GOVERNMENT CONTROL

Medicare payment reform threatens independent practice

PLUS

Boost benefits
Reward staff, save money
The only FDA-approved, multi-dose rescue inhaler that requires

¬ **No hand-breath coordination during inhalation!**¹,²

**Indications** ProAir RespiClick® (albuterol sulfate) Inhalation Powder is indicated in patients 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.

**Important Safety Information**

- ProAir RespiClick® (albuterol sulfate) Inhalation Powder is contraindicated in patients with hypersensitivity to albuterol or patients with a severe hypersensitivity to milk proteins. Rare cases of hypersensitivity reactions, including urticaria, angioedema, and rash have been reported after the use of albuterol sulfate. There have been reports of anaphylactic reactions in patients using inhalation therapies containing lactose.

- ProAir RespiClick® can produce paradoxical bronchospasm that may be life-threatening. Discontinue ProAir RespiClick® and institute alternative therapy if paradoxical bronchospasm occurs.

- Need for more doses of ProAir RespiClick® than usual may be a marker of acute or chronic deterioration of asthma and requires reevaluation of treatment.

- ProAir RespiClick® alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids.

- ProAir RespiClick®, like other beta-adrenergic agonists, can produce clinically significant cardiovascular effects in some patients, as measured by heart rate, blood pressure, and/or symptoms. If such effects occur, the drug may need to be discontinued.

- ProAir RespiClick®, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders (especially coronary insufficiency, cardiac arrhythmias, and hypertension), convulsive disorders, hyperthyroidism, and diabetes.

- Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs in patients with asthma. Do not exceed the recommended dose.

**References:**

1. ProAir RespiClick Prescribing Information. Horsham, PA: Teva Respiratory, LLC, April 2016.
Prescribe ProAir RespiClick® (albuterol sulfate) Inhalation Powder for your new and existing patients ages 4 and up

- No spacers required!
  ProAir RespiClick® was designed to be used without a spacer¹

- No washing, priming, or shaking needed!²

ProAir RespiClick®
(albuterol sulfate) Inhalation Powder

Important Safety Information (continued)
- Immediate hypersensitivity reactions may occur. Discontinue ProAir RespiClick® immediately
- ProAir RespiClick® may produce significant hypokalemia in some patients, which has the potential to produce adverse cardiovascular effects. The decrease is usually transient, not requiring supplementation
- Potential drug interactions can occur with beta blockers, diuretics, digoxin, or monoamine oxidase inhibitors, and tricyclic antidepressants
- In controlled studies of ProAir RespiClick® in patients 12 years of age and older, adverse events that occurred at an incidence rate of at least 1% and greater than placebo included back pain (2% vs 1%), pain (2% vs <1%), gastroenteritis viral (1% vs <1%), sinus headache (1% vs <1%), and urinary tract infection (1% vs <1%)
- In controlled studies of ProAir RespiClick® in patients 4 to 11 years of age, adverse events that occurred at an incidence rate of at least 2% and greater than placebo included nasopharyngitis (2% vs 1%), oropharyngeal pain (2% vs 1%), and vomiting (3% vs 1%)

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

For more information visit ProAir.com
6.1 Clinical Trials Experience
A total of 1289 subjects were treated with PROAIR RESPICLICK during the clinical development program. The most common adverse reactions (≥1% and > placebo) were back pain, pain, gastroenteritis viral, sinus headache, and urinary tract infection. 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. Adults and Adolescents 12 years of Age and Older: The adverse reaction information presented in Table 1 below concerning PROAIR RESPICLICK is derived from the 12-week blinded treatment period of three studies which compared PROAIR RESPICLICK 180 mcg four times daily with a double-blind matched placebo in 653 asthmatic patients 12 to 76 years of age.

Table 1: Adverse Reactions Experienced by Greater Than or Equal to 1.0% of Adult and Adolescent Patients in the PROAIR RESPICLICK Group and Greater Than Placebo in three 12-Week Clinical Trials

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>PROAIR RESPICLICK 180 mcg QID</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back pain</td>
<td>6 (2%)</td>
<td>4 (1%)</td>
</tr>
<tr>
<td>Pain</td>
<td>5 (2%)</td>
<td>2 (&lt;1%)</td>
</tr>
<tr>
<td>Gastroenteritis viral</td>
<td>4 (1%)</td>
<td>3 (&lt;1%)</td>
</tr>
<tr>
<td>Sinus headache</td>
<td>4 (1%)</td>
<td>3 (&lt;1%)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>4 (1%)</td>
<td>3 (&lt;1%)</td>
</tr>
</tbody>
</table>

1. This table includes all adverse events (whether considered by the investigator drug related or unrelated to drug) which occurred at an incidence rate of greater than or equal to 1.0% in the PROAIR RESPICLICK group and greater than placebo.

In a long-term study of 168 patients treated with PROAIR RESPICLICK for up to 52 weeks (including a 12-week double-blind period), the most commonly reported adverse events greater than or equal to 5% were upper respiratory infection, nasopharyngitis, sinusitis, bronchitis, cough, oropharyngeal pain, headache, and pyrexia. In a small cumulative dose study, tremor, palpitations, and headache were the most frequently occurring (>5%) adverse events.

Pediatric Patients 4 to 11 Years of Age: The adverse reaction information presented in Table 2 below concerning PROAIR RESPICLICK is derived from a 3-week pediatric clinical trial which compared PROAIR RESPICLICK 180 mcg albuterol 4 times daily with a double-blind matched placebo in 185 asthmatic patients 4 to 11 years of age.

Table 2: Adverse Reactions Experienced by Greater Than or Equal to 2.0% of Patients 4 to 11 Years of Age in the PROAIR RESPICLICK Group and Greater Than Placebo in the 3 Week Trial

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>PROAIR RESPICLICK 180 mcg QID</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>2 (2%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Oropharyngeal pain</td>
<td>2 (2%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3 (3%)</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

6.2 Postmarketing Experience
In addition to the adverse reactions reported from clinical trials with PROAIR RESPICLICK, the following adverse events have been reported during use of other inhaled albuterol sulfate products: urticaria, angioedema, rash, bronchospasm, hoarseness, oropharyngeal edema, and arthralgias (including atriol fibrillation, supraventricular tachycardia, extrasystoles), rare cases of aggravated broncho-
spasms, lack of efficacy, asthma exacerbation (potentially fatal), muscle cramps, and various oropharyngeal side effects such as throat irritation, altered taste, glossitis, tongue ulceration, and gagging. 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. In addition, albuterol, like other sympathomimetic agents, can cause adverse reactions such as angina, hypertension, palpitations, central nervous system stimulation, insomnia, headache, nervousness, tremor, muscle cramps, drying or irritation of the oropharynx, hypokalemia, hyperglycemia, and metabolic acidosis.

7 DRUG INTERACTIONS
Other short-acting sympathomimetic bronchodilators should not be used concomitantly with PROAIR RESPICLICK. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects.
7.1 Beta-Blockers

Beta-adrenergic-receptor blocking agents not only block the pulmonary effect of beta-agonists, such as PROAIR RESPICLICK, but may produce severe bronchoconstriction. Therefore, patients with asthma should not normally be treated with beta-blockers. However, under certain circumstances, eg, as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-adrenergic-blocking agents in patients with asthma. In this setting, consider carefully the risk/benefit ratio for beta-blockers, although they should be administered with caution.

7.2 Diuretics

The ECG changes and/or hypokalemia which may result from the administration of non-potassium sparring diuretics (such as loop or thiazide diuretics) can be accentuated in beta-agonist users, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of beta-agonists with non-potassium sparring diuretics. Consider monitoring potassium levels.

7.3 Digoxin

Mean decreases of 16% and 22% in serum digoxin levels were demonstrated after single dose intravenous and oral administration of albuterol, respectively, to normal volunteers who had received digoxin for 10 days. The clinical significance of this finding is not known for patients with obstructive airway disease who are receiving albuterol and digoxin on a chronic basis is unclear. Nevertheless, it would be prudent to carefully evaluate the serum digoxin levels in patients who are currently receiving digoxin and PROAIR RESPICLICK.

7.4 Monoamine Oxidase Inhibitors or Tricyclic Antidepressants

PROAIR RESPICLICK should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of albuterol on the cardiovascular system may be potentiated. Consider alternative therapy in patients taking MAO inhibitors or tricyclic antidepressants.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.1.1 Risk Summary

There are no randomized clinical studies of use of albuterol during pregnancy. Available data from published epidemiological studies and postmarketing case reports of pregnancy outcomes following inhaled albuterol use do not consistently demonstrate a risk of major birth defects or miscarriage. There are clinical considerations with use of albuterol in pregnant women [see Clinical Considerations]. In animal reproduction studies, when albuterol sulfate was administered subcutaneously to pregnant mice there was evidence of cleft palate at less than and up to 9 times the maximum recommended human daily inhalation dose (MRHDID) [see Data].

The estimated background risk of major birth defects and miscarriage for the indicated population(s) are unknown. In the U.S. general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Disease Associated with Cerebral and/or Embryo/Fetal Risk

In women with poorly or moderately controlled asthma, there is an increased risk of preeclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. Pregnant women should be closely monitored and medication adjusted as necessary to maintain optimal control.

Labor and Delivery

Because of the potential for beta-agonist interference with uterine contractility, use of PROAIR RESPICLICK for relief of bronchospasm during labor should be restricted to those patients in whom the benefits clearly outweigh the risk. PROAIR RESPICLICK has not been approved for the management of pre-term labor. Serious adverse reactions, including pulmonary edema, have been reported during or following treatment of premature labor with beta-agonists, including albuterol.

Data

Animal Data

In a mouse reproduction study, subcutaneously administered albuterol sulfate produced cleft palate formation in 5 of 111 (4.5%) fetuses at an exposure nine-tenths the maximum recommended human dose (MRHDID) for adults (on a mg/m² basis at a maternal dose of 0.25 mg/kg) and in 10 of 108 (9.3%) fetuses at approximately 9 times the MRHDID (on a mg/m² basis at a maternal dose of 2.5 mg/kg). Similar effects were not observed at approximately one-eleventh the MRHDID for adults (on a mg/m² basis at a maternal dose of 0.025 mg/kg); Cleft palate also occurred in 22 of 72 (30.5%) fetuses from females treated subcutaneously with saline at a maternal serum albuterol concentration (passive maternal transfer) of 1.55 ng/mL. In a rabbit reproduction study, orally administered albuterol sulfate induced cranioschisis in 7 of 19 fetuses (37%) at approximately 750 times the MRHDID (on a mg/m² basis at a maternal dose of 50 mg/kg). In a rat reproduction study, an albuterol sulfate/HFA-134A formulation administered by inhalation did not produce any teratogenic effects at exposures approximately 80 times the MRHDID (on a mg/m² basis at a maternal dose of 10.5 mg/kg).

A rat study in which pregnant rats were dosed with radionabeled albuterol sulfate demonstrated that drug-related material is transferred from the maternal circulation to the fetus.

8.2 Lactation

Risk Summary

There are no available data on the presence of albuterol in human milk, the effects on the breast-fed child, or the effects on milk production. However, plasma levels of albuterol after inhaled therapeutic doses are low in humans, and if present in breast milk, albuterol has a low oral bioavailability [see Clinical Pharmacology (12.3)].

The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for albuterol and any potential adverse effects on the breastfed child from albuterol or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of PROAIR RESPICLICK for the treatment or prevention of bronchospasm in children 12 to 17 years of age and older with reversible obstructive airway disease is based on two 12-week clinical trials in 318 patients 12 years of age and older with asthma comparing doses of 180 mcg four times daily with placebo, one long-term safety study in children 12 years of age and older, and one single-dose crossover study comparing doses of 90 and 180 mcg with albuterol sulfate inhalation aerosol (ProAir® HFA) in 71 patients [see Clinical Studies (14.1)]. The safety and effectiveness of PROAIR RESPICLICK for treatment of exercise-induced bronchospasm in children 12 years of age and older is based on single-dose crossover study in 38 patients age 16 and older with exercise-induced bronchospasm comparing doses of 180 mcg with placebo [see Clinical Studies (14.2)]. The safety profile for patients ages 12 to 17 was consistent with the overall safety profile seen in these studies. The safety and effectiveness of PROAIR RESPICLICK in children 4 to 11 years of age is based on two single-dose, controlled, crossover studies: one with 61 patients comparing doses of 90 and 180 mcg with matched placebo and albuterol HFA MDI and one with 15 patients comparing a dose of 180 mcg with matched albuterol HFA MDI. In one 3-week clinical trial in 185 asthmatic children 4 to 11 years of age comparing a dose of 180 mcg albuterol 4 times daily with placebo [see Clinical Studies (14.1)]. The safety and effectiveness of PROAIR RESPICLICK in pediatric patients below the age of 4 years have not been established.

8.5 Geriatric Use

Clinical studies of PROAIR RESPICLICK did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy [see Warnings and Precautions (5.4, 5.7)].

Beta-agonist agonists, including albuterol, are known to be substantially excreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

10 OVERDOSAGE

The expected symptoms with overdosage are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the symptoms listed under ADVERSE REACTIONS, eg, seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats per minute, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, and insomnia.

Hypokalemia may also occur. As with all sympathomimetic medications, cardiac arrest and even death may be associated with abuse of PROAIR RESPICLICK. Hypokalemia may also occur. As with all sympathomimetic medications, cardiac arrest and even death may be associated with abuse of PROAIR RESPICLICK. Treatment consists of discontinuation of PROAIR RESPICLICK together with appropriate symptomatic therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of PROAIR RESPICLICK.
The federal government must rethink its strategy of working to put small medical practices out of business. First, it required small offices to invest in electronic health records (EHRs) and participate in the gauntlet that is Meaningful Use or face penalties. Most physicians complied and, to this day, continue to struggle in the digital era of patient care. Others said, “Go ahead and dock my pay.”

Next, the Affordable Care Act promised greater care for more Americans, but gave little support to already overburdened doctors. Our readers recently gave Obamacare a resounding “F” grade. They continue to stick it out—caught in the middle between patients and payers on a daily basis—and remain dedicated to improving the well-being of those in their care.

And now, on the horizon looms the Quality Payment Program and all of its alphabet soup: MACRA, MIPS and APMs. No matter what you call it, at least this time, the Centers for Medicare & Medicaid Services (CMS) actually recognized that small practices were going to be in trouble, estimating losses in the range of $600 million for practices with one to nine physicians. They later backtracked, citing old data and yet-to-be-solidified accommodations planned for these practices.

CMS did announce $100 million over 5 years in “technical assistance” to help practices with 15 or fewer clinicians succeed under its Quality Payment Program. The problem is that $20 million a year for the hundreds of thousands of docs with Medicare patients who qualify for a daily basis—perhaps that’s enough to buy “Medicare Payment Reform for Dummies” and ear plugs to block out the screams of peers and staff.

Now there’s been strong indicators that the wise folks at CMS will make further concessions to physicians and perhaps even delay metric reporting from the currently proposed target date of Jan. 1, 2017—less than four months away.

There are things CMS can do to level the field for smaller practices. Former federal regulator Farzad Mostashari, MD, outlined them in our last issue: compare small practices to their peers in terms of size, promote payment models limiting loss, and get out of the business of using single-year data for larger timeframes. Seems simple, right?

But the question remains: Will CMS come to its senses and realize that driving small practices into joining the local hospital or health system is failing and that small practices are stronger than they thought? Or will they realize that picking on the smaller kid on the playground repeatedly doesn’t make the little guy weaker, it strengthens him and fuels the fight within even more?

My money’s on the little guy.
“You have to look at benefits as part of total compensation.”
TED WILLIAMS, JD, THE WILLIAMS GROUP, DES MOINES, IOWA
PAGE 40

“You really need a team. ... You only have so much energy and so much time in the day.”
LAUREN OSHMAN, MD, CHICAGO, ILLINOIS
PAGE 46

87% of solo practices are expected to face Medicare reimbursement penalties under MACRA in 2019.
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Government control

Medicare payment reform threatens independence

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The ICD-10 grace period ends in October, so doctors must prepare

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Some physicians believe advocating for patients is part of the job

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FUNNY BONES

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Advil® delivers fast relief

You always deliver the best-quality care. So when your patients are suffering from acute pain, recommend the clinically proven, superior choice for efficacy versus acetaminophen.¹,²*

Advil® Liqui-Gels® work faster than Tylenol® for tension headaches

In a double-blind, randomized, parallel-group study evaluating the onset, relief, and safety in the treatments of tension-type headaches, Advil liquid-filled capsules (ibuprofen 400 mg) were significantly faster than acetaminophen 1000 mg and placebo for all time-to-relief measures. Advil also demonstrated significantly superior overall analgesic efficacy and provided a clinically relevant advantage of speed.¹

Subjects (%)

<table>
<thead>
<tr>
<th></th>
<th>PBO=placebo, IBU=ibuprofen, APAP=acetaminophen.</th>
<th>P=0.007 for IBU vs PBO.</th>
<th>P=0.465 for APAP vs PBO, meaningful relief.</th>
<th>P=0.039 for APAP vs PBO, complete relief.</th>
<th>P=0.001 for IBU vs APAP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete relief at 3 hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBU</td>
<td>75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>APAP</td>
<td>32</td>
<td></td>
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</tr>
<tr>
<td>PBO</td>
<td>0</td>
<td></td>
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</tbody>
</table>

Percentage of subjects obtaining meaningful relief by 30 minutes and complete relief by 3 hours.

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At OTC doses, Advil has a proven favorable overall safety profile, including gastrointestinal, cardiovascular, and acute overdose safety.³-⁶


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*Among OTC brands.

Use as directed.
Are EHRs truly helping patients?

I have my third EHR for nearly two years now. Athena has been better than the previous two but recently they upgraded their system and now it takes a lot longer to enter and/or access data. And I am not aware that this upgrade is going to improve the health outcomes of patients. We need to encourage the government to investigate whether or not EHRs have improved health and/or outcomes of patients and their health.

David H. Spingarn, DO
SARATOGA SPRINGS, NY

ABIM makes doctors feel like ‘cash cows’

The problem is that as physicians we are starting to feel like cash cows for the various boards. ABIM had a surplus ... feels as if we shouldn’t be charged the arm and leg that we are for taking our exams. It takes time away from family, from the practice and we incur large costs between lost office hours and the fees for taking the test, and for many the cost of travel to go take the exam. Not to mention all of the board review materials. It ends up costing thousands and the stress in immense. Stress over passing (failing means loss of livelihood), stress finding time to study, stress paying for all of it. This is why so many of us are unhappy.

Amy Straiko-Howerton, MD
ROSEBORO, NC

Concern over hospitalists solved

In her essay “Transitional care: The unintended consequences of hospitalists’ rise (July 10, 2016),” Mary Bauman, MD expressed concern over the growing role of hospitalists in what she refers to as “transitional care.”

For many patients, seeing new doctors who don’t know them can be intimidating of course.

Here is how I deal with the problem:

I try to make at least one phone call to my patients when admitted to explain what is happening. And if they are admitted through the emergency room I speak to the physician there.

For those patients who are sicker I try to make a “social call” to the hospital.

I am not always successful in doing these things, but it helps to bridge the “transitional care” gap.

Also at my hospital, from time to time, we discuss ways to improve communication between physicians and hospitalists.

All things considered, primary care physicians depend heavily on the help of hospitalists. It would be impossible for them to carry on an office practice and see patients in the hospital.

Edward Volpintesta, MD
BETHEL, CT
he question was raised whether legislative action should be required to aide in resolving the opioids crises. Are you kidding me? Some seem to think that legislative action is the answer to just about everything these days and now want legislators to draft laws telling us how to manage patients with pain when they don’t know how to care for their febrile three-year-old at three in the morning so they bring them to the emergency room.

I have been on the front lines of pain control as an emergency physician at a level one trauma center for 30 years and unequivocally feel this “opioids crises” phenomenon placed squarely on the backs of primary care physicians, has caused an overreaction by the medical community lead by the CDC.

This as a result of outside pressures largely by the media with high profile cases, pressures from the government and the medical community under pressure to do something—anything to curb the rise in opioids overdoses and rise in heroin use.

The CDC stepped in and imposed unrealistic guidelines in the use of opioids. We went from a compassionate aggressive approach—you know the pain scores being requested every few minutes and as soon as the patient stepped into the ED with liberal use of opioids with an emphasis on comfort care—to treatment strategies for those acute pain patients requiring opioids prescriptions (unless of course you had renal colic which would bump you up to a week’s worth of meds) and God forbid you have chronic pain without a diagnosis of cancer.

What on God’s green Earth did the CDC base this on? How did they come up with these numbers? Did someone sitting at the CDC roundtable have the misfortune of passing a stone prompting a little more leniency with those patients. And who came up with the idea that unless you have cancer your chronic pain isn’t worthy of adequate pain management?

There are those, including myself, that believe the CDC actions may likely lead to major unintended consequences such as not only under treatment in pain management, but an escalation of the heroin epidemic, making the crises much worse.

When will we learn that establishing medical guidelines based on poor evidence will more than likely result in poor outcomes. Certainly some lives may be saved of those who misuse or abuse opioids, but at what price to those in our society which struggle with quality of life issues due to pain?

Recently, a department head at a prestigious medical facility in a talk on the opioids crises told the listening audience, “If you have a patient with chronic pain issues that doesn’t have cancer and your considering opioids, DON’T! Period. End of story.” I find this extremely disturbing as a medical provider. Yet this seems to be the culture being cultivated by those in the CDC camp.

For the CDC to come up with such indiscretionary guidelines for opioids use based on little if any good evidence—even so far as plugging in numbers, I think is quite unwise and would expect more from this trusted agency. They went from adjusting the shower temperature knob from being a bit too hot, to ice cold, with hundreds of thousands of patients in the shower.

Maybe if such a thing was orchestrated 20 years ago. a good faith pass would be in order, but in this day and age of evidence-based medicine I find it appalling.

Rodney M. Staats MD
WICHITA, KANSAS

Disappointed in JAMA, physicians deserve more credit

In reference to the article, “Irresponsible to say physicians can be bought to put patient care second (June 25, 2016),” I am very disappointed by JAMA’s article. It is an insult to the integrity of physicians that we are influenced by pharmaceutical companies providing research and development of new medications that change patients’ lives. I rely on companies to give me information about new medications so I can learn what is available and then make an educated decision on what I prescribe.

Physicians go to school for many years to understand pharmacology of medications and make ethical decisions for our patients. It is truly disheartening that we are not given more credit for our ability to make impartial decisions.

Deborah Winiger, MD
VERNON HILLS, ILLINOIS
Fighting back: Take charge and embrace independence

Healthcare’s transition to value-based payments is ratcheting up the pressure on independent medical practices battling for survival, and data is the ammunition they need to have any chance of winning.


HIPAA resource center
The latest on how to keep your practice compliant with federal privacy and security rules
MedicalEconomics.com/tag/hipaa-resource-center

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http://buff.ly/1QJWgun

Health IT
Silicon Valley’s vision to transform healthcare #google #technology
http://buff.ly/1nuKs6J

MOC
MOC, recertifications are ‘cancers’ doctors should rally against via @hlgreenberg
http://buff.ly/1QAmCkE
A PCSK9 INHIBITOR FOR INTENSIVE, PREDICTABLE LDL-C REDUCTION in adults with clinical ASCVD or HeFH on maximally tolerated statin therapy as an adjunct to diet

Indication
- Repatha® is a PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor antibody indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL cholesterol (LDL-C).
- Limitations of Use: The effect of Repatha® on cardiovascular morbidity and mortality has not been determined.

Important Safety Information
- Contraindication: Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha®.
- Allergic reactions: Hypersensitivity reactions (e.g., rash, urticaria) have been reported in patients treated with Repatha®, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.
- Adverse reactions: The most common adverse reactions (> 5% of Repatha®-treated patients and more common than placebo) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.
  In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2% of Repatha®-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to Repatha® treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for Repatha® and placebo, respectively).
- Adverse reactions from a pool of the 52-week trial and seven 12-week trials:
  Local injection site reactions occurred in 3.2% and 3.0% of Repatha®-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha®-treated patients and placebo-treated patients were 0.1% and 0%, respectively. Allergic reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for Repatha® and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).
  Neurocognitive events were reported in less than or equal to 0.2% in Repatha®-treated and placebo-treated patients.
  In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1,988 patients treated with Repatha® had at least one LDL-C value < 25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and Repatha® dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by Repatha® are unknown.
  Musculoskeletal adverse reactions were reported in 14.3% of Repatha®-treated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for Repatha® and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).
- Immunogenicity: Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with Repatha®.

Please see Brief Summary of full Prescribing Information on adjacent page.

REPATHA® (evolocumab)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information

1. INDICATIONS AND USAGE

1.1 Primary Hyperlipidemia

REPATHA is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH), in clinical practice.

REPATHA is not indicated for use in patients without familial hypercholesterolemia (HoFH) who require additional lowering of low density lipoprotein cholesterol (LDL-C).

1.2 Homozygous Familial Hypercholesterolemia

REPATHA is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

1.3 Limitations of Use

The effect of REPATHA on cardiovascular morbidity and mortality has not been determined.

4. CONTRAINDICATIONS

REPATHA is contraindicated in patients with a history of a serious hypersensitivity reaction to REPATHA [see Warnings and Precautions (5.1)].

5. WARNINGS AND PRECAUTIONS

5.1 Allergic Reactions

Hypersensitivity reactions (e.g., rash, urticaria) have been reported in patients treated with REPATHA, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with REPATHA, treat according to the standard of care, and monitor until signs and symptoms resolve.

6. ADVERSE REACTIONS

The following adverse reactions are also discussed in other sections of the label:

- Allergic Reactions [see Warnings and Precautions (5.1)]

6.1 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 clinical practice.

Table 1. Adverse Reactions Occurring in Greater than or Equal to 3% of REPATHA-treated Patients and More Frequently than with Placebo in Study 2

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=302) %</th>
<th>REPATHA (N=599) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>9.6</td>
<td>10.5</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>6.3</td>
<td>9.3</td>
</tr>
<tr>
<td>Influenza</td>
<td>6.3</td>
<td>7.5</td>
</tr>
<tr>
<td>Back pain</td>
<td>5.6</td>
<td>6.2</td>
</tr>
<tr>
<td>Injection site reactions†</td>
<td>5.0</td>
<td>5.7</td>
</tr>
<tr>
<td>Cough</td>
<td>3.6</td>
<td>4.5</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>3.6</td>
<td>4.5</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>3.0</td>
<td>4.2</td>
</tr>
<tr>
<td>Headache</td>
<td>3.6</td>
<td>4.0</td>
</tr>
<tr>
<td>Myalgia</td>
<td>3.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2.6</td>
<td>3.7</td>
</tr>
<tr>
<td>Musculoskeletal pain</td>
<td>3.0</td>
<td>3.3</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2.3</td>
<td>2.2</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2.6</td>
<td>3.0</td>
</tr>
<tr>
<td>Gastroenteritis</td>
<td>2.0</td>
<td>3.0</td>
</tr>
</tbody>
</table>

†includes erythema, pain, bruising

Adverse Reactions in Seven Pooled 12-Week Controlled Trials

In seven pooled 12-week, double-blind, randomized, placebo-controlled trials, 993 patients received 140 mg of REPATHA subcutaneously every 2 weeks and 1059 patients received 420 mg of REPATHA subcutaneously monthly. The mean age was 57 years (range: 18 to 80 years), 29% were older than 65 years, 49% women, 85% White, 5% Black, 9% Asian, and 5% Hispanic. Adverse reactions reported in at least 1% of REPATHA-treated patients, and more frequently than in placebo-treated patients, are shown in Table 1.

Table 2. Adverse Reactions Occurring in Greater than 1% of REPATHA-treated Patients and More Frequently than with Placebo in Pooled 12-Week Studies

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=1224) %</th>
<th>REPATHA† (N=2052) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>3.9</td>
<td>4.0</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.2</td>
<td>2.3</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>2.0</td>
<td>2.1</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>1.6</td>
<td>1.8</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.2</td>
<td>1.8</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1.0</td>
<td>1.6</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>1.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>1.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Cough</td>
<td>0.7</td>
<td>1.2</td>
</tr>
<tr>
<td>Influenza</td>
<td>1.1</td>
<td>1.2</td>
</tr>
<tr>
<td>Contusion†</td>
<td>0.5</td>
<td>1.0</td>
</tr>
</tbody>
</table>

†140 mg every 2 weeks and 420 mg once monthly combined

Adverse Reactions in Eight Pooled Controlled Trials (Seven 12-Week Trials and One 52-Week Trial)

The adverse reactions described below are from a pool of the 52-week trial (Study 2) and seven 12-week trials. The mean and median exposure durations of REPATHA in this pool of eight trials were 20 weeks and 12 weeks, respectively.

Local Injection Site Reactions

Injection site reactions occurred in 3.2% and 3.0% of REPATHA-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in REPATHA-treated patients and placebo-treated patients were 0.1% and 0%, respectively.

Allergic Reactions

Allergic reactions occurred in 5.1% and 4.7% of REPATHA-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for REPATHA and placebo, respectively), eczema (0.4% versus 0.2%), urticaria (0.4% versus 0.2%), and angioedema (0.4% versus 0.1%).

Neurocognitive Events

In placebo-controlled trials, neurocognitive events were reported in less than or equal to 0.2% in REPATHA-treated and placebo-treated patients.
Low LDL-C Levels
In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1988 patients treated with REPATHA had at least one LDL-C value < 25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and REPATHA dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by REPATHA are unknown.

Musculoskeletal Events
Musculoskeletal adverse reactions were reported in 14.3% of REPATHA-treated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for REPATHA and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).

Adverse Reactions in Patients with Homozygous Familial Hypercholesterolemia
In a 12-week, double-blind, randomized, placebo-controlled trial of 49 patients with HoFH (Study 4), 33 patients received 420 mg of REPATHA subcutaneously once monthly [see Clinical Studies (14.3)]. The mean age was 31 years (range: 13 to 57 years). 49% were women, 90% White, 4% Asian, and 6% other. The adverse reactions that occurred in at least two (6.1%) REPATHA-treated patients, and more frequently than in placebo-treated patients, included:
- Upper respiratory tract infection (9.1% versus 6.3%)
- Influenza (9.1% versus 0%)
- Gastroenteritis (6.1% versus 0%)
- Nasopharyngitis (6.1% versus 0%)

6.2 Immunogenicity
As with all therapeutic proteins, there is potential for immunogenicity. The immunogenicity of REPATHA has been evaluated using an electrochemiluminescent bridging screening immunoassay for the detection of binding anti-drug antibodies. For patients whose sera tested positive in the screening immunoassay, an in vitro biological assay was performed to detect neutralizing antibodies.

In a pool of placebo- and active-controlled clinical trials, 0.1% of patients treated with at least one dose of REPATHA tested positive for binding antibody development. Patients whose sera tested positive for binding antibodies were further evaluated for neutralizing antibodies; none of the patients tested positive for neutralizing antibodies.

There was no evidence that the presence of anti-drug binding antibodies impacted the pharmacokinetic profile, clinical response, or safety of REPATHA, but the long-term consequences of continuing REPATHA treatment in the presence of anti-drug binding antibodies are unknown.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to REPATHA with the incidence of antibodies to other products may be misleading.

8. USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
There are no data available on use of REPATHA in pregnant women to inform a drug-associated risk. In animal reproduction studies, there were no effects on pregnancy or neonatal/infant development when monkeys were subcutaneously administered evolocumab from organogenesis through parturition at dose exposures up to 12 times the exposure at the maximum recommended human dose of 420 mg every month. In a similar study with another drug in the PCSK9 inhibitor antibody class, humoral immune suppression was observed in infant monkeys exposed to that drug in utero at all doses. The exposures where immune suppression occurred in infant monkeys were greater than those expected clinically. No assessment for immune suppression was conducted with evolocumab in infant monkeys. Measurable evolocumab levels were observed in combination at comparable levels to maternal serum, indicating that evolocumab, like other IgG antibodies, crosses the placental barrier. FDA's experience with monoclonal antibodies in humans indicates that they are unlikely to cross the placenta in the first trimester; however, they are likely to cross the placenta in increasing amounts in the second and third trimester. Consider the benefits and risks of REPATHA and possible risks to the fetus before prescribing REPATHA to pregnant women.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data
Animal Data
In cynomolgus monkeys, no effects on embryo-fetal or postnatal development (up to 6 months of age) were observed when evolocumab was dosed during organogenesis to parturition at 50 mg/kg every 2 weeks by the subcutaneous route at exposures 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg every 2 weeks. No test of humoral immunity in infant Iactation was conducted with evolocumab.

8.2 Lactation
Risk Summary
There is no information regarding the presence of evolocumab in human milk, the effects on the breastfed infant, or the effects of milk production. The development and juvenile use data for breastfed patients are not available. Consider the potential clinical need for REPATHA and any potential adverse effects on the breastfed infant from REPATHA or from the underlying maternal condition. Human IgG is present in human milk, but published data suggest that breast milk antibodies do not enter the neonatal and infant circulation in substantial amounts.

8.4 Pediatric Use
The safety and effectiveness of REPATHA in combination with diet and other LDL-C-lowering therapies in adolescents with HoFH who require additional lowering of LDL-C were established based on data from a 12-week, placebo-controlled trial that included 10 adolescents (ages 13 to 17 years old) with HoFH [see Clinical Studies (14.3)]. In this trial, 17 adolescents received REPATHA 420 mg subcutaneously once monthly and 3 adolescents received placebo. The effect of REPATHA on LDL-C was generally similar to that observed among adult patients with HoFH. Including experience from open-label, uncontrolled studies, a total of 14 adolescents with HoFH have been treated with REPATHA, with a median exposure duration of 9 months. The safety profile of REPATHA in these adolescents was similar to that described for adult patients with HoFH.

The safety and effectiveness of REPATHA have not been established in pediatric patients with HoFH who are younger than 13 years old.

The safety and effectiveness of REPATHA have not been established in pediatric patients with primary hyperlipidemia or HoFH.

8.5 Geriatric Use
In controlled studies, 1420 patients treated with REPATHA were ≥ 65 years old and 171 were ≥ 75 years old. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

8.6 Renal Impairment
No dose adjustment is needed in patients with mild to moderate renal impairment. No data are available in patients with severe renal impairment [see Clinical Pharmacology (12.5)]

8.7 Hepatic Impairment
No dose adjustment is needed in patients with mild to moderate hepatic impairment (Child-Pugh A or B). No data are available in patients with severe hepatic impairment [see Clinical Pharmacology (12.3)].

13. NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
The carcinogenic potential of evolocumab was evaluated in a lifetime study conducted in the hamster at dose levels of 10, 30, and 100 mg/kg administered every 2 weeks. There were no evolocumab-related tumors at the highest dose at systemic exposures up to 38- and 15-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. The mutagenic potential of evolocumab has not been evaluated; however, monoclonal antibodies are not expected to alter DNA or chromosomes.

There were no adverse effects on fertility (including estrous cycling, sperm analysis, mating performance, and embryonic development) at the highest dose in a fertility and early embryonic developmental toxicology study in hamsters when evolocumab was subcutaneously administered at 30, 100, and 100 mg/kg every 2 weeks. The highest dose tested corresponds to systemic exposures up to 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. In addition, there were no adverse evolocumab-related effects on surrogate markers of fertility (reproductive organ histopathology, mating, sperm analysis, or sperm parameters) in a 6-month chronic toxicity study in sexually mature monkeys subcutaneously administered evolocumab at 3, 30, and 300 mg/kg once weekly. The highest dose tested corresponded to 744- and 300-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC.

13.2 Animal Toxicology and/or Pharmacology
During a 3-month toxicity study of 10 and 100 mg/kg once every 2 weeks in male and female rats, there were no effects of evolocumab on the humoral immune response to keyhole limpet hemocyanin (KLH) after 1 to 2 months exposure. The highest dose tested corresponded to exposures 54- and 21-fold higher than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. Similarly, there were no effects of evolocumab on the humoral immune response to KLH (after 3 to 4 months exposure) in a 6-month study in cynomolgus monkeys at dose levels up to 300 mg/kg once weekly evolocumab corresponding to exposures 744- and 300-fold greater than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC.

This Brief Summary is based on the REPATHA® Prescribing Information v2, 09/15

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U.S. License Number 1080
Patent: http://pat.amgen.com/repatha/
The board members and consultants contribute expertise and analysis that help shape the content of Medical Economics.

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Payer mega-mergers blocked—for now

What will it mean to doctors that the U.S. Department of Justice (DOJ) filed suit this summer to block two mergers involving health plan giants?

Both mergers were announced in July 2015, with Anthem, largest of the Blue Cross/Blue Shield plans, acquiring Cigna in a merger valued at $54 billion; and Aetna acquiring Humana in a deal valued at $39 billion. These are four of the five largest insurance plans nationally, with an estimated 86 million covered lives.

The DOJ said the mergers would increase concentration, harm competition and decrease incentives to innovate, ultimately eroding quality of care.

“It will stifle competition,” said Robert Seligson, president of the Physicians Advocacy Institute. “These huge plans would limit a lot of the negotiation that now goes on between payers and providers, making it much more one-sided.”

Matthew Katz, executive vice president and CEO of the Connecticut State Medical Society, adds, “you could end up with these goliaths that dictate to providers. It puts more power in for-profit engines that are more focused on level of profit than care delivery.”

The DOJ suit against the four healthcare giants could have several outcomes, sources say, including decisions by the plans to drop the mergers, or vigorously defend them in court, or a compromise settlement to address DOJ’s concerns, perhaps through divestitures in certain local markets. Medicare Advantage penetration will be a particular focus for the regulators. The legal landscape is also complicated by the involvement of 16 state attorneys general joining the DOJ’s challenges to one or both mergers.

Mergers are often promoted for their potential to improve economies of scale and efficiency and thereby improve the quality of services. The insurers have also cited their ability to design new products employing technology to help better-informed consumers stay connected with their doctors. But healthcare isn’t like other industries, because insurance companies bargain with providers—who are now also busy consolidating, both with similar providers across regions and with other provider types across the care continuum, says Amanda Starc, PhD, a healthcare economist at the Wharton School of the University of Pennsylvania in Philadelphia.

“You might make the argument that mergers can bring down costs of healthcare, but there is little empirical evidence for that,” she says.
Recent analysis by the consulting firm McKinsey & Co. reveals that many insurers are losing money in Affordable Care Act (ACA) individual markets, with aggregate year-over-year losses more than doubling, and with post-tax margins between –9% and –12%. Losses like these resulted in UnitedHealth Group leaving the California ACA market after only a year.

That decision, as well as other insurers leaving some markets has sounded some alarm bells, particularly among opponents of the ACA.

Health policy expert Joel White, president of the Council for Affordable Health Coverage, notes this is a phenomenon happening all over the country because not enough people are signing up and insurers are losing money.

According to the Congressional Budget Office only about 10 million of the expected 21 million people have enrolled.

What does this mean for physicians?

Adam C. Powell, Ph.D., president of Payer+Provider Syndicate, notes that physicians who had contracts with insurers that departed the exchanges but not with other insurers may lose patients. Conversely, physicians with contracts with the remaining health plans may gain from the exodus.

According to the Kaiser Family Foundation, residents of 650 counties will be limited to just one health insurance company in the healthcare marketplaces next year. This significantly and negatively impacts consumers because lack of choice means no competition and thus no incentive to hold down prices.

Therefore, in order to control costs, carriers that remain on the exchanges will have to limit their network access and try to reduce payments to providers—both of which will clearly put a strain on physicians and prompt more to drop out of these networks.

Rick Bates, chief executive officer and co-founder of SingleCare, notes physicians can continue to focus on providing optimal care to their patients, but might find they are spending more time dealing with administrative issues.

In general, many lower-tier ACA plans have high deductibles, meaning patients pay more out of pocket and it creates additional paperwork and administrative headaches for physicians, taking their attention away from providing quality care.

One big concern is how this will affect a provider’s ability to get the best reimbursement rates for his or her practice. Bates explains that when providers can work with multiple insurer networks, they have more bargaining power and can negotiate more favorable rates. But with fewer insurers in the market, remaining insurers have more leverage (through less competition) and can try to force a doctor to lower their prices—requiring doctors to replace that revenue by taking on more patients to compensate for the lower rates of reimbursement.

Physicians want to focus on providing care, but as long as they’re dealing with looming legislative complexities, that focus may remain hazy.
GOVERNMENT CONTROL

Medicare payment reform threatens independent practice

by JORDAN ROSENFELD Contributing author

HIGHLIGHTS

 Critics of MACRA fear MIPS’s extensive reporting requirements, and physicians who choose the alternative payment model (APM) route may be signing the death warrant for their practices.

 Not all experts feel that MACRA will cause problems, but see it instead as a reflection of necessary growing pains in the healthcare industry.

 PAYING PHYSICIANS for the value and quality of care they provide may sound great in theory, but independent physicians have been burned time and time again by previous government efforts to achieve that goal. The Affordable Care Act and Meaningful Use were programs with good intentions but bad results, costing time and money, physicians say, and plans for Medicare payment reform are already inspiring ripples of dread.

 Independent physicians in particular express grave concern for the future of their livelihood, as their practices will suffer the most under the requirements set forth by the Centers for Medicare & Medicaid Services (CMS) and what feels like repeated pressure to sell to a large group or hospital, or perhaps even leave medicine altogether.

 “Healthcare reform, at least in its current iteration, has just been a systematic unraveling of private, independent practice. It makes all physicians subject to being widgets on an assembly line,” says Christopher Unrein, DO, FACP an independent internist for 25 years.

 The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was passed to replace the widely-disliked sustainable growth rate (SGR) formula that had been used to determine physician Medicare fees. It also represents a major step in the larger effort to reduce fee-for-service healthcare and shift toward a system of value-based payment. At press time, CMS has issued a proposed rule for MACRA, with a final rule expected later this fall.

 In addition, the law represents CMS’s answer to physicians’ frustrations with quality reporting under various programs by eliminating some reporting complexity. But skeptics fear it will create new headaches, especially for smaller practices. The federal government itself states in the proposed rule for MACRA that as many as 87% of solo practices are expected to face penalties of up to $300 million in 2019 through the Merit-based Incentive Payment System (MIPS).

 MACRA intends to achieve its aims by providing financial incentives to physicians who provide high-quality, cost-effective care, and penalizing those who don’t. But many independent physicians feel the measures are weighted to favor bigger practices.
and may be paying little more than lip service to the idea of improving patient care.

CMS’ acting administrator, Andy Slavitt, has clarified that the $300 million estimate was based on 2014 data, and reassured members of Congress in a listening on MACRA that his agency is focused on providing flexibility for solo and small practices.

Physician Unrein is among many in independent practice who aren’t convinced.

“I don’t think [MACRA] is really about taking care of people. It’s made to look like it, but is it really?” says Unrein. The internist feels it’s designed more to control and homogenize the practice of medicine, adding, “Unfortunately people are messy and don’t fit into a box very well.”

LOSS OF INDEPENDENCE

Critics of MACRA fear MIPS’s extensive reporting requirements, and physicians who choose the alternative payment model (APM) route—via certain accountable care organizations (ACOs) or patient-centered medical homes, for example—may be signing the death warrant for their practices.

“Their choices really are to try to figure out a way to do all the reporting required under MIPS, which will be basically impossible for these little practices, or join an alternative payment model,” either by selling to a hospital or health system or a hospital-run ACO, letting the latter handle the tasks, says James C. Capretta, PhD, a senior fellow at the Ethics and Public Policy Center and a former associate director in the White House’s Office of Management and Budget during the George W. Bush administration. He considers MACRA “flawed and ill advised” and worries that small practices will have to work harder than large groups to score high enough on MIPS to earn payment incentives or avoid penalties.

Capretta feels there will be a “political eruption” among smaller and independent physicians as a result, and that even large practices may revolt over this new law. “After the 2016 election, the physicians will say we can’t live with this, and they’ll try to come up with carve outs or other ways of allowing people to survive outside of this massive restructuring,” he predicts. Unrein suspects there hasn’t been more outcry by the large medical societies, such as the American Medical Association (AMA), because MACRA was an answer to their long battle to kill SGR. “The federal government had a chance to get the AMA and all of organized medicine to bite because they were going to kill SGR at last,” he says.

Leon Driss, MD, a solo internist and geriatrician in Lakeside, Arizona, who has been practicing for 30 years, fears that MIPS will be “the undoing” of his practice. He is anticipating the day he has to quit his practice as a result. He has little choice but to go the MIPS route, he says, because he didn’t implement an electronic health record (EHR) for time and cost reasons, considering himself “very efficient” and “more cost-effective than most doctors” at running a practice.

Driss joined an ACO only because the structure of the practice model will

---

**HOW MIPS SCORE IS CALCULATED**

<table>
<thead>
<tr>
<th>MIPS performance categories</th>
<th>2019</th>
<th>2020</th>
<th>2021 and beyond</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>50%</td>
<td>45%</td>
<td>30%</td>
</tr>
<tr>
<td>Advancing Care Information</td>
<td>25%</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td>(formerly Meaningful Use)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical practice improvement activities</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>Cost / Resource use</td>
<td>10%</td>
<td>15%</td>
<td>30%</td>
</tr>
</tbody>
</table>
Alternative Payment Model (APM)

Physicians who choose an APM will receive a 5% annual bonus to fee-for-service payments if they can prove they receive substantial revenue through an APM.

Substantial revenue can be defined in two ways. The first option is, by 2019-2020, 25% of Medicare payments must be attributable to the APM, increasing to 50% in 2021. The second option is, starting in 2021, 50% of combined payments from Medicare and other payers must be attributable to the APM.

APMs will have their own payment rules, depending on the particulars of the payment arrangement of the organization. Options for APM include use of a shared savings/financial risk arrangements, such as accountable care organizations or use of bundled payments.

Use of a patient-centered medical home (PCMH) can quality if the PCMH is shown to improve quality without lower costs, or can lower costs without harming quality care.

Merit-based Incentive Payment System (MIPS)

- Under this program, traditional fee-for-service payments will be adjusted, either with bonuses or penalties, depending on a physician's score on a new reporting program.
- The new reporting program will replace and combine aspects of the Physician Quality Reporting System (PQRS), Meaningful Use, and the value-based modifier.
- Physicians will receive a score between 0 and 100 based on four areas: Clinical quality, meaningful use, resource use and practice improvement. The details of each of these areas will need to be worked out during the rulemaking process.
- Scoring weights in these areas may be adjusted to account for a physician's ability to successfully report on each area. Physicians will receive credit for improvement from year to year.
- Physicians with the best MIPS scores can potentially earn “exceptional performance” bonuses.

TWO ROADS TO PAYMENT

2016 is the year to start considering your practice’s future payments. In 2019, and each year after that, physicians who receive Medicare payments will have to choose one of two paths:

- Physicians with the best MIPS scores can potentially earn “exceptional performance” bonuses.
- Use of a patient-centered medical home (PCMH) can quality if the PCMH is shown to improve quality without lower costs, or can lower costs without harming quality care.
comes in for blood tests, sending them to a weight loss class, making dietary changes and so on. “From my perspective, if providers do these kinds of things it does nothing but strengthen that relationship."

However, Driss points out that, as is true with most doctors, he has little control over the healthcare choices his patients make. He worries that patients may be noncompliant despite his best efforts, which “harms me even though I’m doing the best I can.” He gives a hypothetical of a patient with a heart condition who does heavy lifting against his advice, and winds up in the ER with chest pain. “If that patient has a procedure, and gets a $40,000 bill, I didn’t have any way to intervene or stop that.”

Other physicians feel that MIPS does little to actually improve patient care. Unrein says, “The fact that I can click a bunch of boxes on an electronic [health record] doesn’t mean I’m a good physician.” He feels that MIPS—perhaps like Meaningful Use—will reward completion of tasks over “empathy, compassion, listening and caring.”

TOO MUCH BUREAUCRACY?
Critics of MACRA, such as Capretta, are concerned about putting so much regulatory power in the hands of the government. “The federal government is putting itself in the position of being the arbiter of what is quality physician care in Medicare and, beyond that, in the United States,” he says.

He and others are also worried that the MIPS quality indicators are imprecise, and they don’t trust the government to update their information in a timely manner, much less accurately assess and track physician quality or patient outcomes.

Numeroff feels that while MACRA is well-intentioned—connecting payment and outcome—it’s likely to make more work for all physicians, and potentially drive up the cost of procedures, especially those performed in a hospital setting rather than a doctor’s office, which can often be more expensive. “Here you have physicians who are spending 25% of their time or more filling out forms and making sure that their coding is right in order to get paid,” she says.

CMS: HOW MIPS IS FLEXIBLE FOR SMALL PRACTICES
The U.S. Centers for Medicare and Medicaid Services (CMS) has responded to criticism that the Merit-based Incentive Payment System (MIPS) is unfair to small practices by producing a document explaining how officials view MIPS as a more flexible and more responsive system than previous value-based pay systems.

**Quality**
For individual doctors and small groups, MIPS calculates only two population measures based on claims data, instead of the three population measures required for larger groups. In addition, the Quality category reduces the reporting burden by generally requiring physicians and other clinicians to only report on six rather than nine quality measures. It also allows for partial credit for measures and allows physicians to choose measures that fit their practices.

**Advancing Care Information**
CMS proposes moving away from a pass-fail program design to a flexible design that allows clinicians to select a customizable set of measures that reflects how they use electronic health records (EHRs) in their day-to-day work.

**Clinical Practice Improvement Activities**
To accommodate small practices and practices located in rural or health professional shortage areas, this category allows clinicians to submit a minimum of one activity of any weight (e.g., medium or high) to achieve partial credit or two activities of any weight to achieve full credit. This is a reduced requirement than for other clinicians who would need to report at least three high priority measures in order to receive full credit.

**Cost / Resource use**
The score would be based on Medicare claims, meaning no reporting requirements for clinicians. If a clinician does not have enough patient volume for any cost measures, which is generally a minimum of 20 cases pertaining to a particular measure, then a cost score would not be calculated. CMS would reweight the Cost category to zero, and adjust the other MIPS performance category scores to make up the difference in the MIPS score.

Source: CMS
CMS does offer some exemptions from participating in MIPS for small practices. Physicians or groups who receive $10,000 or less in Medicare reimbursements or who have 100 or fewer Medicare patients can be exempted from the MIPS payment adjustment. Also, if a physician or practice lacks sufficient measures or activities in one of the four MIPS performance categories, CMS will allow an exclusion of that category, and adjust the score based on the remaining criteria. Further, independent physicians may also be allowed to join “virtual groups” to combine MIPS reporting, though CMS has said it won’t finalize the guidelines for this until at least 2018, a full year after it plans to collect data to determine penalties.

NECESSARY GROWING PAINS
Not all experts feel that MACRA will cause problems, but see it instead as a reflection of necessary growing pains in the healthcare industry.

Pourat of UCLA feels it will take time for MACRA to achieve its goals, which she feels are generally well-intentioned. “What the law is asking is that physicians do a bit more than just deliver care; [it is] asking physicians to show that what they are doing is actually consistent with the guidelines,” she says. She adds that even if a small percentage of physicians improve patient care as a result of the law, “we would be ahead of where we were.”

Indeed, while MACRA may hasten some small practices’ demise, their numbers had been shrinking for some time even prior to the law's enactment, and many already have relationships with hospitals and hospital systems. Data from the Medical Group Management Association's (MGMA) physician compensation and production surveys show that the percentage of physicians in practices owned by a hospital or integrated delivery system increased from 24% in 2004 to 49% in 2011.

In addition, as of 2012 only 53.2% of physicians were full or part-time owners of their practices. Moreover, doctors coming out of medical school with high debt levels, as many now do, are less likely to set up solo shops due to financial concerns.

“I think it would be wrong to single out MACRA as the overriding force trying to drive physicians out of independent practice,” says Mark J. Werner, MD, CPE, director of clinical consulting for the Chartis Group, a Chicago-based healthcare advisory organization. He sees MACRA’s changes as just another shift in an industry that has been undergoing a “tremendous amount of fundamental transformation” in common with many other major industries.

Werner feels MACRA is necessary to bring about collaboration and innovation among practices and hospitals. Yet he acknowledges that such changes are “awkward, challenging and stressful” and understands that change is not easy. Still, he acknowledges that such changes are going to make some people feel threatened. “That’s a part of the magnitude of change going on.”

ALTERNATIVE APPROACHES
If, as Capretta believes, physicians ultimately reject MACRA and find ways to opt out or force Congress to create new legislation, what other sorts of models might support a value-based payment system that allows small practices to thrive?

Capretta envisions a model where insurers would offer beneficiaries a “fair choice and competition, with financial consequences” something like Medicare Part D today.

Or, younger physicians may consider engaging in direct pay, says Ashesh Patel, MD FACP, a primary care physician in Washington, D.C., who has been in solo practice for 10 years. In lieu of MIPS or giving up his autonomy to a hospital practice, he’s considering adopting a direct pay model, bypassing Medicare and insurers altogether.

Unrein feels that there’s a lack of trust between physicians and the government. “When you’re putting [a system] in place that implicitly says, ‘We don’t trust you,’ you’re undermining one of the foundational pillars of what it is to practice medicine.”

Ultimately, while MACRA may not represent the perfect solution, Werner feels that there’s strong bipartisan understanding that “payment reform is necessary, needs to continue to evolve and convey accountability to providers.”

Pourat is more philosophical, saying, “You have to think of this as a great time for experimentation, because you’re not going to find a perfect solution that you’re going to implement overnight and that’s the end of it. We are talking about a very complex problem.”

—CHRISTOPHER UNREIN, DO, INDEPENDENT INTERNIST
Preparation for the new ICD-10 codes

by DONNA J. RUGG and MARIA N. WARD Contributing authors

New ICD-10 procedure and diagnosis codes—added as a result of the thawing of a partial code freeze in effect since 2011—are coming October 1. The new codes continue the trend started with ICD-10 implementation to provide greater specificity, telling an even better patient story and keeping pace with ever-changing demands for health information.

**Reasons for the code freeze**

The partial code freeze was instituted in October 2011 to facilitate the ICD-10 transition by stabilizing the code set while systems changes, education and other preparations were underway.

The partial freeze stipulated that, until one year after ICD-10 implementation, only limited annual code updates would be implemented so as to acknowledge new technologies and new diseases.

**Getting ready for additional codes**

Physician practices should review both the alphabetic Index and the tabular list of the final addenda released in June. There are frequently changes to how conditions are classified (in the index) that may result in a different code, but not necessarily a new code.

For example, a diagnosis of bacteriuria would be assigned N39.0 on September 30, 2016, and R82.71 on October 1, 2016. As with any code update, healthcare professionals will need to revise reference sheets and stay in touch with their vendors to ensure electronic health record (EHR) and billing software are updated and tested before implementation.

**Codes affecting all specialties**

Many of the ICD-10-CM diagnosis codes will affect providers regardless of specialty. Codes more common to internal medicine, family medicine and cardiology practices include:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I16.0</td>
<td>Hypertensive urgency</td>
</tr>
<tr>
<td>I16.1</td>
<td>Hypertensive emergency</td>
</tr>
<tr>
<td>I16.9</td>
<td>Hypertensive crisis, unspecified</td>
</tr>
</tbody>
</table>

Approximately 259 new codes are simply expansions of laterality in eye conditions, for example:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E10.3211</td>
<td>Type 1 diabetes mellitus with mild non-proliferative diabetic retinopathy with macular edema - right eye</td>
</tr>
<tr>
<td>E10.3212</td>
<td>Type 1 diabetes mellitus with mild non-proliferative diabetic retinopathy with macular edema - left eye</td>
</tr>
<tr>
<td>E10.3213</td>
<td>Type 1 diabetes mellitus with mild non-proliferative diabetic retinopathy with macular edema - bilateral</td>
</tr>
<tr>
<td>E10.3219</td>
<td>Type 1 diabetes mellitus with mild non-proliferative diabetic retinopathy with macular edema - unspecified eye</td>
</tr>
</tbody>
</table>

The code for pre-diabetes, R73.03, was created to provide greater specificity. Currently, pre-diabetes falls under the more general code, R73.09 for “Other abnormal glucose.”
Codes affecting Internal Medicine

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L02.213</td>
<td>Periorbital cellulitis</td>
</tr>
<tr>
<td>R31.21</td>
<td>Asymptomatic microscopic hematuria</td>
</tr>
<tr>
<td>R97.21</td>
<td>Rising PSA following treatment for malignant neoplasm of the prostate</td>
</tr>
<tr>
<td>R82.71</td>
<td>Bacteriuria, which is currently classified to N39.0 for UTI</td>
</tr>
<tr>
<td>M25.54-</td>
<td>Hand joint pain with sixth character laterality. This additionally reclassifies the condition to the joint section.</td>
</tr>
</tbody>
</table>

Cervical disc disorders have been expanded to separate the mid-cervical levels into individual codes with the use of a sixth character. For example:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M50.020</td>
<td>Cervical disc disorder with myelopathy, mid-cervical region, unspecified level</td>
</tr>
<tr>
<td>M50.021</td>
<td>Cervical disc disorder at C4-C5 level, with myelopathy</td>
</tr>
<tr>
<td>M50.022</td>
<td>Cervical disc disorder at C5-C6 level, with myelopathy</td>
</tr>
<tr>
<td>M50.023</td>
<td>Cervical disc disorder at C6-C7 level, with myelopathy</td>
</tr>
</tbody>
</table>

Zika virus is being added to coincide with the World Health Organization’s (WHO) planned update of the same code.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A92.5</td>
<td>Zika virus</td>
</tr>
</tbody>
</table>

Codes Affecting Family Medicine

Family medicine providers will find new, commonly-used codes related to obstetric and newborn patients. The biggest change related to newborn codes is the creation of code category Z05—Observation and evaluation of newborn for suspected conditions. The change also removes the phrase “suspected to be” from the code titles in categories P00-P04.

Additionally, the option of “complicating childbirth and puerperium” has been added to various codes, resulting in more accurate code assignment.

Other related codes include:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>O44.20-O44.33</td>
<td>Partial placenta previa – with and without hemorrhage</td>
</tr>
<tr>
<td>O24.415-O24.435</td>
<td>Gestational diabetes controlled by oral hypoglycemic drugs</td>
</tr>
</tbody>
</table>

Cardiology

Cardiology practices should be aware of specific codes for some cardiac congenital anomalies. Current codes Q25.2 and Q25.4 have been expanded to create codes for some specific conditions including the following:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q25.21</td>
<td>Interruption of the aortic arch</td>
</tr>
<tr>
<td>Q25.41</td>
<td>Absence and aplasia of the aorta</td>
</tr>
<tr>
<td>Q25.42</td>
<td>Hypoplasia of the aorta</td>
</tr>
<tr>
<td>Q25.45</td>
<td>Double aortic arch</td>
</tr>
<tr>
<td>T82.855</td>
<td>Stenosis of a coronary artery stent</td>
</tr>
</tbody>
</table>
The next ICD-10 hurdle: Prepare for payer scrutiny

What's changing about coding in October, and what physicians need to do to prepare

by LISA ERAMO, MA Contributing author

WHEN THE CLOCK struck midnight on October 1, 2015, the healthcare industry shifted from the antiquated ICD-9 disease classification system to the more refined ICD-10. One milestone achieved. Can physicians assume it will be smooth sailing now that one major hurdle has been crossed?

Not quite. There is yet another hurdle to cross in the coming months—navigating the conclusion of the ICD-10 grace period—a year-long moratorium on retrospective denials of unspecifed claims.

CMS announced the grace period after it reached an agreement with the American Medical Association that had advocated for additional delays of ICD-10. During the grace period, which ends October 1, auditors won’t penalize physicians retrospectively for non-specific codes as long as the codes are in the correct family or group. However, this flexibility only pertains to Medicare Part B claims. The grace period doesn’t apply to instances in which a specific code is required for medical necessity purposes.

Many physicians who have weathered the ICD-10 storm effectively continue to wonder whether problems lie ahead. “Payers haven’t actually said what will happen next, but I think the expectation is specificity and documentation accuracy,” says Deborah Grider, CCS-P, CDIP, CPC, a healthcare consultant at Karen Zupko & Associates who performs documentation audits for specialty groups and independent physician practices. “We’re already starting to see a trickle of denials from commercial payers for unspecific codes.”

ICD-10 SUCCESS—SO FAR

Though experts say greater payer scrutiny could be on the way, for now, the transition—once predicted as a doomsday scenario—was barely noticeable. In fact, many physician practices flipped the ICD-10 switch and subsequently continued in a ‘business-as-usual’ manner.

Consider Brad Bibb, MD, MBA, a primary care physician. Bibb’s private practice is one of a five-clinic group located in rural areas of Arkansas. He works with one nurse practitioner and sees about 35 patients per day. “It was a complete non-issue for us. It kind of reminded me of Y2K. Everyone thought it would be a big issue, and it ended up being nothing,” he adds.

Given the small size of his practice, Bibb says he relied almost entirely on his EHR vendor when making the transition to ICD-10. Prior to ICD-10, Bibb switched vendors to ensure that the EHR could keep up with all of the regulatory changes, including ICD-10 and Meaningful Use. “Having an EHR vendor that is invested in you getting
paid means they have to be up to date on all of this so I don't need to worry about it. I couldn't have devoted the time,” he adds.

Not only did Bibb's EHR vendor provide all his ICD-10 training, it also includes a rules-based engine that helps prevent denials on the front end—something he says is critical because of the added specificity inherent in ICD-10. “I don't have the resources in a small rural practice to hire people to do this type of monitoring,” he adds.

Like many EHRs, the technology Bibb uses in his practice essentially walks him through the code selection process, making it easier to achieve the necessary specificity. He hasn’t experienced any denials or delays in cash flow since the ICD-10 go-live.

Anecdotal stories published by the Coalition for ICD-10—a broad-based health-care industry advocacy group—echo the fact that the transition has been positive for many stakeholders. “So glad it hasn’t been a nightmare like people anticipated,” wrote Carey Wagner, CMM, practice manager at California Cardiac Surgeons, on the Coalition’s website.

Having sufficient time to prepare was critical to overall industry-wide success, according to a post-ICD-10 implementation survey conducted by the Workgroup for Electronic Data Interchange (WEDI). The survey found that both delays of ICD-10—one in 2013 and the second in 2014—improved providers’ abilities to test ICD-10 claims, resulting in a smoother transition.

**EHRs to the Rescue**

EHR technology also played a large role in physicians' success. “I know of many physicians even in rural and small practices who say it has gone very smoothly. It makes me suspect that most EHR vendors were really truly prepared to help us through this,” says Michael L. Munger, MD.

Munger, a Kansas-based primary care physician, says his practice of 105 physicians and 25 nurse practitioners benefitted from its EHR, but still has work to do to capitalize on the technology. For the first month post-transition, he says, the volume of code possibilities in the EHR was overwhelming, making it difficult to maintain his workload of 25 patients per day. “It took longer at the point of care, or we were spending extra time at the end of the day and evening to get the right codes,” he says.

In response, some physicians in Munger’s practice reduced their workloads by one or two appointments per day while others simply worked through their lunch hour or into the evening to get the work done, he says.

Brad Walsh, MD, says bookmarking codes within his EHR has been very helpful. He has bookmarked more than 100 diagnoses, many of which he uses often.

Productivity, volume of denials and cash flow have remained stable in ICD-10 at Walsh’s Arkansas-based practice, which employs three family physicians and one internal medicine physician. He sees between 16 and 20 patients per day. “We have continued to bill as we always had and continue to receive payments on time,” he adds.

Walsh has used an EHR since 2011. He suspects that practices without an EHR didn’t make the transition as smoothly. “If you’re still billing on paper and not submitting claims electronically—or if you had an EHR that didn’t keep up with this—ICD-10 would be a nightmare,” he adds.

Texas-based cardiologist Paul Roach, MD, agrees. “For organizations that have not adopted an electronic record, I could see how ICD-10 could create a huge disruption in the billing process,” he says.

Roach’s practice that includes 28 physicians and nine nurse practitioners is owned by a larger health system that assisted with ICD-10 training. “It has been going quite well,” he says. “I think there was a lot of angst and anticipation that it was going to be very cumbersome and create an extra documentation burden, but with the electronic records, it has been a non-event.”

Roach says their EHR vendor auto-populates diagnoses established during the ini-
Arkansas-based primary care physician Lonnie S. Robinson, MD, says ICD-10 has had virtually no effect on his workflow. His practice, which employs eight family physicians and three advanced nurse practitioners, took out a line of credit in anticipation of cash flow problems, but hasn’t had to use it. Robinson continues to see about 25 to 35 patients per day.

Working with a scribe has helped Robinson maintain productivity. The scribe is present in the exam room and prompts him for the additional documentation specificity required in ICD-10. “My goal is to resolve the documentation before I leave the room.”

Smoother Transition for Payers
As with providers, payers have weathered the ICD-10 transition effectively as well. “Overall, the transition to ICD-10 been much smoother than anyone could have expected,” says Mike Denison, PMP, senior director at Change Healthcare, a clearinghouse that processes 8.8 million transactions and manages $1.7 trillion annually for payers, providers, and vendors nationwide. “There were isolated issues, but there was also a heighted industry focus and sense of urgency to resolve any issues encountered.”

In the initial months following the October 2015 transition, the overall claim rejection rate for provider claims submitted through Change Healthcare was never more than 0.4% above the pre-ICD-10 transition baseline, says Denison. Overall payer rejections actually were slightly below the pre-transition baseline. He says claim rejections specific to diagnosis code edit rules occurred only 1.5% more frequently than they did compared to the pre-transition baseline.

“The healthcare industry went through a major code set update, but it was an update to a known and established standard [ICD]. I think that helped a lot,” he says.

The most common reason for clearinghouse-level medical claim rejections following the transition was that providers were coding the wrong version of ICD based on the date of service submitted, says Denison.

Jim Daley, IT director at Blue Cross Blue Shield of South Carolina, past chair of WEDI, and WEDI’s ICD-10 workgroup co-chair, says denials have been minimal.

“There was a lot of work involved—and certainly there was a high cost to do this—but with the time allotted, it went off pretty smoothly,” he says. “ICD-10 is in the systems, it’s functioning, and now it’s mostly about fine-tuning.”

Blue Cross Blue Shield of Michigan created a command center to monitor all internal and external activity post-implementation, says Juanita Savage, RN, MBA, director of medical affairs, reimbursement strategy, and ancillary program management. Savage provided the following feedback via email:

“Claims volumes have come in as expected, and there are no claims processing issues to report. System changes and rules we put in place are working as designed. Currently, we are not receiving ICD-10-related questions from providers.”

In fact, Daley says he hasn’t heard of any payers experiencing significant issues with the ICD-10 transition. “Payers, in particular, spent a lot of time preparing for ICD-10. They’re also accustomed to handling large mandates and implementation.”

Clare Krusing, press secretary at America’s Health Insurance Plans (AHIP), concurs. “The transition has been smooth so far,” Krusing wrote in an email.”Health plans had prioritized ICD-10 readiness and were prepared for the initial deadlines and subsequent ones thereafter.”
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Since the official launch, they have been working with their vendor partners and providers to make sure the transition has been smooth.”

Perhaps the most significant payer challenge thus far pertained to Medicare Administrative Contractor (MAC) updates to National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), both of which limit Medicare coverage to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).

“We had some issues early on where some of the medical policies didn’t include all of the ICD-10 diagnosis codes. We may still have some of those incomplete policies out there,” says Grider.

Shortly after implementation, the Centers for Medicare & Medicaid Services (CMS) released a clarification reminding MACs to translate all NCD and LCD coverage policies to ICD-10. CMS declined an interview with Medical Economics for this story. A spokesperson for CMS said in an email that the agency had no comment regarding the current state of the transition.

In a February 2016 blog post, CMS Acting Administrator Andy Slavitt reflected positively on the ICD-10 transition. “In the first month of implementation, we received approximately 1,000 inquiries and responded to 100 percent of them within three business days. We will never achieve perfection, but we will be visible and hold ourselves accountable for solving problems,” he wrote.

The agency also published ICD-10 metrics for the fourth quarter of 2015 showing only 1.9% of total claims were rejected.

### PREPARING FOR 2017 AND BEYOND

However, many fear that payers have used the last several months to perform data analytics so they can target providers who report large volumes of unspecified codes paid based on their CPT codes,” says Grider. “But I always tell them that your diagnosis codes do drive payment because if the diagnosis codes don’t support medical necessity, you’re not getting paid.”

Daley says payers could notice reporting patterns in which the diagnosis code is always the same—particularly when the code is highly specific. This may trigger an audit, he adds.

### 5 tips to prepare your practice for the end of the ICD-10 grace period

The ICD-10 grace period officially ends on October 1; however, only time will tell if—and when—payers begin to demand greater specificity. In the meantime, consider these five tips to ensure compliance in the short and long term:

1. **Think ‘specificity’ at all times.**

   Don’t default to the first code in the EHR drop-down menu, says Deborah Grider, CCS-P, CDIP, CPC, a healthcare consultant. Instead, look for the most specific code. “Doctors don’t always pay attention to their diagnosis codes because they get

2. **Validate code selection during each encounter.**

   For example, a physician may “favorite” a code in the EHR for diabetes (e.g., E08.21, diabetes mellitus due to underlying condition with diabetic nephropathy) because he or she treats this condition most frequently. However, what if every claim includes this same exact diagnosis? Even with its specificity, the code may not be the best option for every visit, especially if a patient has another manifestation of the diabetes.

   Daley says payers could notice reporting patterns in which the diagnosis code is always the same—particularly when the code is highly specific. This may trigger an audit, he adds.

3. **Track key performance indicators (KPI).**

   Every practice should keep close tabs on the following KPIs, says Grider:

   - **Coder and physician productivity.**
     “Slower productivity means slower cash flow, and if you don’t do an assessment, you won’t know that this is
Once given the opportunity to do so, Grider suspects that physicians may see an increase in the number of claims that are suspended with a request for additional documentation. When they submit this documentation, they could be opening themselves up for additional scrutiny, she adds.

If specificity audits do occur, they probably won’t happen immediately, says Daley. “I can’t speak for all payers, but I highly doubt there will be a big bump in specificity audits on October 1,” he adds. “We all want to make this work with the least amount of disruption. It’s painful and costly on both sides when claims are delayed or denied.” He thinks many payers will undertake a period of provider education before they begin penalizing audits or other actions.

Denison agrees that payers will probably not barrage physicians with specificity audits on October 1, 2016. “Requirements for increased specificity will likely be in the form of contractual policy changes and naturally evolve within emerging pay-for-performance payment models,” he says. “Any changes from a government perspective will be effectively communicated, and providers should be well aware ahead of time.”

At this point, many physicians and payers have begun to focus on the large number of new ICD-10 codes that go into effect October 1 of this year. CMS and the Centers for Disease Control and Prevention will add about 1,900 diagnosis codes and 3,651 hospital inpatient procedure codes to the ICD-10 coding system for healthcare claims in fiscal year 2017.

As the industry moves forward with ICD-10, Robinson says physicians must learn to adapt in an increasingly data-driven healthcare environment. “I think most of my colleagues would prefer to just take care of the patient and not worry about some of these nuances of coding and billing,” he says. “But it is our new reality.”

Unspecified codes. Run a frequency report for the practice’s most common diagnoses. Do any of the codes for these diagnoses tend to end in “0” or “9” (indicating an unspecified diagnosis)? If so, determine whether documentation improvement, coder education, or both are required.

Overall denial rate (and denial rate by payer). How does this rate compare with that of ICD-9 during the same month of the previous year?

Reasons for denials. Examine each denial to better understand the reason, says Grider. For example, is the denial due to an invalid or incomplete code? If the practice is paper-based and keying in its own codes, is there a denial due to a transposition of characters? Is the clearinghouse functioning properly? One of Grider’s clients discovered that its clearinghouse was accidentally deleting the 7th character on all injury codes, causing a rejection.

Perform an ICD-10-CM documentation audit. Does the documentation match the actual ICD-10-CM code selected? For example, a physician documents “right hip fracture” but selects an ICD-10-CM code in the EHR for “trochanteric fracture of the right femur.” “The documentation doesn’t match the code selected. This is a big issue, especially with Medicare audits,” says Grider.

Hire a certified coder. Certified coders not only possess an in-depth knowledge of official coding guidelines, they can also help the practice stay on track with coding updates and denial management. In addition, certified coders can help develop a “cheat sheet” of documentation requirements for the practice’s top 25 diagnoses as well as the key terms that physicians must type in the EHR to produce the most specific code.
Group visits can improve chronic condition management

With preparation and team effort, group sessions can be a revenue stream, improve care and boost patient satisfaction

by JANET COLWELL Contributing author

WEARY OF TRYING to manage complex diseases in 15-minute increments, many primary care physicians are trying group visits as a way to spend more time with their patients and potentially improve outcomes.

The group visit model has gained traction in recent years as physicians look for ways to improve care without jeopardizing the financial health of their practices.

“In today’s healthcare environment, it’s challenging to simultaneously maintain access, engage patients and improve quality of care,” says Marianne Sumego, MD, an internist and director of shared medical appointments at Cleveland Clinic in Cleveland, Ohio. “Group visits can help us address all three of those challenges.”

Group visits typically include about a dozen patients who share the same chronic condition, such as diabetes or heart disease, but physicians have also been using the visits to address other issues, such as advance care planning and weight loss. The meetings typically start in the same way as a typical office visit, with clinicians taking vital signs and adjusting medications privately, then move into group presentations on disease-related topics, social interaction and support, and assistance with disease self-management.

Besides improving care, group visits can make good financial sense, because they enable physicians to see multiple patients at once. Physicians can use the same Current Procedural Terminology (CPT) codes for reimbursement as they would for a one-on-one office visit.

“You need a setting where you can host a group and there’s a lot of prep work involved on the front end,” says Dennis Saver, MD, part of a 12-physician group practice in Vero Beach, Florida, who has been holding diabetes group sessions for the past decade. “But once it’s up and running, it becomes easier to keep it going.”

PATIENTS THRIVE IN GROUPS

Several recent studies suggest that group visits, also known as shared medical appointments, can have...
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GROUP VISITS

Best Practices

Preparation and planning are key to sustaining a successful group visit program, say physicians who’ve tried the model. It takes considerable time upfront to train staff, communicate with patients and line up content and guest speakers, advises Dennis Saver, MD, a primary care physician in a group practice in Vero Beach, Florida. However, once a program is in place it becomes fairly routine and easy to maintain.

Saver and other physicians offered the following tips for success:

- **Involves your team.** Explain the concept of group visits to staff and how it will affect the office workflow and staff roles, says Marianne Sumego, MD, an internist and director of shared medical appointments for Cleveland Clinic in Cleveland, Ohio. “Talk about what it will take to get a dozen patients checked in at a time,” she says. “Your team should be involved from the beginning in developing the plan for implementation.”

- **Think through the logistics.** Allow 30 to 45 minutes at the beginning of the visit for checking in patients, taking vital signs, and refilling prescriptions, notes Saver. To save time on the back end, he gives patients an appointment card for their next visit during check-in.

- **Determine an appropriate size.** To decide on the size of the group, double the number of patients you would normally see individually during the same block of time used for a group visit, says Sumego. Practices should arrive at a number that’s small enough to manage but large enough to benefit the program financially.

- **Invite guest speakers.** Ask specialists in related disease areas to give presentations on specific themes, says Saver. For example, his diabetes sessions have featured podiatrists talking about foot care and certified diabetes educators discussing food and diet issues.

- **Don’t try to do it alone.** It’s very difficult to lead a group while also taking notes and conducting individual patient check-ins, says Jean Antonucci, MD, a solo primary care physician in Farmington, Maine. Physicians need support staff to help with checking in, charting and coding so that they don’t end up working too much overtime.

A direct impact on improved patient outcomes. They’ve also been shown to increase patient satisfaction and patient engagement in self-managing their diseases.

“I used to try to squeeze a discussion about low or high blood sugar into five minutes during individual visits with each of my diabetes patients,” says Saver. “With group visits, I can spend more time on important topics, and less time repeating myself.”

The Diabetes Master Clinician Program, a web-based registry and training program, has documented a similarly positive trend. Saver, who uses the registry in his practice, says that his diabetes patients who take part in the group visits have 0.4%-0.6% lower HbA1c levels than those who do not.

At Cleveland Clinic’s chronic disease group sessions, there have been many cases of the group positively affecting patient decisions, says Sumego.

In one case, a woman with a family history of colon cancer expressed reluctance to schedule a follow-up appointment after her screening test showed a precancerous polyp. However, she decided to proceed with the follow-up after another participant described how a routine screening test had detected her cancer early enough to be treated.

“There’s value in patients encouraging each other that we as physicians are not able to capture when we see them one-on-one,” says Sumego. “This case was a really important lesson to me that one of the main benefits of shared medical appointments is to leverage the value of sharing experiences among peers.”

GETTING STARTED

Group visits can take a variety of forms and it’s up to each physician to determine the format and content. However, Saver advises seeking out support from professional groups or other physicians before getting started. In his own practice, Saver relied on the training manual produced by the Master Diabetes Clinician Group, which offers a step-by-step guide to preparing for a successful first session.

One of the first hurdles is establishing a venue for the visits, says Saver, who hosts meetings in his office’s employee lunchroom. To protect patient privacy and ensure that they don’t run afoul of Health Insurance
Portability and Accountability Act (HIPAA) regulations, some physicians have patients sign confidentiality and HIPAA disclosure forms. By signing such forms, patients confirm that their participation in the group is voluntary and promise to keep all information discussed during the visit confidential.

It’s also important to get everyone on staff involved in the planning process, says Sumego.

“Your team is critical and should be included in developing the workflow and the implementation plan from the beginning,” she says. “Talk with everyone about what it will take to check in 12 patients at once.”

The Master Diabetes Clinician Group guide recommends starting with a full staff meeting to explain how group visits are different from support groups in that they provide medical evaluation, medication adjustment, and care coordination in addition to support for self-management. Physicians should also explain that the group visit replaces some of the routine one-on-one office visits.

At the same time, it’s essential to identify someone in the practice—whether it’s the physician or another clinical staff member—who can act as facilitator and has the skills to lead and manage interactive group discussions, says Saver. “Group visits are not meant to be lectures,” he notes. “The process should be fun and useful and encourage patients to share their personal experiences and insights with others.”

Group visits usually focus on one chronic illness but can encompass several. Jean Antonucci, MD, a primary care physician with a solo practice in Farmington, Maine, conducted group visits for about two years with a small group of patients. Participants had various chronic diseases, including diabetes and depression, and were drawn together by the need for support.

Antonucci says the meetings improved overall care but she stopped offering them because they were too difficult to manage on her own. She had to hold the sessions after business hours in order to use a waiting room she shares with another physician, and without support staff to help, she got bogged down in documentation.

“The patients loved it but it ended up being too much work for me,” she says. “You really need someone to help with charting so you can focus on leading the meeting.”

To determine the best size for the group, double the number of patients that would normally be seen in the approximate two-hour block reserved for the visit, says Sumego. That number should be small enough to facilitate group discussions but large enough to be financially beneficial for the practice.

Always plan for less than 100% turnout, the Master Clinician Group guide advises. As a general rule, about 30% of those invited will not come and, of those that do attend, only 70% will return for another visit.

Finally, develop an agenda with a series of planned topics and speakers, says Saver. He divides his meetings into two parts: A topical issue such as diabetes and eye disease or foot care takes up the first hour, followed by a refreshment break. The second hour focuses on disease management issues, such as HbA1C measurements, recognizing symptoms of high or low blood sugar, and sharing tips or experiences among patients.

Saver often invites specialists to speak at the meetings on diabetes-related topics. For example, an ophthalmologist might give a presentation about eye disease or a dietician might talk about food and nutrition issues.

The key is to tailor the content to the needs of the group, says Antonucci.

“I picked people who had very high needs and were not likely to have social support,” she says. “I dealt with general issues around health confidence and problem solving because that’s what many of these patients have the most trouble with.”

— DENNIS SAVER, MD, VERO BEACH, FLORIDA
Make smarter decisions with practice benefit dollars

How to build an attractive employee benefit package that doesn’t break the bank

by JANET KIDD STEWART Contributing author

HIGHLIGHTS

- Customizing benefits to your specific practice is the best way to save money and maximize impact.

- Once physicians decide on a level of benefits for their staff, many make the mistake of not articulating those benefits appropriately.

ATTRACTION EXCELLENT employees to a medical practice should be relatively easy, in theory. Practices can offer better hours and holiday schedules for nurses and other clinical personnel than a hospital, and the work is often seen as less stressful and more stable than a hospital setting for other employees.

As hospitals consolidate into larger organizations, however, they can more cost-effectively offer a larger, richer set of benefits, and small practices have to compete with that as they find talent.

Increasingly, medical practices are having to ramp up benefits offerings to compete for talent, despite having the hours and scheduling advantage, says Forrest “Bo” Olson, CPA, president of Oklahoma City, Oklahoma-based Olson Neaves & Co.

"Traditionally, medical offices have been able to offer better working conditions and a more relaxed work environment than hospitals, and hospital workers were willing to earn less and have fewer benefits for that," says Olson. Today, though, he says prospective hires are more reluctant to jump ship if a small practice can’t keep pace.

Robert Berenson, MD, a board-certified internist and healthcare policy expert with Washington, D.C.-based Urban Institute, says he is sure some staff prefer a smaller, independent practice environment, but such an employer is "financially vulnerable."

Earlier in his career, Berenson worked for 12 years in a group practice. Small practices' vulnerability will mean increased perceived job insecurity for their employees, he says, and budgets for staff benefits will have to constrict under continued demands for cost cuts and compliance with new regulations.

Happily, there are exceptions. Deborah Blalock, MD, a solo gastroenterologist in Oklahoma City, Oklahoma, says her practice has grown to the point where she recently decided to hire a second employee. She’s been interviewing candidates, and recently found one she says is excellent, but who told her she needs a retirement plan in order to accept the position.

Rather than bolting to the next resume, Blalock took stock of the financials of her practice, consulted her advisers and decided to offer the candidate—and her current staffer, a valued, longtime employee—401(k) plans. "I feel my practice has grown to the point I can afford to give benefits to attract the type of employee who will represent me and the quality I try to give my patients," Blalock says.

→ 42
Technology plays a vital role in my field. By treating patients with the latest innovations, I restore more than hearing; I restore hope.
NEW REGULATIONS
Another challenge: new U.S. Labor Department rules implementing the Fair Labor Standards Act will impact practice owners, says Christine Walters, JD, owner of FiveL, an employee benefits consulting practice located in Westminster, Maryland. Beginning Dec. 1, employees earning below $47,476 a year will be considered non-exempt and must be paid overtime, Walters says. The previous threshold was just $23,660. The change will hurt small businesses' ability to offer flex-time benefits, a key retention tool, she says.

Practice owners can respond by bumping pay of workers close to the threshold up to the new exempt status, or by establishing a new mix of regular and overtime pay rates, she says, but many will lose the option of informally compensating longer hours one week with flex-time the next.

Many states also are considering predictive scheduling laws, mandating that employers pay a portion of wages to workers whose shifts are canceled due to low business volume or customer cancellations, she says. Those dollars also take away from an employer's ability to provide flex-time.

RETIREMENT PLANS
Many small practices have retirement plans known as Simplified Employee Pension–Individual Retirement Accounts (SEP-IRAs), he says, but those typically use at least a three-year schedule for qualifying for the plan, which often virtually eliminates most lower-paid medical office staffers. “Most medical office employees don’t last three years,” Olson, who advises Blalock, says, and if they do, the funding requirements are often prohibitive. “My suggestion was to go ahead and establish a 401(k) plan for both workers.” The cost for small practices is about $1,500 to establish the plan, another $1,500 a year in maintenance costs, plus whatever matching funds are given to employees annually, he says.

Plan costs vary widely depending on the provider and number of employees, but generally 401(k) plan costs have been falling in recent years, experts say, so offering retirement benefits as a way to retain good staff is becoming a bit easier.

A lot of medical practices today are using so-called “safe-harbor” 401(k) plans, says Eric Droblyen, CPC, president and chief executive of Mobile, Alabama-based Employee Fiduciary, a company that provides plans to small and mid-sized companies. Under those plans, practices can choose to offer a retirement-plan match of 4% of salary to employees who make their own contributions into the plan.

RX FOR BETTER BENNIES
A few more tips for getting the most from your benefits dollar

TO THINE OWN SELF, INSURE.
Even practices with as few as five to seven physicians should look into self-insuring for healthcare, says Andy Swanson, CMPE, vice president of the Englewood, Colorado-based Medical Group Management Association Health Care Consulting Group. It costs nothing to have an insurance broker run some competitive quotes on catastrophic coverage to supplement a self-insured plan, so it’s worth the investment of time, he says.

THINK WELLNESS–FINANCIAL, THAT IS.
More small- to mid-sized employers are focusing on financial wellness benefits over health incentives, according to a recent survey by the Society for Human Resources Management (SHRM), headquartered in Alexandria, Virginia. Relatively low- or even no-cost financial education can be provided by a retirement plan record keeper or local bank, says Evren Esen, MSW, director of survey programs for SHRM. “It’s not necessarily a high cost, but it can be a benefit employees really value,” she says. Popular areas of help many workers ask for include coping with financial stress, debt management and first-time homebuyer assistance.

TALK ABOUT IT.
Particularly in small group practices with just a handful of employees, it can be awkward to address cost-savings on benefits like health insurance, says Swanson. “Nobody is really talking to their employees about healthcare utilization, but it’s important to do it,” he says. “Take a sticky situation and turn it into one where the employee feels valued.” If an employee gets cancer, for example, offering to work together to keep costs down for both employee and employer while getting the best possible care is one way to do that, he says.
You have to look at benefits as part of total compensation. I’ve seen people leave their employers for a supposed raise, but if they factor in benefits they are actually taking a pay cut.”

— TED WILLIAMS, JD, CO-PRINCIPAL, THE WILLIAMS GROUP, DES MOINES, IOWA

Alternatively, they can give a 3% match to all employees along with a New Comparability Plan, a type of profit-sharing plan that allows large contributions from practice owners nearing retirement while still providing benefits to lower-level employees. Contribution limits in the plans are based on the projected level of benefits they will generate in retirement, allowing for smaller contributions from younger staffers because they have decades for the benefits to accumulate.

HEALTH BENEFITS
Getting the right practice model in place also affects the quality and quantity of benefits that can be offered, says Clint Flanagan, MD, a primary care practitioner in a five-physician group in the Boulder, Colorado, area. In addition to the group’s traditional fee-for-service practice, Flanagan founded a membership-based direct primary care practice about six years ago, Nextera Healthcare. Nextera, a separate business, has about 20 affiliated providers in Colorado.

For his roughly 15 employees, Flanagan offers company-paid membership in Nextera for primary care, and offers a high-deductible health plan alongside that benefit. There’s also a 401(k) plan with an employer-paid match, vacation pay, bonuses for top performers and occasional social events to keep up morale, he says.

ASK STAFF
Offering the direct-pay service to patients and other employers has resulted in enough growth to cover the costs associated with the more generous benefits, Flanagan says. In addition, he routinely queries staff members and monitors usage of the practice benefits to make sure employees are actually using them.

For some employees, paid time off might be more valuable than health insurance, for example. Get employee feedback on priorities through focus groups and exit interviews, he recommends.

That’s a key component of good benefit plan design, says Lenny Sanicola, CCP, spokesman for World at Work, a human resources association with offices in Scottsdale, Arizona, and Washington, D.C. Think about what kind of employees you are drawing when the “help wanted” signs are posted, he says. Depending on the demographic, they might actually prefer part-time work to full time. Or they may already have health coverage through a spouse’s workplace.

NON-TRADITIONAL PERKS
Small practices can also use their size to an advantage when it comes to certain benefits. Smaller employers might not be able to compete in the core benefits like 401(k) plans and insurance, but they often have the flexibility to offer spot incentives to recognize excellent work, Sanicola says.

“Appreciation and recognition is very important to some people,” even if the actual dollar amount is small, he says. Other ways to stand out, he says, include offering low-cost benefits that are essentially discounts on services. Homeowners insurance at group rates, pet insurance and identity theft protection are all examples, he says.

Even just bringing in free breakfast once a week for staff members can go a long way toward making employees feel more invested at work, he says. Those personal touches can stand out in markets where so many employers are offering standard benefit packages that they become commoditized, Sanicola says.
I feel my practice has grown to the point I can afford to give benefits to attract the type of employee who will represent me and the quality I try to give my patients.”

— DEBORAH BLALOCK, MD, SOLO GASTROENTEROLOGIST, OKLAHOMA CITY, OKLAHOMA

WHEN IN DOUBT, FLEX
Workplace flexibility, letting employees have as much control over their schedules as possible as long as they get the job done, is a key challenge, says Walters. "Employers are spending a lot of time on this question of how much leave they can offer," she says. What used to be standard five to seven days of paid holidays, for example, might now be seven personal days for employees and letting them decide when to take them.

To balance that flexibility with the realities of scheduling a medical office, more employers are giving their employees the responsibility of finding someone to cover the shifts they want off, she says.

COMMUNICATE
Once physicians decide on a level of benefits for their staff, many make the mistake of not articulating those benefits appropriately, says Ted Williams, JD, co-principal of The Williams Group, a human resources management firm in Des Moines, Iowa. "You have to look at benefits as part of total compensation,” he says. “I’ve seen people leave their employers for a supposed raise, but if they factor in benefits they are actually taking a pay cut because their employer didn’t know how to fully explain their current package.”

Expressing benefits—even mandated ones like worker’s compensation and unemployment benefits—in actual dollar terms helps make that clear, Williams says.

KEEP COSTS IN CHECK
Also, keep the general hiring climate in mind for your location, he says. Generally, workplaces in states without traditionally heavy union representation have lower benefit levels, for example, so there may be more room to incentivize workers, he says.

And to help keep an eye on total costs, consider capping the amount of unused sick time employees can bank, he says. He suggests alerting employees upfront that no more than two weeks can be saved.

Customizing benefits to your specific practice is the best way to save money and maximize impact, he says. He believes a lot of small practices miss opportunities to leverage data, from informal conversations to staff polling that can quickly highlight what’s important to staff. "I don’t see employers paying attention to their demographics so they can recruit and retain, and budget in a way that gets them the biggest bang for the money spent on benefits,” he says.

Another common mistake: Failing to negotiate health benefits. “They just go lock-step and don’t negotiate with carriers, allowing carriers to dictate the offering,” he says. "We take the position that carriers are there to serve us and we will shop them, so don’t just present us with a 5% premium increase with an attitude of take it or leave it.”

Even if you’re shopping for benefits on your own, at least consult with other physicians to get a sense of what’s being offered, he says. "I encourage clients to exchange a lot of information with peers. I’m not sure physicians appreciate how much leverage they have as a group.”

D.C. CORNER:
Why Congress is turning its attention to chronic care
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Should physicians be financial advocates for their patients?
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Physicians as consumer advocates

Patients are on the hook for more of their healthcare costs, prompting calls for doctors to get involved

by JAMES F. SWEENEY Contributing author

FOR LAUREN OSHMAN, MD, the patient’s financial condition was as much of a problem as his medical condition.

Her new patient had type 2 diabetes, for which he was being treated with canagliflozin (Invokana) and insulin glargine (Toujeo). His previous doctor had given him samples, but the manufacturers eventually stopped providing the freebies, so the doctor wrote him a prescription for the two drugs immediately before the patient came to see Oshman.

When he went to fill the prescriptions, the patient was shocked to find that the non-formulary drugs would cost him $700 a month, which he could not afford, even though they were covered under Medicare Part D.

And, just like that, the patient’s finances threatened Oshman’s ability to give him the care he needed. “Those are the days I go home steaming,” says the suburban Chicago primary care physician.

For her and many other primary care doctors, treating patients increasingly includes helping them find ways to afford the healthcare they need.

Whether a physician should take into account a patient’s financial condition when developing a treatment plan is a difficult question. What does it mean to consider whether a patient can afford healthcare? Should the doctor avoid certain treatments because of the cost? Should the doctor take steps to lower the cost of treatment, and, if so, what steps?

There is no doubt that high healthcare costs can hurt patient care. Patients struggling with debt might skip treatments or not fill prescriptions. In other instances, patients cut back on other necessities, such as food and housing, in order to afford care.

“It’s ugly out there and it’s getting worse,” says George Ellis, MD, FACP, an internal medicine physician in Youngstown, Ohio, and chief medical adviser of Medical Economics. “I have patients tell me all the time ‘I can’t afford that drug’. Patients are getting destroyed with these high deductibles.”

While the Affordable Care Act means more Americans have private health insurance, it doesn’t mean they can easily afford the costs. According to the 2015 Commonwealth Fund Health Care Affordability Index, 25% of privately insured working-age adults have high healthcare costs burdens relative to their incomes. It also found that 53% of privately insured people with low incomes have unaffordable health costs.

The Consumer Financial Protection Bu-
Physicians as consumer advocates

You really need a team.

There is no way a primary care physician can see patients all day and do this kind of research as well. You only have so much energy and so much time in the day.”

—LAUREN OSHMAN, MD, CHICAGO, ILLINOIS

reau estimates that half of all collection accounts on credit reports are due to medical debt, and many bankruptcies are linked to medical debt. A Kaiser Family Foundation study showed that deductibles rose eight times faster than wages in the past 10 years.

High costs affect patients’ healthcare decisions, the Commonwealth Fund study found. Forty percent of adults with deductibles that amounted to 5% or more of income reported that because of their deductible they had not gone to the doctor when sick, did not get a preventive care test, skipped a recommended follow-up test, or did not get needed specialist care. Of adults with lower deductibles relative to their income, 21% said they did not get needed care because of their deductible.

Avoiding healthcare can harm patients immediately and in the future if problems get worse because they’re not treated. Minor problems become major and major ones can become life-threatening. Ellis notes that the laxatives prescribed for his recent colonoscopy cost $180. Add that cost to a procedure many patients are reluctant to undergo anyway and it only increases the likelihood that people will skip it.

CONSIDERING CARE ALONE

Not all physicians feel a responsibility to consider their patients’ financial situation.

Greg Fihn, DO, a primary care physician in Las Vegas, is sympathetic when his patients complain about costs and he prescribes generics and shares drug makers’ coupons when he can, but doesn’t feel it’s his duty to go beyond that. He says he was never trained to take patient costs into account.

“There are things [patients] could get done and treatments they could receive, but they can’t because of the cost,” he says. “Depending on the importance of the patient profile of care, I tell them this is important, they need to save up.”

Carrie Horwitch, MD, FACP, MPH, chairs the American College of Physicians (ACP) Ethics, Professionalism and Human Rights Committee. The Seattle internist says the organization advocates judicious and appropriate use of medical resources while avoiding unnecessary expenses.

Horwitch says discussing patients’ ability to afford treatment should be part of informed decision-making, but warns against letting it become too great a factor. “Cost is always secondary, or even tertiary, to the overall care of the patient,” she says.

Ellis says he will do what he can to help patients but, in the end, “I am a physician. I will prescribe what I think helps you heal.”

COST AS A SIDE EFFECT

Others argue that prescribing treatment without taking into account its financial impact on patients is short-sighted and ignores a huge factor in determining whether a treatment will be effective.

Gary Seto, MD, a primary care physician in Pasadena, California, says he considers costs similar to a side effect of a drug or procedure. “I think it is part of any practice to find the best way to balance the cost of the treatment,” he says. “I try to frame everything as a cost-benefit solution.”

His methods include, when appropriate, ordering prescriptions in larger doses than necessary and telling patients to cut them in half, instructing patients how to look for low-cost pharmaceuticals and even sometimes recommending herbal supplements rather than prescription drugs, such as honey for a cough or ginger for menstrual cramps. “I’m not an alternative medicine doctor by any means, but when there is something available that has the same effect as medicine, I have no problems prescribing it,” he says.

Sometimes, doctors don’t take costs into account because they don’t know how expensive drugs and procedures are, says Samir Qamar, MD, a primary care practitioner in Las Vegas and founder of MedLion, a direct primary care model. Whenever he addresses a group of doctors, he asks them the cost of the last CT scan they ordered. Typically, no one knows, he says.

MedLion lowers costs using methods as telemedicine and negotiated discounts for lab services. “There has to be a desire on the part of our physicians to help patients save money on healthcare costs,” Qamar says.

HAVING THE TALK

How do physicians broach the potentially touchy subject of whether a patient can afford a drug, test or treatment?

Sometimes, they don’t have to. Physicians interviewed for this article said patients are increasingly likely to ask about costs and speak up if it’s more than they can afford.

Ellis says he often sees this at the urgent care center he owns in Youngstown. Many patients will argue the cost and demand dis-
There are many resources for patients and physicians who want to keep healthcare costs down:

**Prescriptions**

*Manufacturers* — Many pharmaceutical manufacturers offer free or discounted medications. A free service run by the industry, Partnership for Prescription Assistance, can link patients to the manufacturer of drugs. Many manufacturers’ sites also offer discounts and coupons.

*Drug discount cards* — These promise savings on drugs not covered by insurance. There are many programs, such as Together Rx Access and one offered by Caremark and the National League of Cities. Patients should research these carefully to find the one that works best for them.

*$4 generics* — A number of pharmacies and retailers, including Wal-Mart, Kroger, Target and Winn-Dixie, sell popular generic medications for $4 or $10. And warehouse clubs like Costco and Sam’s Club will sell drugs to non-members.

*GoodRx* — Searches local pharmacies for low-cost prescription drugs, discounts and coupons. Free to users. Similar services include WeRx and LowestMed.

**Medical Procedures**

Independent imaging centers typically charge less for MRIs, CTs and ultrasounds than do hospitals. Physicians can check the rates of local centers and send patients to the least expensive one. Companies like NeedyMeds and New Choice Health make it easy to compare prices.

**Cash**

Many clinics and hospitals offer deep discounts to those who pay cash. Of course, many patients can’t afford even that, but it can be an option worth exploring. However, in some cases, these arrangements are forbidden by the contract between insurers and providers.

**Insurance**

Uninsured patients might not know that they are eligible for insurance subsidies under the Affordable Care Act or other state and federal insurance programs. Staff can help enroll eligible patients. Others might be unaware that preventative services are free.

Advise insured patients about to undergo a procedure to check that every medical professional and facility involved is in their network. Even if everything else is covered, an unexpected bill from an out-of-network anesthesiologist can be a shock.

**Other Resources**

Sometimes, hospitals and large healthcare systems offer free screenings and tests during community health fairs and outreach programs. Local governments also frequently organize similar events, usually aimed at low-income populations. A physician’s office can ask local health networks and health departments to notify them of these events when they occur and pass the information on to patients.

**Labs**

Some businesses offer blood, urine and other tests at discount prices, sometimes without a prescription or doctor’s order. Typically, a patient orders a test online, visits a local lab and gets the results online, which they can then share with their physicians. Examples include DirectLabs and LabCorp. Free clinics and government health departments often offer free HIV and STD testing.

Some patients are reluctant to admit financial problems. Still others might not know they face a problem until they get the bill or fill a prescription. Many patients are unaware of healthcare costs or are unfamiliar with what their insurance covers. And those patients might decide they can’t afford treatment. “The doctor never finds out until the patient comes back and says they never filled the prescription,” says Qamar.
Doctors shouldn’t assume insured patients can pay for care. Shrinking coverage and rising deductibles make care out of reach for them, too.

Lynne Lillie, MD, a primary care practitioner in Rochester, Minnesota, says she raises the question of affordability in the exam room. “To be able to talk about the cost of care is very important,” she says. “There are folks who very much appreciate having their physicians consider the healthcare costs and take other factors into consideration.”

Sometimes, she says, the physician must talk a patient out of an unnecessary and expensive procedure they’ve requested. That can raise fears of withholding care or misperceptions of Obamacare.

It’s practically impossible, for physicians in multiple payer networks to know the details and costs for each patient’s plan. The best advice is to tell the patient to research their coverage and check with healthcare professionals to learn what’s covered.

**TIME IS MONEY**

Actively trying to save patients money places another burden on already overtaxed doctors.

Oshman says it took her and her nurse about four hours on the phone to find her diabetic patient drugs he could afford, time for which she is not reimbursed. She described that case as a victory, but she’s had others where she’s been unable to help her patients get healthcare they can afford.

“There has to be a desire on the part of our physicians to help patients save money on healthcare costs.”

— Samir Qamar, MD, Medlion, Las Vegas, Nevada

“You really need a team,” she says. “There is no way a primary care physician can see patients all day and do this kind of research as well. You only have so much energy.”

All of the work doesn’t need to be done by the doctor. Motivated patients can take steps to save themselves money without compromising care; sometimes, all it takes is for the physician to make them aware.

Some say the medical home model offers the best option for controlling costs because it eliminates redundancies, coordinates care and incorporates non-medical resources.

“It’s about the right care at the right place at the right time.” “If we do this right, we’re going to see people save money.”

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