a wholesale integration of all of these functions within some of these EHR systems. The trend will help us manage our practices more effectively and efficiently, and it ultimately will simplify a very complex billing process and make entering and tracking reimbursements, claim denials, collections, and financial analytics that much easier.

When we examined my practice's internal systems and ways to improve our revenue cycle, our cash flow improved.

My suggestions? Start by examining the capabilities of your EHR system. For the past year, I have been working with athenahealth's practice management system and noted a decrease in claims denials secondary to coding errors, lack of modifiers, or incorrect insurance. In fact, in being part of the 2-year *Medical Economics* EHR Best Practices Study, which is working with multiple EHR vendors, I

have been exposed to many systems in the market that can help you advance in a variety of ways to improve and streamline your practice's revenue cycle.

Next, look at your revenue cycle processes as they relate to the pre-encounter, patient-doctor encounter, and back-office operation. We sought to improve our efficiency in the pre-encounter phase. In fact, we wanted to streamline the processes of our front-office staff as patients enter the practice.

Typically, at this point, the patient's demographics are obtained, and his or her insurance information is acquired and verified before the encounter. The patient's eligibility is verified prior to the office visit at 2 weeks, again at 24 hours, and on the day of service. Not only does insurance verification at the time of the visit help us manage and collect copays before the encounter, it also can substantially reduce denials on the back end.

Because of changing reimbursement models, more and more patients will have out-of-pocket deductibles. Therefore, collecting co-pays and deductibles at the time of the encounter is going to take on even greater significance to a practice's financial health.

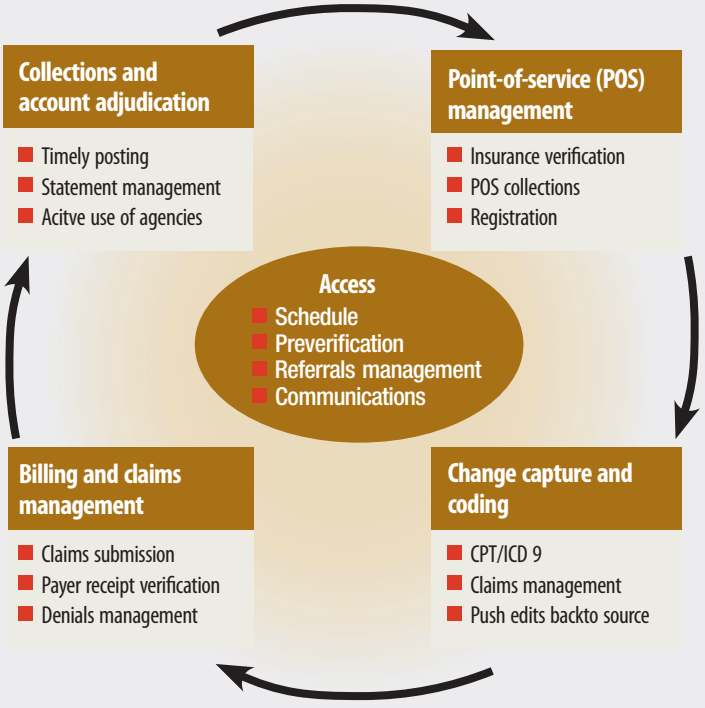
Once these steps have been completed, the patient is ready to see the physician, where a note is completed. The amount of information obtained during the exam, the complexity of the exam, the amount of documentation, and the complexity of decision making will all determine the evaluation and management (E/M) level of care and International Classification of Diseases, Ninth Revision, (ICD9) codes used during the encounter. The ICD codes and E/M level of care will provide the necessary information for charge entry, another critically important step.

As physicians, we not only drive patient care, we also generate most of the revenue for the practice. We clearly are the most valuable asset of the practice. Realizing this role, I have taken on the responsibility of charge capture and submitting claims for submission to payers as well. Why? RCM has enabled me to enter charges at the end of the day, and my doing so results in fewer lost charges (or omission of charges). Reviewing ancillary services performed during visits enables me to capture charges omitted by nursing or medical assistants.

With declining reimbursements, it is critical to capture all charges and submit them in a timely fashion with proper coding. If you have a bad claim, tools such as Code Checker guide you to use correct modifiers or choose a more specific diagnosis.

Ultimately, better managing your revenue cycle will improve your financial performance. And as the healthcare market shifts to reducing costs overall, we need to look at every management strategy available to help us remain economically viable so we can continue to offer high quality care to the asset we care about most: our patients.

Understanding the revenue cycle



Future RCM considerations:

- High-balance patient deductibles
- Pay-for-performance
- Budget-based payment models

Source: Rose B. Shattuck, from the MGMA seminar "Maximizing a Health Revenue Cycle: Making the Most of Your Revenue Cycle Performance Using Proven Tools and Best Practices." Feb. 8-9, 2007, Boston. Reprinted with permission from the MGMA-ACMPE, 104 Inverness Terrace East, Englewood, CO 80112. www.mgma.com.

The author practices internal medicine in Boardman, Ohio, and is a member of the Medical Economics *Editorial Board.*

@ Visit our EHR Best Practices Study page at www.MedicalEconomics.com/EHRBestPractices.

Send your questions for participants to medec@advanstar.com.

Tech Talk

USING SINGLE HIT VENDOR HAS BENEFITS, DRAWBACKS

by **LYLE MELICK**

Newer federal laws and regulations related to using electronic health record systems and safeguarding patient information under changes to the Health Insurance Portability and Accountability Act may have your medical practice taking a closer look at its technology-related needs.

Physicians and their practice managers are starting to see that complying with these laws and mandates will require a greater use of information technology and are exploring the pluses and minuses of using a single vendor versus multiple vendors for their HIT needs.

PROS

The advantages of using one vendor:

- **One point of contact.** To start with, you have only one point of contact for all your HIT needs. You don't have to partially troubleshoot a problem to decide which vendor to call or mediate between vendors if the practice management software vendor says the Internet service provider is causing the problem.
- **More resources.** Core HIT vendors usually have a larger staff to pull into large projects as well as access to all the equipment and software required to fully troubleshoot and solve any problems you may experience.

CONS

On the other hand, the disadvantages of using a single vendor:

- **Expense.** Larger vendors will have more overhead than smaller, niche vendors and can be more expensive. So although the vendor may only assign one technician and the help desk to your account full-time, the costs of all its other technicians, sales staff, and office staff will factor into the pricing of its services.
- **Potential delays.** Core vendors may try to solve all your problems in-house, delaying escalation to equipment and software vendors. Although they are less likely to encounter a problem requiring vendor intervention than is a smaller, niche vendor, delays in seeking additional support could affect your practice.

WHAT TO LOOK FOR

Base your decision on a provider on three factors:

- **Experience.** An experienced HIT vendor will have standard policies for dealing with equipment failures and Internet outages. It should be able to monitor your equipment and software around the clock for signs of impending problems and undertake proactive maintenance to help prevent failures. It should have the capability to monitor and routinely test your data backups to ensure that your data are protected, possibly including some form of off-site archival.
- **Connections.** Check client references for your potential new HIT vendor. Ask about the problem that has taken the longest to resolve and about any surprises they may have encountered after signing with the vendor. Ask how long they have been a client and what vendor staff turnover has been like. Good HIT service companies pride themselves on attracting and keeping good talent.
- **Leadership.** Ask your potential HIT vendor about the company's approach to customer service. Look for a company that acts more like a partner and finds creative ways to meet your technology needs.

Hiring a single HIT vendor to address your hardware, software, and networking needs can seem expensive, but doing so may be more economical for your practice in the long run. Having one number to call to solve a technology problem can get you back in action quicker because you avoid vendor squabbles.

Look for a vendor that can meet your needs, matches your service philosophy, and wants to support your business so that you can spend more time caring for your patients. ■

The author is information technology manager for SS&G Healthcare Services in Akron, Ohio. Send your healthcare technology-related questions to ***medec@advanstar.com****.*

Doctor's Bag

NEW TELEMEDICINE KIT ENABLES VIDEO CONFERENCING

VoIP Supply's Telemedicine Kit—built from LifeSize Video Conferencing, a division of Logitech—provides physicians with remote patient monitoring and distance medical services to conduct quick visual check-ups for reviewing medical history, performing basic physical exams, or manage chronic diseases such as diabetes or asthma in patients.

The Health Insurance Portability and Accountability Act-compliant kits are designed to help a practice start video conferencing. Patients need a home computer and Web camera to participate and also should sign a consent form to be treated via telemedicine.

Telemedicine carts may increase productivity for doctors, providing opportunities for more billable hours and the provision of more direct services. Another potential benefit is that patients may not have to wait an extended period of time to see a physician.

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Ambio automatically logs readings, which can be viewed in a secure, Web-based portal and can be printed or emailed as needed. Users can be notified when their test strip supplies are low and need to be reordered.

A single device costs $49.97 and includes a glucose meter with wireless connectivity as well as an annual subscription costing about $4.99 per month. Wireless blood pressure meters and weight scales are sold separately.

The system has been named one of eWeek's "10 health and fitness tools to track exercise, chronic conditions."

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Both workstations allow caregivers to work seated or standing.

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Doctors: Patients should be able to update but not view full records

Patients should be able to update their electronic health records but should not be able to have full access to them, according to physician participants in a survey by Accenture.

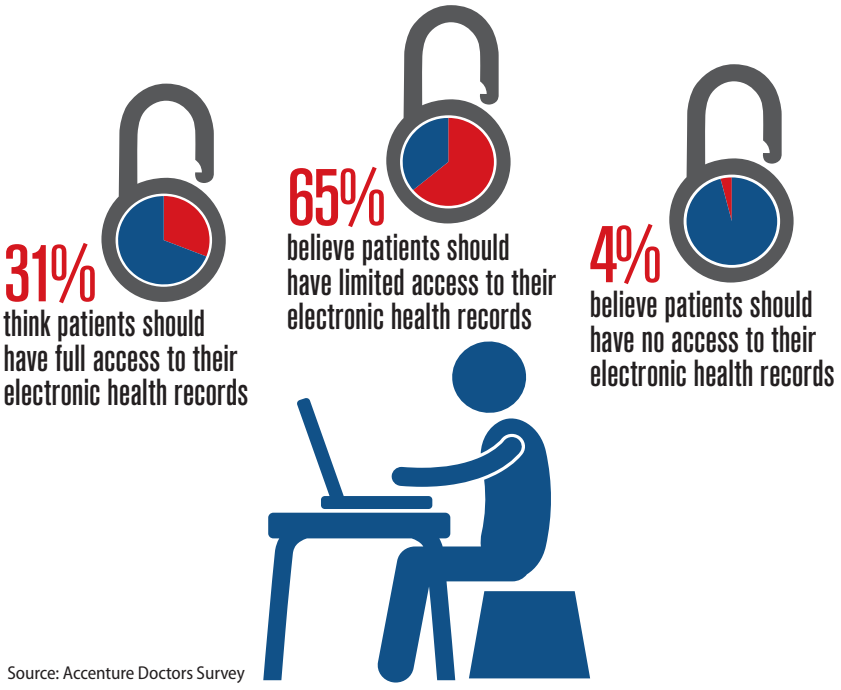
Eighty-two percent of U.S. respondents said they want patients to actively take part in their own healthcare by updating their records. Only a third of physicians (31%), however, believe that patients should have full access to their records; 65% believe that patients should have limited access, and 4% say they should have no access.

Most U.S. doctors said that patients should be able to update some or all standard information in their records, including demographics (95%), family medical history (88%), medications (87%), and allergies (85%). Also, most doctors (81%) believe patients should be able to add clinical updates such as new symptoms or self-measured metrics.

Nearly half (49%) of respondents said patient access to records is crucial to providing effective care, but only 21% currently allow patients to have online access to their medical summaries or patient charts.

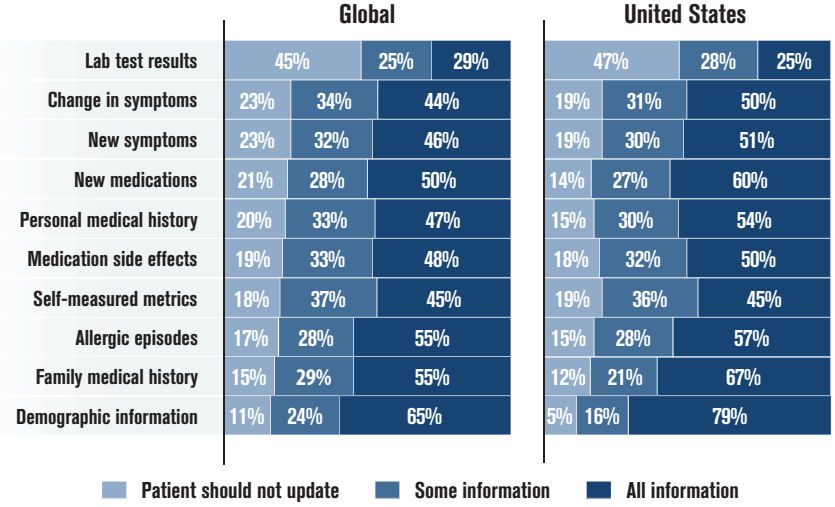
More than half (53%) believe that electronic records have improved care quality, and most (84%) say they are somewhat or strongly committed to promoting electronic records in their clinical practice. Most (77%) also believe the right investments in adopting electronic records are being made, and 83% believe they will become integral to effective patient care in the next 2 years.

U.S. physician views on patient access to medical records



Source: Accenture Doctors Survey

Information patients should be able to update in an EHR



Source: Accenture Doctors Survey

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