SURVIVING MERGER MANIA

What healthcare consolidation means for physicians and patients

EMPLOYMENT CONTRACTS
RED FLAGS TO WATCH FOR

EHR UPGRADES
IS YOUR SYSTEM FALLING BEHIND?
NEXPLANON is indicated for use by women to prevent pregnancy.

SELECTED SAFETY INFORMATION

Who is not appropriate for NEXPLANON

- NEXPLANON should not be used in women who have known or suspected pregnancy; current or past history of thrombosis or thromboembolic disorders; liver tumors, benign or malignant, or active liver disease; undiagnosed abnormal genital bleeding; known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past; and/or allergic reaction to any of the components of NEXPLANON.

WARNINGS and PRECAUTIONS

Complications of insertion and removal

- NEXPLANON should be inserted subdermally and be palpable after insertion. Palpate immediately after insertion to ensure proper placement. Undetected failure to insert the implant may lead to unintended pregnancy. Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.

- Insertion and removal-related complications may include pain, paresthesias, bleeding, hematoma, scarring, or infection. If NEXPLANON is inserted too deeply (intramuscular or in the fascia), neural or vascular injury may occur. Implant removal may be difficult or impossible if the implant is not inserted correctly, inserted too deeply, not palpable, encased in fibrous tissue, or has migrated. If at any time the implant cannot be palpated, it should be localized and removal is recommended.

- There have been postmarketing reports of implants located within the vessels of the arm and the pulmonary artery, which may be related to deep insertions or intravascular insertion. Endovascular or surgical procedures may be needed for removal.

NEXPLANON and pregnancy

- Be alert to the possibility of an ectopic pregnancy in women using NEXPLANON who become pregnant or complain of lower abdominal pain.

- Rule out pregnancy before inserting NEXPLANON.

Educate her about the risk of serious vascular events

- The use of combination hormonal contraceptives increases the risk of vascular events, including arterial events [stroke and myocardial infarction (MI)] or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis (DVT), retinal vein thrombosis, and pulmonary embolism). Women with risk factors known to increase the risk of these events should be carefully assessed. Postmarketing reports in women using the nonradiopaque etonogestrel implant have included pulmonary emboli (some fatal), DVT, MI, and stroke. NEXPLANON should be removed if thrombosis occurs.
SELECTED SAFETY INFORMATION (continued)

• Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, NEXPLANON should not be used prior to 21 days postpartum.

• Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Consider removing the NEXPLANON implant if case of long-term immobilization due to surgery or illness.

Counsel her about changes in bleeding patterns

• Women are likely to have changes in their menstrual bleeding pattern with NEXPLANON, including changes in frequency, intensity, or duration. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy. In clinical studies of the non-radiopaque etonogestrel implant, changes in bleeding pattern were the most common reason reported for stopping treatment (11.1%). Counsel women regarding potential changes they may experience.

Be aware of other serious complications, adverse reactions, and drug interactions

• Remove NEXPLANON if jaundice occurs.

• Remove NEXPLANON if blood pressure rises significantly and becomes uncontrolled.

• Prediabetic and diabetic women using NEXPLANON should be carefully monitored.

• Carefully observe women with a history of depressed mood. Consider removing NEXPLANON in patients who become significantly depressed.

• The most common adverse reactions (≥10%) reported in clinical trials were headache (24.9%), vaginitis (14.5%), weight increase (13.7%), acne (13.5%), breast pain (12.8%), abdominal pain (10.9%), and pharyngitis (10.5%).

• Drugs or herbal products that induce enzymes, including CYP3A4, may decrease the effectiveness of NEXPLANON or increase breakthrough bleeding.

• The efficacy of NEXPLANON in women weighing more than 130% of their ideal body weight has not been studied. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. Therefore, NEXPLANON may be less effective in overweight women.

• Counsel women to contact their health care provider immediately if, at any time, they are unable to palpate the implant.

• NEXPLANON does not protect against HIV or other STDs.

Please read the adjacent Brief Summary of the Prescribing Information

NEXPLANON must be inserted by the expiration date stated on the packaging. NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive implant. The implant should be inserted within 3 years of the expiration date stated on the packaging. NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive implant. The implant should be inserted within 3 years of the expiration date stated on the packaging. NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive implant. The implant should be inserted within 3 years of the expiration date stated on the packaging. NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive implant. The implant should be inserted within 3 years of the expiration date stated on the packaging. NEXPLANON is a long-acting (up to 3 years), reversible, hormonal contraceptive implant. The implant should be inserted within 3 years of the expiration date stated on the packaging. 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14. Fluid Retention
Hormonal contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention. It is unknown if NEXPLANON causes fluid retention.

15. Contact Lenses
Contact lens wearers who develop visual changes or less tolerance should be assessed by an ophthalmologist.

16. In Situ Broken or Bent Implant
There are reports of broken or bent implants while in the patient’s arm. Based on e vitro data, when an implant is broken or bent, the release rate of etonogestrel may be slightly increased. When an implant is removed, it is important to remove it in its entirety (see Dosage and Administration).

17. Monitoring
A woman who is using NEXPLANON should have a yearly visit with her healthcare provider for a blood pressure check and for other indicated health care.

18. Drug-Laboratory Test Interactions
Some drugs or herbal products that may decrease the effectiveness of HCs include efavirenz, phenytoin, including cytochrome P450 3A4 (CYP3A4), may decrease the plasma concentrations of HCs and concomitant medications to identify potential interactions.

Adverse reactions that resulted in a rate of discontinuation of ≥1% are shown in Table 3.

Table 3: Adverse Reactions Leading to Discontinuation of Treatment in 1% or More of Subjects in Clinical Trials of the Non-Radioactive Etonogestrel Implant (IMPLANON)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>All Studies N = 942</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding irregularities*</td>
<td>11.1%</td>
</tr>
<tr>
<td>Emotional Lability†</td>
<td>2.3%</td>
</tr>
<tr>
<td>Weight Increase</td>
<td>2.3%</td>
</tr>
<tr>
<td>Headache</td>
<td>1.6%</td>
</tr>
<tr>
<td>Acne</td>
<td>1.3%</td>
</tr>
<tr>
<td>Depression‡</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

*Includes “frequent”, “heavy”, “prolonged”, “spotting”, and other patterns of bleeding irregularity.
† Among US subjects (N=330), 2.4% experienced depression that led to discontinuation.
‡ Among US subjects (N=330), 6.1% experienced emotional lability that led to discontinuation.

Other adverse reactions that were reported by at least 5% of subjects in the non-radioactive etonogestrel implant clinical trials are listed in Table 4.

Table 4: Common Adverse Reactions Reported by ≥5% of Subjects in Clinical Trials With the Non-Radioactive Etonogestrel Implant (IMPLANON)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>All Studies N = 942</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>24.9%</td>
</tr>
<tr>
<td>Vaginitis</td>
<td>14.5%</td>
</tr>
<tr>
<td>Weight increase</td>
<td>13.7%</td>
</tr>
<tr>
<td>Acne</td>
<td>13.5%</td>
</tr>
<tr>
<td>Breast pain</td>
<td>12.8%</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>10.9%</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>10.5%</td>
</tr>
<tr>
<td>Leukocytosis</td>
<td>9.6%</td>
</tr>
<tr>
<td>Flu-like symptoms</td>
<td>7.6%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>7.2%</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>7.2%</td>
</tr>
<tr>
<td>Back pain</td>
<td>6.8%</td>
</tr>
<tr>
<td>Emotional lability</td>
<td>6.5%</td>
</tr>
<tr>
<td>Nausea</td>
<td>6.4%</td>
</tr>
<tr>
<td>Pain</td>
<td>5.6%</td>
</tr>
<tr>
<td>Nervousness</td>
<td>5.6%</td>
</tr>
<tr>
<td>Depression</td>
<td>5.5%</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>5.4%</td>
</tr>
<tr>
<td>Insertion site pain</td>
<td>5.2%</td>
</tr>
</tbody>
</table>

In a clinical trial of NEXPLANON, in which investigators were asked to examine the implant site after insertion, implant site reactions were reported in 8.6% of women. Erythema was the most frequent implant site complication, reported during and/or shortly after insertion, occurring in 3.2% of subjects. Additionally, hematomas (3.0%), bruising (2.0%), pain (1.1%), and swelling (0.7%) were reported.

Effects of Other Drugs on Hormonal Contraceptives
Substances decreasing the plasma concentrations of hormonal contraceptives (HCs) and potentially diminishing the efficacy of HCs: Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the plasma concentrations of HCs and potentially diminish the effectiveness of HCs or increase breakthrough bleeding.

Some drugs or herbal products that may decrease the effectiveness of HCs include etonogestrel, phenylbutazone, barbiturates, carbamazepine, benzphetamine, felbamate, griseofulvin, oxcarbazepine, rifampicin, lamotrigine, valproic acid, and, products containing St John’s wort. Interactions between HCs and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Counsel women on an alternative non-hormonal method of contraception or a back-up method when enzyme inducers are used with HCs, and to continue back-up non-hormonal contraception for 28 days after discontinuing the enzyme inducer to ensure contraceptive reliability.

Substances increasing the plasma concentrations of HCs: Co-administration of certain HCs and strong or moderate CYP3A4 inhibitors such as itraconazole, voriconazole, fluconazole, grapefruit juice, or ketoconazole may increase the plasma concentrations of progestins, including etonogestrel.

Hormonal contraceptives may affect the metabolism of other drugs. Consequently, plasma concentrations may either increase (for example, cyclosporine) or decrease (for example, lamotrigine). Consult the labeling of all concurrently-used drugs to obtain further information about interactions with hormonal contraceptives or the potential for enzyme alterations.

USE IN SPECIFIC POPULATIONS

1. Pregnancy
Risk Summary
NEXPLANON is contraindicated during pregnancy because there is no need for pregnancy prevention in a woman who is already pregnant (see Contraindications). Epidemiologic studies and meta-analyses have not shown an increased risk of genital or non-genital birth defects (including cardiac anomalies and limb-reduction defects) following maternal exposure to low dose CHCs prior to conception or during early pregnancy. No adverse development outcomes were observed in pregnant rats and rabbits with the administration of etonogestrel during organogenesis at doses of 315 or 781 times the anticipated human dose (60 μg/day) NEXPLANON should be removed if maintaining a pregnancy.

2. Nursing Mothers
Lactation
Risk Summary
Small amounts of contraceptive steroids and/or metabolites, including etonogestrel are present in human milk. No significant adverse effects have been observed in the production or quality of breast milk, or on the physical and psychomotor development of breastfed infants. Hormonal contraceptives, including etonogestrel, can reduce milk production in breastfeeding mothers. This is less likely to occur when etonogestrel is established; however, it can occur at any time in some women. When possible, advise the nursing mother about both hormonal and non-hormonal contraceptive options, as steroids may not be the initial choice for these patients. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for NEXPLANON and any potential adverse effects on the breastfed child from NEXPLANON or from the underlying maternal condition.

3. Pediatric Use
Safety and efficacy of NEXPLANON have been established in women of reproductive age. Safety and efficacy of NEXPLANON are not expected for postpubertal adolescents. However, no clinical studies have been conducted in women less than 18 years of age. Use of this product before menarche is not indicated.

4. Geriatric Use
The product has not been studied in women over 65 years of age and is not indicated in this population.

5. Hepatic Impairment
Risk Summary
No studies were conducted to evaluate the effect of hepatic disease on the disposition of NEXPLANON. The use of NEXPLANON in women with active liver disease is contraindicated (see Contraindications).

6. Overweight Women
The effectiveness of the etonogestrel implant in women who weighed more than 130% of their ideal body weight has not been defined because such women were not studied in clinical trials. Serum concentrations of etonogestrel are inversely related to body weight decrease with time after implant insertion. It is therefore possible that NEXPLANON may be less effective in overweight women, especially in the presence of other factors that decrease serum etonogestrel concentrations such as concomitant use of hepatic enzyme inducers.

OVERDOSE
Overdose may result if more than one implant is inserted. In case of suspected overdose, the implant should be removed.

NONCLINICAL TOXICOLOGY
In a 24-month carcinogenicity study in rats with subdermal implants releasing 10 and 20 mg etonogestrel per day (equivalent to approximately 1.8-3.6 times the systemic steady state exposure in women using NEXPLANON), no drug-related carcinogenic potential was observed. Etonogestrel was not genotoxic in the in vitro Ames/Salmonella reverse mutation assay, the chromosomal aberration assay in Chinese hamster ovary cells or in the in vivo mouse micronucleus test. Fertility in rats returned after withdrawal from treatment.

PATIENT COUNSELING INFORMATION
See FDA-Approved Patient Labeling.

Contraindication about the insertion of NEXPLANON implant. Provide the woman with a copy of the Patient Labeling and ensure that she understands the information in the Patient Labeling before insertion and removal. A USER CARD and consent form are included in the packaging. Have the woman complete a consent form and retain it in your records. The USER CARD should be filled out and given to the woman after insertion of the NEXPLANON implant so that she will have a record of the location of the implant in the upper arm and when it should be removed.

Counsel women to contact their healthcare provider immediately if, at any time, they are unable to palpate the implant.

Counsel women that NEXPLANON does not protect against HIV or other STDs.

Counsel women that the use of NEXPLANON may be associated with changes in their normal menstrual bleeding patterns so that they know what to expect.

For more detailed information, please read the Prescribing Information.

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Don’t drink the healthcare consolidation Kool-Aid

Don’t be fooled. When mergers occur, patients and physicians lose; executives at the top are the only ones who truly win.

The troubling trend of healthcare consolidation is gaining momentum, and Americans are paying a heavy price. Not only is this merger mania destroying our nation’s healthcare system, it’s also decimating our middle class. However, if consolidation is healthcare’s cancer, consumers are the cure.

Every week, we hear reports of hospitals buying up doctor’s practices and merging with other hospitals. For example: Advocate Health Care and Aurora Health Care finalized their $11 billion deal last April to form the nation’s 10th largest tax-exempt health system; Dignity Health and Catholic Health Initiatives are marching toward a $28 billion deal.

More recently, we’ve heard about insurers merging with health providers and retail pharmacies: UnitedHealth’s subsidiary Optum is buying DaVita Medical Group, a group of several hundred independent doctors and clinics, for nearly $5 billion. In April, Medicare insurance giant Humana bought 22-clinic Family Physicians Group in Central Florida. Now rumor has it Walmart might buy Humana. And, of course, CVS Health Corp. and Aetna continue to move toward their $69 billion union.

Many, many similar but smaller deals occur weekly.

Mergers were up 13 percent last year, setting a record for the most healthcare mergers and acquisitions in recent history, according to a Kaufman Hall report. The first quarter of 2018 was the busiest start for healthcare mergers in over a decade, according Bloomberg.

None of this bodes well for consumers.

Regardless of what the merging parties say about streamlining care and greater efficiencies, when healthcare entities merge, costs only go one way: up, way up. Ask those trying to convince you of the benefits to point to one study that shows costs go down after a merger, or that quality goes up. They can’t.

A recent study from the nonprofit Physicians Advocacy Institute reported that hospitals buying up doctors’ practices was the leading driver in soaring Medicare costs. Between 2012 and 2015, Medicare costs rose $3.1 billion, primarily due to the 49 percent uptick in hospital-employed doctors that occurred over the same period. And that study only looked at four procedures. Imagine the tally if all procedures were accounted for.

When hospitals merge, price increases on the order of 20 percent to 30 percent are common, and can exceed 50 percent, Carnegie Mellon University economist Martin Gaynor said in a recent report. What’s more, he added, many studies have found that patient health outcomes are substantially worse at hospitals in concentrated markets where there is less competition.

The only parties who benefit when healthcare entities merge are the executives at the top.

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Meanwhile, consumers foot the bill in the way of higher premiums and more tax dollars going to pay for healthcare.

THE CURE FOR CONSOLIDATION CANCER

Meanwhile, consumers foot the bill in the way of higher premiums and more tax dollars going to pay for healthcare.
“As physicians, we can start to change the market by... educating patients about why they, too, must only go to independent doctors”

No wonder healthcare bills are the number one reason Americans declare bankruptcy, and healthcare costs consume 20 percent of the average family’s budget.

Yet health entities continue to merge, grow, gain market share, and increase their bargaining power with payers. The bigger they are, the more they get. So the mergers continue. Until someone does something. But who?

Not the hospitals. They lobbied hard to get the system here, and they’re profiting handsomely. Every time they merge, they profit more.

Not the insurance companies. They have no incentive to bring premiums down, especially because under the Affordable Care Act’s “Medical Loss Ratio” rule insurers can keep only 20 percent of every healthcare dollar, and put at least 80 percent must go toward claims, or rebate the rest.

Though presumably well-intentioned, the government’s plan backfired. Insurers quickly figured that 20 percent of a higher premium is more than 20 percent of lower one, so guess which way premiums have gone?

Not lawmakers. An eye-opening visit to opensecrets.com will tell you how much money your representative gets in campaign funding from hospitals and insurance companies. The American Hospital Association alone spent $22 million in 2017 lobbying lawmakers.

That leaves the rest of us. Educated consumers and brave physicians are the cure for consolidation cancer.

As physicians, we can start to change the market by remaining or becoming independent, by referring only to other independent doctors and free-standing outpatient centers, and by educating patients about why they, too, must only go to independent doctors.

We also must push for transparency in healthcare pricing, so consumers can shop for healthcare based on price and value, and—most important—we must just say no when slick-talking executives come to town serving up pitchers of “consolidation Kool-Aid.”

If we don’t, we can expect a lot more of our money to pour directly into health executives’ pockets, covering the costs for their skyboxes.

Marni Jameson Carey is executive director of the Association of Independent Doctors, a national nonprofit organization. Before joining AID, she was a senior health reporter for Tribune Media, writing for the Los Angeles Times and the Orlando Sentinel. A nationally syndicated columnist, Carey is also the author of four books. She can be reached at info@aid-us.org.
Cover: Sebastian Kaulitzki/Science Photo Library/Getty Images

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SMATER BUSINESS. BETTER PATIENT CARE.
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Interactive
Your voice
Vitals
Our adviser
Funny Bone
The AGA recommends PEG laxatives (like MiraLAX) as a first-line constipation treatment¹

✔ 96% patient satisfaction rate*
✔ #1 GI-recommended laxative for over 10 years

Start with MiraLAX for proven relief of occasional constipation.

Use as directed on product labeling or as directed by your doctor.
Bayer, the Bayer Cross, and MiraLAX are trademarks of Bayer.
Empower staff to drive revenue cycle performance

As payer reimbursements shrink and the number of high-deductible health plans grows, healthcare organizations must find new ways to optimize their revenue cycles to increase patient and payer collections. One often overlooked strategy is better investing in revenue cycle staff so they more consistently and capably perform their jobs.

Regular and comprehensive training is a good first step in engaging revenue cycle staff. The training should focus on the tasks involved in a staff person’s job, as well as communicate where the individual fits in the broader revenue cycle department—and the impact of his or her performance on others.

For example, front-end staff should understand the importance of correctly entering patient demographic and insurance information and how errors could have downstream effects for the back-end staff such as significant rework, delayed payments, and denials.

Front-end staff also should appreciate the value of sharing an estimate with patients and collecting payment at the time of service, rather than having the back-end staff follow up with patients after the encounter. Individuals are less likely to pay in a timely fashion or in full if the request for payment comes after the care episode ends.

Organizations should consider incorporating team-building exercises that partner front-end and back-end staff into training. These exercises can help the two groups get to know one another better and build collaborative relationships. When everyone feels they are on the same team and striving for the same goals, they are more likely to think creatively about different ways to solve problems.

Staff should also receive training on interacting with patients. In most cases, patient access or front desk staff are patients’ first person-to-person point of contact. Similarly, the billing and collections staff are frequently the last interaction patients have before their care encounter ends.

MORE ONLINE For the rest of the story, visit bit.ly/empower-staff-drive-revenue.

Slideshow spotlight

Navigating patients’ medical cannabis questions

Despite the growing popularity of cannabis for both medical and recreational use among the general population, it is still a touchy subject for medical professionals. If patients are asking questions about medical cannabis and its benefits, here are some tips to help physicians navigate the questions and get patients the answers that they need.

To view, visit bit.ly/patient-medical-cannabis-questions.
Nurse practitioners are critical providers of patient care

Since when did physicians allow insurance companies to decide what medicines a patient can have? Insurance companies are playing with patients’ lives. The idea of a “prior authorization” is demeaning, and intensely frustrating. This is why doctors are burned out. I want our medical associations to reverse this so that an insurance company needs MY prior authorization to change any medicine that I prescribed. Let them ask me if it’s OK to give the diabetic patient Trident instead of Januvia. My prescription order should mean something after the years I went to medical school to earn the privilege to write it!

Gayathri Raju, DO
HOFFMAN ESTATES, ILL.

“NPs have been providing primary, acute and specialty care to patients of all ages and walks of life for nearly half a century.”

Physicians, not payers, should control prior authorizations

Joyce M. Unstruck, Ph.D., C-FNP, APRN, FAANP
President, American Association of Nurse Practitioners

Since when did physicians allow insurance companies to decide what medicines a patient can have? Insurance companies are playing with patients’ lives. The idea of a “prior authorization” is demeaning, and intensely frustrating. This is why doctors are burned out. I want our medical associations to reverse this so that an insurance company needs MY prior authorization to change any medicine that I prescribed. Let them ask me if it’s OK to give the diabetic patient Trident instead of Januvia. My prescription order should mean something after the years I went to medical school to earn the privilege to write it!

Gayathri Raju, DO
HOFFMAN ESTATES, ILL.

“My prescription order should mean something after the years I went to medical school to earn the privilege to write it!”
Your patients are stressed out by healthcare costs

It’s not uncommon for patients to be anxious when seeing their doctor. But the largest source of patient anxiety is not health concerns—it’s whether they can afford treatment. A recent patient survey conducted by the Transamerica Center for Health Studies found that issues relating to the cost of receiving healthcare is one of the major stressors on the life of American adults, with 62% saying that healthcare costs is a major source of stress, second only to general money concerns (72%). Here’s are three findings from this survey:

**FINDING 1:**
Patients say healthcare is too expensive

- **Affordability**
  - **1 in 5** patients say they cannot afford routine healthcare expenses, including prescription drugs.
  - **79%** of patients surveyed say pharma companies are responsible for high prices.
  - **69%** of patients pay significant healthcare expenses by using:
    - savings (35%)
    - credit cards (28%)
    - disposable income (24%)
    - loans from family members (8%)
    - 401(k) account withdrawals (6%)
  - **1 in 3** Americans saw an increase in their premiums, out-of-pocket expenses and deductibles in 2018.

**FINDING 2:**
Americans are “extremely concerned” about healthcare policy changes concerning pre-existing conditions

- **Pre-existing condition**
  - **35%** of all adults fear losing coverage because of a pre-existing condition if healthcare laws change.

- **Chronic condition**
  - **62%** of patients said they have a chronic condition.

**FINDING 3:**
The nation remains divided on the Affordable Care Act

- **Government mandate**
  - **56%** of respondents do not believe the government should mandate health coverage.

The patients who feel this way are overwhelmingly:

<table>
<thead>
<tr>
<th>Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>60%</td>
</tr>
<tr>
<td>Baby Boomers</td>
<td>63%</td>
</tr>
<tr>
<td>Live in rural areas</td>
<td>66%</td>
</tr>
</tbody>
</table>

Source: “Stressed Out: Americans and Healthcare,” Transamerica Center for Health Studies, August 2018
The forces driving the latest wave of consolidation in healthcare and what it means for doctors and their patients

by JEFFREY BENDIX, senior editor

When doctors talk about the biggest challenges facing the profession, they generally focus on topics such as burnout, the shortcomings of EHRs, and the transition to value-based care. Often overlooked, however, is the rapid consolidation taking place throughout the healthcare industry, a trend with profound implications for the availability and affordability of medical care.

Whether it's hospitals buying up independent medical practices, hospital systems swallowing one another, or insurance companies merging with pharmacy chains, the prevailing attitude now is that bigger is better.

Among providers, that sentiment results in part from the uncertainty created by shifting payment models and competition from new entrants in the industry, says Anthony LoSasso, PhD, professor in health policy and administration at the University of Illinois-Chicago and executive director of the American Society of Health Economists.

"The feeling is that size will protect them [hospitals and doctors] in the face of new initiatives, be they market-driven or government-instituted policies," LoSasso says. "Essentially, they're trying to buy a seat at the table."

QUICKENING PACE

While consolidation hasn't received as much attention as, say, the price of prescription drugs, it's far from a new phenomenon. A 2014 study for the National Bureau of Economics Research, for example, noted that more than 1,000 hospital mergers had taken place since 1994. In 2015 Congressional testimony Leemore S. Dafny, PhD, now a
professor of business administration at the Harvard Business School, showed that in 2006 the four largest commercial insurers already controlled 74 percent of the health-care insurance market. (By 2014 it was 83 percent.)

That said, the pace of consolidation has increased dramatically in the last few years. Consider that in 2018 alone:

- Texas-based hospital systems Baylor Scott & White Health and Memorial Hermann Health announced plans to merge, creating a 68-hospital system with annual revenue of more than $14 billion.
- Philadelphia-based Jefferson University said it would acquire Einstein Healthcare Network, creating an 18-hospital system in and around Philadelphia.
- Cincinnati-based Mercy Health completed an $8 billion merger with Maryland-based Bon Secours Health System to form the nation’s fifth-largest Catholic health system, with 43 hospitals and more than 2,100 physicians.
- Summa Health, headquartered in Akron, Ohio, revealed it was seeking to merge or partner with another healthcare system.
- Drugstore chain CVS received government approval to buy Aetna, the country’s third-largest health insurance company, for $69 billion.
- Health insurance giant Cigna and pharmacy benefit manager Express Scripts received the government’s OK for their $52-billion merger.

All this activity follows a year that saw 967 merger and acquisition deals among healthcare payers and providers, according to the PwC Health Research Institute.

**DRIVERS OF CONSOLIDATION**

Experts cite a variety of motivations for the accelerating pace of mergers and acquisitions among healthcare providers, most of which involve the drive to grow revenue and profits.

That leads hospital systems, for example, to acquire primary care practices to increase the size of their patient base, ensure that patients are referred to specialists within their system, and take advantage of lucrative facility fees—the charges tacked on to services and procedures performed at a medical practice when it becomes part of a hospital system.

“The idea is, ‘let’s capture as much of the...
patient dollar and as much of the patient services as we can, and let’s keep it under one organizational umbrella,” explains Timothy Hoff, PhD, professor of healthcare systems and healthcare policy in the D’Amore-McKim School of Business at Northeastern University in Boston.

The movement toward value-based reimbursements is another catalyst for hospitals to buy independent primary care practices, Hoff says, in that it causes hospitals to broaden their focus beyond inpatient care and expensive surgical procedures.

“Essentially they [hospitals] are looking to reinvent themselves, and that involves placing more emphasis on services like primary care and population health,” Hoff says. That process, in turn, spurs hospital systems to acquire primary care practices and even establish new primary care “access points,” such as urgent care centers.

The result, Hoff says, is that even under value-based payment models, “consolidation will keep moving along because there are rewards for getting ahold of a patient population and providing them with a range of services, from prevention to primary care to acute care. And big hospital systems think that with more primary care access points they can be one-stop shops for all those kinds of services.”

Bringing more patients under a single corporate umbrella also gives hospital systems more leverage when negotiating with insurance companies, notes J.B. Silvers, PhD, professor of healthcare finance at Case Western Reserve University’s Weatherhead School of Management in Cleveland.

A payer can refuse to include an individual hospital in its network unless the hospital agrees to substantially discount its fees. “You had a pushback sentiment that said, ‘the reason you’re able to get away with that is I’m sitting out here by myself. But if I become part of a larger entity, then it shifts market power from the payer back to the provider,” Silvers explains.

The providers’ growth, in turn, motivates payers to get bigger so as to recapture some of their negotiating leverage, and to join forces with pharmacies and pharmacy benefit managers to try and bring prescription drug costs—a large and rapidly-growing expense—under control.

Meanwhile, independent practices—faced with the expense of EHRs and the staffing and data requirements of value-based care—often find they have little choice but to become part of a hospital system or merge with other practices.

A study commissioned by the Physicians Advocacy Institute released earlier this year found that hospitals acquired 5,000 independent practices between July of 2015 and 2016, and that 42 percent of the nation’s doctors were hospital-employed by July 2016. In 2012 it was 25 percent.

THE IMPACT ON PATIENTS
What’s good for the bottom line of healthcare providers, however, may not always be good for their patients.

“Consolidation [among hospital systems] is always pitched as a positive thing, that it will lead to lower costs and more investment in the things that bring higher quality care,” says Hoff. “But when you look at the research, the opposite of those things can often occur. In highly consolidated markets, patient choice of providers and services is often reduced, and quality can improve but in some cases has been shown either to stay the same or even go down.”

Will the consolidation trend reverse course?

“There’s very little evidence that [increasingly consolidated payers] are passing those savings along to consumers in the form of lower premiums or copays.”

— ERIC SCHNEIDER, MD, FACP, SENIOR VICE PRESIDENT FOR POLICY AND RESEARCH, THE COMMONWEALTH FUND

“There’s very little evidence that [increasingly consolidated payers] are passing those savings along to consumers in the form of lower premiums or copays.”

— ERIC SCHNEIDER, MD, FACP, SENIOR VICE PRESIDENT FOR POLICY AND RESEARCH, THE COMMONWEALTH FUND
**INDICATION**

- **GARDASIL 9** is a vaccine indicated in females 9 through 45 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by human papillomavirus (HPV) Types 16, 18, 31, 33, 45, 52, and 58; precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11.

- **GARDASIL 9** is indicated in males 9 through 45 years of age for the prevention of anal cancer caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11.

- **GARDASIL 9** does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening.

- Recipients of **GARDASIL 9** should not discontinue anal cancer screening if it has been recommended by a health care professional.

- **GARDASIL 9** has not been demonstrated to provide protection against diseases from vaccine HPV types to which a person has previously been exposed through sexual activity.

- **GARDASIL 9** is not a treatment for external genital lesions; cervical, vulvar, vaginal, and anal cancers; or cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VaIN), or anal intraepithelial neoplasia (AIN).

**INDICATION (continued)**

- Not all vulvar, vaginal, and anal cancers are caused by HPV, and **GARDASIL 9** protects only against those vulvar, vaginal, and anal cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.

- Vaccination with **GARDASIL 9** may not result in protection in all vaccine recipients.

**SELECT SAFETY INFORMATION**

- **GARDASIL 9** is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of **GARDASIL 9** or **GARDASIL®** [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].

- Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.

- Safety and effectiveness of **GARDASIL 9** have not been established in pregnant women.

- The most common (≥10%) local and systemic adverse reactions in females were injection-site pain, swelling, erythema, and headache. The most common (≥10%) local and systemic reactions in males were injection-site pain, swelling, and erythema.

- The duration of immunity of **GARDASIL 9** has not been established.

**DOSAGE AND ADMINISTRATION**

- **GARDASIL 9** should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

  - For individuals 9 through 14 years of age, **GARDASIL 9** can be administered using a 2-dose or 3-dose schedule. For the 2-dose schedule, the second dose should be administered 6–12 months after the first dose. If the second dose is administered less than 5 months after the first dose, a third dose should be given at least 4 months after the second dose. For the 3-dose schedule, **GARDASIL 9** should be administered at 0, 2 months, and 6 months.

  - For individuals 15 through 45 years of age, **GARDASIL 9** is administered using a 3-dose schedule at 0, 2 months, and 6 months.

Please read the adjacent Brief Summary of the Prescribing Information.
### BRIEF SUMMARY OF PRESCRIBING INFORMATION

#### Indications and Usage

**Girls and Women**

GARDASIL® 9 is a vaccine indicated in girls and women 9 through 45 years of age for the prevention of the following diseases:

- **Cervical, vulvar, vaginal, and anal cancer** caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58.

- **Genital warts** (condyloma acuminata) caused by HPV types 6 and 11.

- **Cervical intraepithelial neoplasia (CIN) grade 2/3** and cervical adenocarcinoma in situ (AIS).

- **Cervical intraepithelial neoplasia (CIN) grade 1**.

- **Vulvar intraepithelial neoplasia (VIN) grade 2** and grade 3.

- **Vaginal intraepithelial neoplasia (VaIN) grade 2** and grade 3.

- **Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3**.

**Boys and Men**

GARDASIL 9 is indicated in boys and men 9 through 45 years of age for the prevention of the following diseases:

- **Anal cancer** caused by HPV types 16, 18, 31, 33, 45, 52, and 58.

- **Genital warts** (condyloma acuminata) caused by HPV types 6 and 11.

- **Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3**.

**Limitations of Use and Effectiveness**

The health care provider should inform the patient, parent, or guardian that vaccination does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening. Women who receive GARDASIL 9 should continue to undergo cervical cancer screening per standards of care.

Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care provider.

GARDASIL 9 has not been demonstrated to protect against disease from vaccine HPV types to which a person has previously been exposed through sexual activity.

GARDASIL 9 has not been demonstrated to protect against diseases due to HPV types other than 6, 11, 16, 18, 31, 33, 45, 52, and 58.

GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, and anal cancers; CIN, VIN, VaIN, or AIN.

Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, and anal cancers caused by HPV 16, 18, 31, 33, 45, 52, and 58.

GARDASIL 9 does not protect against genital diseases not caused by HPV.

Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients.

#### Dosage

Each dose of GARDASIL 9 is 0.5-mL. Administer GARDASIL 9 as follows:

<table>
<thead>
<tr>
<th>Age</th>
<th>Regimen</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 through 14 years</td>
<td>2-dose</td>
<td>0, 6 to 12 months*</td>
</tr>
<tr>
<td>15 through 45 years</td>
<td>3-dose</td>
<td>0, 2, 6 months</td>
</tr>
</tbody>
</table>

*If the second dose is administered earlier than 5 months after the first dose, administer a third dose at least 4 months after the second dose.

#### Method of Administration

**For intramuscular use only.**

Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. GARDASIL 9 should not be diluted or mixed with other vaccines. After thorough agitation, GARDASIL 9 is a white, cloudy liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use the product if particulates are present or if it appears discolored.

Administer GARDASIL 9 intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

Observe patients for 15 minutes after administration.

#### CONTRAINDICATIONS

Hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or after a previous dose of GARDASIL 9 or GARDASIL®.

#### WARNINGS AND PRECAUTIONS

**Syncpe:** Because vaccines may develop syncpe, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncpe, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncpe is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.

**Managing Allergic Reactions:** Appropriate medical treatment and supervision must be readily available in case of anaphylactic reactions following the administration of GARDASIL 9.

#### ADVERSE REACTIONS

**Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

The safety of GARDASIL 9 was evaluated in seven clinical studies that included 15,703 individuals who received at least one dose of GARDASIL 9 and had safety follow-up. Study 1 and Study 2 also included 7,378 individuals who received at least one dose of GARDASIL 16 as a control and had safety follow-up. The vaccines were administered on the day of enrollment and the subsequent doses administered approximately two and six months thereafter. Safety was evaluated using vaccination report card (VRC)-aided surveillance for 14 days after each injection of GARDASIL 9 or GARDASIL 16.

The individuals who were monitored using VRC-aided surveillance included 9,087 girls and women 16 through 26 years of age, 1,394 boys and men 16 through 26 years of age, and 5,212 girls and boys 9 through 15 years of age (3,436 girls and 1,776 boys) at enrollment who received GARDASIL 9; and 7,078 girls and women 16 through 26 years of age and 300 girls 9 through 15 years of age at enrollment who received GARDASIL 16.

**Table 1: Rates (%) and Severity of Solicited Injection-Site and Systemic Adverse Reactions Occurring within Five Days of Each Vaccination with GARDASIL 9 Compared with GARDASIL (Studies 1 and 3)**

<table>
<thead>
<tr>
<th>Condition</th>
<th>GARDASIL 9</th>
<th>GARDASIL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post-dose 1</td>
<td>Post-dose 2</td>
</tr>
<tr>
<td>Pain, Any</td>
<td>N=7069</td>
<td>N=6979</td>
</tr>
<tr>
<td>Pain, Severe</td>
<td>70.7%</td>
<td>73.5%</td>
</tr>
<tr>
<td>Swelling, Any</td>
<td>0.7%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Systemic Adverse Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>N=6992</td>
<td>N=6743</td>
</tr>
<tr>
<td>Temperature ≥100°F</td>
<td>1.7%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Temperature ≥102°F</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

**Girls and Women 16 through 26 Years of Age**

**Injection-Site Adverse Reactions**

**Systemic Adverse Reactions**

**Girls 9 through 15 Years of Age**

**Injection-Site Adverse Reactions**

**Systemic Adverse Reactions**

**Table 2: Rates (%) and Severity of Solicited Injection-Site and Systemic Adverse Reactions Occurring within Five Days of Each Vaccination with GARDASIL 9**

<table>
<thead>
<tr>
<th>Condition</th>
<th>GARDASIL 9</th>
<th>GARDASIL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post-dose 1</td>
<td>Post-dose 2</td>
</tr>
<tr>
<td>Pain, Any</td>
<td>N=300</td>
<td>N=297</td>
</tr>
<tr>
<td>Pain, Severe</td>
<td>71.7%</td>
<td>71.0%</td>
</tr>
<tr>
<td>Swelling, Any</td>
<td>0.2%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Temperature ≥100°F</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature ≥102°F</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Erythema, Any**

**Erythema, Severe**

**Table 3: Rates (%) and Severity of Solicited Injection-Site and Systemic Adverse Reactions Occurring within Five Days of Each Vaccination with GARDASIL 9**

<table>
<thead>
<tr>
<th>Condition</th>
<th>GARDASIL 9</th>
<th>GARDASIL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post-dose 1</td>
<td>Post-dose 2</td>
</tr>
<tr>
<td>Pain, Any</td>
<td>N=300</td>
<td>N=297</td>
</tr>
<tr>
<td>Pain, Severe</td>
<td>0%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>
GARDASIL® 9 Human Papillomavirus, 9-valent Vaccine, Recombinant

Table 1 (continued)

<table>
<thead>
<tr>
<th>Systemic Adverse Reactions</th>
<th>n=300</th>
<th>n=299</th>
<th>n=285</th>
<th>n=268</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature ≥100°F</td>
<td>2.3</td>
<td>1.7</td>
<td>2.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Temperature ≥102°F</td>
<td>0.3</td>
<td>1.0</td>
<td>1.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

The data for girls and women 16 through 26 years of age are from Study 1 (NCT01654354), and the data for girls 9 through 15 years of age are from Study 3 (NCT01304498). N=number of subjects vaccinated with safety follow-up.

Table 2: Rates (%) of Unsolicited Injection-Site and Systemic Adverse Reactions Occurring among ≥1.0% of Individuals after Vaccination with GARDASIL 9 Compared with GARDASIL (Studies 1 and 3)

<table>
<thead>
<tr>
<th></th>
<th>Girls and Women 16 through 26 Years of Age</th>
<th>Boys and Men 16 through 26 Years of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GARDASIL 9 (Studies 1 and 3)</td>
<td>Study 4 (NCT00543543)</td>
</tr>
<tr>
<td>Injection-Site Adverse Reactions (1 to 5 Days Post-Vaccination, Any Dose)</td>
<td>N=7071</td>
<td>N=639</td>
</tr>
<tr>
<td>Pruritus</td>
<td>5.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Bruising</td>
<td>1.9</td>
<td>1.5</td>
</tr>
<tr>
<td>Hematoma</td>
<td>0.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Mass</td>
<td>1.3</td>
<td>0.6</td>
</tr>
<tr>
<td>Headache</td>
<td>1.4</td>
<td>1.0</td>
</tr>
<tr>
<td>Induration</td>
<td>0.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Reaction</td>
<td>0.6</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Systemic Adverse Reactions (1 to 15 Days Post-Vaccination, Any Dose)

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Girls 9 through 15 Years of Age</th>
<th>Boys and Men 16 through 26 Years of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pruritus</td>
<td>14.6</td>
<td>13.7</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>5.0</td>
<td>4.3</td>
</tr>
<tr>
<td>Nausea</td>
<td>4.4</td>
<td>3.7</td>
</tr>
<tr>
<td>Dizziness</td>
<td>3.0</td>
<td>2.8</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2.3</td>
<td>2.1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1.2</td>
<td>1.0</td>
</tr>
<tr>
<td>Dysphagia pain</td>
<td>1.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Myalgia</td>
<td>1.0</td>
<td>0.7</td>
</tr>
<tr>
<td>Nervous system pain, upper</td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>0.1</td>
<td>0.8</td>
</tr>
</tbody>
</table>

Table 3: Rates (%) of Solicited and Unsolicited Injection-Site and Systemic Adverse Reactions among Boys 9 through 15 Years of Age and among Boys and Men 16 through 26 Years of Age Who Received GARDASIL 9 (Studies 2 and 7)

<table>
<thead>
<tr>
<th></th>
<th>GARDASIL 9</th>
<th>Study 2 (NCT01651949)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solicited Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)</td>
<td>N=1394</td>
<td></td>
</tr>
<tr>
<td>Injection-Site Pain, Any</td>
<td>63.4</td>
<td>63.2</td>
</tr>
<tr>
<td>Injection-Site Pain, Severe</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Injection-Site Erythema, Any</td>
<td>20.7</td>
<td>20.7</td>
</tr>
<tr>
<td>Injection-Site Erythema, Severe</td>
<td>0.4</td>
<td>0.4</td>
</tr>
<tr>
<td>Injection-Site Swelling, Any</td>
<td>20.2</td>
<td>20.2</td>
</tr>
<tr>
<td>Injection-Site Swelling, Severe</td>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>Oral Temperature ≥100.0°F</td>
<td>4.4</td>
<td>4.4</td>
</tr>
<tr>
<td>Oral Temperature ≥102°F</td>
<td>0.6</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Table 3 (continued)

<table>
<thead>
<tr>
<th>Unsolicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)</th>
<th>N=639</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection-Site Pyrexia</td>
<td>7.3</td>
</tr>
<tr>
<td>Injection-Site Fatigue</td>
<td>2.4</td>
</tr>
<tr>
<td>Injection-Site Dizziness</td>
<td>1.4</td>
</tr>
<tr>
<td>Injection-Site Nausea</td>
<td>1.1</td>
</tr>
</tbody>
</table>

Unsolicited Systemic Adverse Reactions (1-15 Days Post-Vaccination, Any Dose)

<table>
<thead>
<tr>
<th>Unsolicited Systemic Adverse Reactions (1-15 Days Post-Vaccination, Any Dose)</th>
<th>N=639</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>9.4</td>
</tr>
<tr>
<td>Injection-Site Pyrexia</td>
<td>8.9</td>
</tr>
<tr>
<td>Injection-Site Nausea</td>
<td>1.3</td>
</tr>
</tbody>
</table>

The data for boys and men 16 through 26 years of age are from Study 2 (NCT00943722). The data for boys and men 16 through 26 years of age for GARDASIL 9 are from Study 7 (NCT01304498).

Serious Adverse Events in Clinical Studies: Serious adverse events were collected throughout the entire study period (range one month to 48 months post-last dose) for the seven clinical studies for GARDASIL 9. Out of the 15,705 individuals who were administered GARDASIL 9 and had safety follow-up, 354 reported a serious adverse event; representing 2.3% of the population. As a comparison, of the 7,378 individuals who were administered GARDASIL and had safety follow-up, 185 reported a serious adverse event, representing 2.5% of the population. Four GARDASIL 9 recipients each reported at least one serious adverse event that was determined to be vaccine-related. The vaccine-related serious adverse reactions were pyrexia, allergy to vaccine, asthmatic crisis, and headache.

Deaths in the Entire Study Population: Across the clinical studies, ten deaths occurred (five each in the GARDASIL 9 and GARDASIL groups); none were assessed as vaccine-related. Causes of death in the GARDASIL 9 group included one automobile accident, one suicide, one case of acute lymphocytic leukemia, one case of hypovolemic septic shock, and one unexplained sudden death 678 days following the last dose of GARDASIL 9. Causes of death in the GARDASIL control group included one automobile accident, one airplane crash, one cerebral hemorrhage, one suicide, one gunshot wound, and one stomach adenocarcinoma.

Systemic Autoimmune Disorders: In all of the clinical trials with GARDASIL 9 subjects were evaluated for new medical conditions potentially indicative of a systemic autoimmune disorder. In total, 2.2% (351/15,703) of GARDASIL 9 recipients and 3.3% (240/7,378) of GARDASIL recipients reported new medical conditions potentially indicative of systemic autoimmune disorders, which were similar to rates reported following GARDASIL, AAHS control, or saline placebo in historical clinical trials.

Clinical Trials Experience for GARDASIL 9 in Individuals Who Have Been Previously Vaccinated with GARDASIL: A clinical study (Study 4) evaluated the safety of GARDASIL 9 in 12-18 year-old girls and women who had previously been vaccinated with three doses of GARDASIL. The time interval between the last injection of GARDASIL and the first injection of GARDASIL 9 ranged from approximately 12 to 36 months. Individuals who were administered GARDASIL 9 or saline placebo and safety was evaluated using VRC-aided surveillance for 14 days after each injection of GARDASIL 9 or saline placebo in these individuals. The individuals who were monitored included 608 individuals who received GARDASIL 9 and 305 individuals who received saline placebo. Few (0.5%) individuals who received GARDASIL 9 discontinued due to adverse reactions. The vaccine-related adverse events that were observed among recipients of GARDASIL 9 at a frequency of at least 1.0% and also at a greater frequency than that observed among saline placebo recipients are shown in Table 4. Overall the safety profile was similar between individuals vaccinated with GARDASIL 9 and those vaccinated with GARDASIL.
with GARDASIL 9 who were previously vaccinated with GARDASIL and those who were naïve to HPV vaccination with the exception of numerically higher rates of injection-site swelling and erythema among individuals who were previously vaccinated with GARDASIL (Table 1 and 4).

**Table 4: Rates (%) of Solicited and Unsolicited Injection-Site and Systemic Adverse Reactions among Individuals Previously Vaccinated with GARDASIL Who Received GARDASIL 9 or Saline Placebo (Girls and Women 12 through 26 Years of Age) (Study 4)**

<table>
<thead>
<tr>
<th>Solicited Adverse Reactions (1-5 Days Post- Vaccination, Any Dose)</th>
<th>GARDASIL 9 N=608</th>
<th>Saline Placebo N=305</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection-Site Pain</td>
<td>90.3</td>
<td>38.0</td>
</tr>
<tr>
<td>Injection-Site Erythema</td>
<td>42.3</td>
<td>8.5</td>
</tr>
<tr>
<td>Injection-Site Swelling</td>
<td>49.0</td>
<td>5.9</td>
</tr>
<tr>
<td>Oral Temperature ≥ 100.4°F</td>
<td>6.5</td>
<td>3.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unsolicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)</th>
<th>GARDASIL 9 N=608</th>
<th>Saline Placebo N=305</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection-Site Pruritus</td>
<td>7.7</td>
<td>1.3</td>
</tr>
<tr>
<td>Injection-Site Hematoma</td>
<td>4.8</td>
<td>2.3</td>
</tr>
<tr>
<td>Injection-Site Reaction</td>
<td>1.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Injection-Site Mass</td>
<td>1.2</td>
<td>0.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unsolicited Systemic Adverse Reactions (1-15 Days Post-Vaccination, Any Dose)</th>
<th>GARDASIL 9 N=608</th>
<th>Saline Placebo N=305</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>19.8</td>
<td>18.0</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>5.1</td>
<td>1.6</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.9</td>
<td>2.0</td>
</tr>
<tr>
<td>Urticaria</td>
<td>3.0</td>
<td>1.6</td>
</tr>
<tr>
<td>Abdominal pain, upper</td>
<td>1.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Influenza</td>
<td>1.2</td>
<td>1.0</td>
</tr>
</tbody>
</table>

The data for GARDASIL 9 and saline placebo are from Study 4 (NCT01047345). *Unsolicited adverse reactions reported by ≥1% of individuals N=number of subjects vaccinated with safety follow-up †For oral temperature: number of subjects with temperature data GARDASIL 9 N=604; Saline Placebo N=304

Safety in Concomitant Use with Menactra and Adacel: In Study 5, the safety of GARDASIL 9 when administered concomitantly with Menactra [Meningococcal (Groups A, C, Y and W-135) polysaccharide Diphtheria Toxoid Conjugate Vaccine] and Adacel [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)] was evaluated in a randomized study of 1,241 boys (n = 621) and girls (n = 620) with a mean age of 12.2 years. Of the 1,237 boys and girls vaccinated, 1,220 had safety follow-up for injection-site adverse reactions. The rates of injection-site adverse reactions were similar between the concomitant group and nonconcomitant group (vaccination with GARDASIL 9 separated from vaccination with Menactra and Adacel by 1 month) with the exception of an increased rate of swelling reported at the injection site for GARDASIL 9 in the concomitant group (14.4%) compared to the nonconcomitant group (9.4%). The majority of injection-site swelling adverse reactions were reported as being mild to moderate in intensity.

**Post-Marketing Experience:** The post-marketing experience is limited post-marketing experience following administration of GARDASIL 9. However, the post-marketing safety experience with GARDASIL is relevant to GARDASIL 9 since the vaccines are manufactured similarly and contain the same antigens from HPV types 6, 11, 16, and 18. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish a causal relationship to vaccine exposure. The following adverse events have been spontaneously reported during post-approval use of GARDASIL 9 and may also be seen in post-marketing experiences with GARDASIL. Blood and lymphatic system disorders: Autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura, lymphadenopathy. Respiratory, thoracic and mediastinal disorders: Pulmonary embolus. Gastrointestinal disorders: Nausea, pancreatitis, vomiting. General disorders and administration site conditions: Asthenia, chills, death, fatigue, malaise. Immune system disorders: Autoimmune diseases, hypersensitivity reactions including anaphylactic/ anaphylactoid reactions, bronchospasm, and urticaria. Musculoskeletal and connective tissue disorders: Arthralgia, myalgia. Nervous system disorders: Ataxia. Endocrine disorders: Precocious puberty, gynecomastia. Metabolism and nutrition disorders: Anorexia. Mental disorders: Depression, aggression, and sleep disturbance. Skin and appendage disorders: Alopecia, hair loss. Eye disorders: Retinal detachment. Ear and mastoid disorders: Vertigo. Cardiac disorders: Palpitations, tachycardia. Vascular disorders: Deep venous thrombosis. Immunological and infectious disorders: Cellulitis. Vascular disorders: Deep venous thrombosis.

**DRUG INTERACTIONS:**

Use with Systemic Immunosuppressive Medications: Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), may reduce the immune responses to vaccines.

**USE IN SPECIFIC POPULATIONS:**

**Pregnancy:**

There is a pregnancy exposure registry to monitor pregnancy outcomes in women exposed to GARDASIL 9 during pregnancy. To enroll or to obtain information about the registry, call Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-800-366-9599.

**Risk Summary:**

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. There are no adequate and well-controlled studies of GARDASIL 9 in pregnant women. Available human data do not demonstrate vaccine-associated increase in risk of major birth defects and miscarriages when GARDASIL 9 is administered during pregnancy.

In one developmental toxicity study, 0.5 mL of a vaccine formulation containing between 1 and 1.5 – fold of each of the 9 HPV antigen types was administered to female rats prior to mating and during gestation. In another study, animals were administered a single human dose (0.5 mL of GARDASIL 9) 5 and 2 weeks prior to mating, on gestation day 6. In a second study, animals were administered a single human dose (0.5 mL of GARDASIL 9) 5 and 2 weeks prior to mating, on gestation day 6, and on lactation day 7. No adverse effects on pre- and post-weaning development were observed. There were no vaccine-related fetal malformations or variations.

**Lactation:**

Available data are not sufficient to assess the effects of GARDASIL 9 on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for GARDASIL 9 and any potential adverse effects on the breastfed child from GARDASIL 9 or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

**Pediatric Use:** Safety and effectiveness have not been established in pediatric patients below 9 years of age.

**Geriatric Use:** The safety and effectiveness of GARDASIL 9 have not been evaluated in a geriatric population, defined as individuals aged 65 years and over.

**Immunocompromised Individuals:** The immunologic response to GARDASIL 9 may be diminished in immunocompromised individuals.

For more detailed information, please read the Prescribing Information.

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Before physicians decide to join a practice or a hospital, they should know if doing so aligns with their professional and personal goals. This is an important decision, and before they take it, doctors should do the necessary research to determine if their prospective new employer is right for them.

UNDERSTANDING THE CULTURE OF A LARGE PRACTICE

Doctors should get a feel for the culture of the new employer—i.e., its internal dynamics, how people relate to one another, how personalities mesh, and if there is life after office hours.

“You’re looking at whether or not you like the individual physicians in the group,” says Russell Still, CVA, CHBC, executive vice president of Medical Management Associates, a healthcare consulting firm in Atlanta that provides management resources and counsel for physicians in private practice. “You want to find out if they’ve had other employed physicians and, if they’re not there anymore, you want to talk to them to find out why they left.”

The new doctor also should understand the work ethic is of the physicians who lead the organization. “If you’re looking for balance in your life, do they have balance in theirs?” asks Still. “Are they just working all the time?”

How decisions are made, and by whom, and how much autonomy and decision-making power doctors have is a critical cultural issue.

“Ask if decisions are made by physicians or by business people in the boardroom,” says Robert M. McLean, MD, FACP, president-elect of the American College of Physicians and medical director of clinical quality for the Northeast Medical Group, in New Haven, Conn.

While McLean thinks that non-physicians may be qualified to make those decisions at times, he nevertheless says that “frequently, doctors have more trust in physicians making the big management decisions. That often is a major cultural factor.”

If doctors want to be part of the management structure, they should say that up front.

“You should be very clear that you want to be more participatory and exercise some leadership,” says Scott Joy, MD, MBA, FACP, medical director of Colorado Care Partners and chief medical officer of the Continental Division of the HCA Physician Services Group in Denver.

“During the negotiation, ask what committees you can serve on—such as EHR or quality improvement,” Joy says. “You’re going to have better opportunities to be on committees by making that part of the contract that you negotiate.”

Doctors should ask the practice leaders why they want to hire a new member. “You’d
be surprised, but sometimes people don’t ask why they’re looking,” says Wanda Parker, a principal with the HealthField Alliance, in Danbury, Conn.

Parker also suggests doctors ask prospective employers about their expectations for a new employee or associate—i.e., what duties do they want the new doctor to assume? How many and what types of patients do they want the doctor to see? What are their long-term goals for the doctor? What are the quality metrics they want the doctor to satisfy? How will the doctor mesh with the other physicians and non-physician members of the staff?

Culture also includes what doctors are allowed to do aside from seeing patients. Can they teach or do research or donate their services elsewhere?

“Sometimes they don’t want people to do outside activities because they feel it detracts from their commitment to the practice,” says Parker. “In other cases, the practice will be absolutely thrilled if the doctor volunteers for the local football team to be their sports medicine doctor.”

**BUY-IN VAGUENESS AND OTHER RED FLAGS**

Investigating the organization’s culture also should help doctors detect any problems that might dissuade them from signing on. A huge warning sign is any vagueness or reluctance about spelling out the precise conditions, and costs, of becoming a partner in the future.

“The big red flag for me is when they won’t talk about the ultimate buy-in to the practice,” says Still. Doctors who get nothing more than a general promise of partnership someday may never attain that status and end up feeling like victims of a bait-and-switch ploy.

If doctors have particular expectations about when and under what circumstances they would become partners, they must protect themselves by getting those expectations spelled out in the contract.

Another potential problem is that the fee a physician ordinarily must pay to become a partner could be prohibitively expensive, where a doctor might have to borrow money to do it. “Doctors should always know up front what the buy-in’s going to be and how it’s going to be calculated,” Parker says. “And what happens when one of those partners leaves? Will they have to buy that person out?”

Frequent turnover, either among staff, the leadership or physicians, is another worrisome indicator, according to Joy.

“If your average tenure of a doctor is a year and a half, that’s not good,” he says.

Average tenures can vary, where doctors leave for personal reasons, differences with the practice leaders, or, increasingly, the desire to remain independent instead of staying with groups that affiliate with hospitals/health systems. There really isn’t a set average tenure for group practices, though Still suggests a new doctor may be with the practice for two to four years before becoming a partner.

“Doctors should ask about how long the practice manager’s been there and what the average staff and physician turnover are.”

A parallel concern is when a practice that
Trends

Physician employment may be financially pressed skimps on staff to save money and thereby makes it harder for physicians to do their work.

“If you don’t have enough care coordinators or medical assistants to do some of the data management legwork, it’s going to be really hard to meet some of the quality metrics,” says McLean. The best way to find out about staffing levels is to ask and, if given a tour of the office, request a tour during work hours, be aware of how many staff are present, take notes and ask about staff functional responsibilities. Focus particularly on the front desk and clinical assistants – the staffers who are essential to the patient’s office visit.

COMPENSATION AND CONTRACTS
Not only should doctors know what their pay will be and how it’s determined, they should understand exactly what their contract means, and what issues the practice is willing to negotiate up front.

Still says it’s possible to find out the local pay rates for physicians who do similar work, and advises hiring a consultant who has access to survey data or works in physician hiring not only in your specialty but in the local market. That information might also be available online from sources such as the American Medical Group Association or a compensation and benefits analysis firm such as Sullivan & Cotter, or at a local library.

Moreover, doctors should know what formula a prospective employer uses to determine salary and other benefits. “How much of the formula is balancing productivity expectations versus other things—around quality and value, data, oversight and management—that take time and energy?” McLean says.

Also, is some of the compensation formula based on quality bonus payments and shared savings contracts? In that regard, McLean offers a hypothetical example: If the insured savings that totaled 70 percent of a practice’s shared savings in a given year are completely gone the following year, would the practice try to compensate for that loss by cutting back or eliminating quality bonuses.

Determining the compensation isn’t always as simple as quoting a flat-rate salary.

“If you don’t think it’s fair, then don’t sign.

Work it out or go somewhere else.”

— RUSSELL STILL, CVA, CHBC, EXECUTIVE VICE PRESIDENT, OF MEDICAL MANAGEMENT ASSOCIATES, ATLANTA

“Sometimes, if you have a higher guaran-

tee, you’ll be paid at a lower RVU rate,” says Joy. “If you want a higher RVU rate, you get a lesser guarantee. You also want to ask about signing bonuses and CME bonuses that are available.”

Flat-rate salaries sometimes are offered, but many practices offer additional pay based on collections in excess of a threshold—usually the new physician’s direct costs divided by the income rate.

Contract stipulations such as restrictive covenants (i.e., contract provisions restricting the future conduct of the doctor, such as competing with the practice for a certain period after leaving it, or soliciting or engaging with patients of that practice after leaving it) and non-compete clauses might seem problematic, but Still says doctors should expect them, and not sign an agreement if they intend to break it later on.

“If you don’t think it’s fair, then don’t sign,” he says. “Work it out or go somewhere else.”

And not all such covenants and clauses carry the same legal weight. “Are they really enforceable in your state based upon precedent?” McLean asks.

To find that out, doctors should consult attorneys with specific experience litigating that type of contractual language. Also, enforceability can depend upon factors such as the practice specialty and location, the specific circumstances of a doctor’s termination, and if a court feels that a non-compete clause is unreasonable (e.g., preventing a doctor from practicing in a territory that’s much larger than the area from which a practice derives most of its patients).

Termination clauses can be deceptive, as when doctors negotiate multi-year contracts that they think keep them safely employed for that period.

“What they don’t realize is the contract is only as long as their termination clause, so if the termination clause is 90 days, then your contract is really a 90-day contract,” Parker says. “And then what happens if bonuses are due and the person is terminated?”

While a no-cause notice provision might seem to undermine the value of having a contract, there are other aspects of the relationship that require contract protections for both parties, such as designated responsibilities and salaries. “With no contract,
Trends

Physician employment

“What [many physicians] don’t realize is the contract is only as long as their termination clause, so if the termination clause is 90 days, then your contract is really a 90-day contract. And then what happens if bonuses are due and the person is terminated?”

— WANDA PARKER, PRINCIPAL, THE HEALTHFIELD ALLIANCE, DANBURY, CONN.

To sidestep these potential contractual minefields, doctors should hire a healthcare attorney who is steeped in healthcare law to review the contract and assist with the negotiations, says McLean.

HOSPITALS CAN BE A DIFFERENT STORY
In some ways, working for a hospital can be like working for a medical practice, but in other ways it can be quite different. In weighing the relative merits of joining a private practice or a hospital, doctors should take those differences into account.

A hospital might be less accommodating than a group practice in the way it treats a doctor. “You go to work for a hospital and it’s all about business decisions and profitability, and if things aren’t working, they’re more likely to fire you than a practice would,” says Still.

As with a medical practice, it’s important to know if physicians or non-physicians are calling the shots at the hospital. McLean implies that hospitals headed by non-physicians may be lower in quality.

“Are enough physicians making decisions to have a medical perspective on healthcare delivery?” asks McLean, who notes that studies show that most of the top 100 healthcare systems are led by physicians. “Having physicians in charge might make doctors more comfortable.”

Contract terms likely are less negotiable with hospitals. “In a hospital situation, where you might have 50 employed doctors, you’re going to get a cookie-cutter contract which says you’ve got four weeks of vacation and one week of CME and here’s your salary,” says Parker.

Sometimes, doctors can have the best of both worlds by joining a private practice that has close relations with a hospital by virtue of having its offices on the hospital campus. These can include perks like preferred parking, free meals in the physician dining room and CME classes, as well as opportunities for personal growth.

Joy, who works on a medical center campus, says doctors in larger and specialty-based practices with that kind of proximity to a hospital can develop productive relationships with the hospital leadership.

While this wouldn’t necessarily involve admitting patients, doctors instead could get to know hospital leaders through service on committees and participate in the leadership’s outreach into the community. In that way, physicians could make themselves known in that community.

...
6 considerations when selling/buying a practice

Lately, I have seen an uptick in the number of physician practices being purchased and sold. Many of my clients prefer to handle the negotiations themselves and only come to me once they have a signed letter of intent (LOI) or another similar document. But a poor or incomplete LOI can pose expensive problems or cause a transaction to fall apart.

When negotiating a LOI, consider the following:

**Define post-deal terms.** What commitment is the buyer making to the seller to retain their services once the deal is completed? Will the physician(s) be offered an employment agreement? Will the agreement reflect similar terms related to the location, hours, compensation, and benefits they enjoyed prior to the sale? What about tail and non-compete clauses?

Many sellers make assumptions based on oral agreements and are later surprised when the offered terms are different—to the point of being unacceptable. I also think it’s a great idea if the LOI identifies essential non-physician employees in the practice and the terms they will be offered, including the preservation of their seniority as it relates to benefits.

**Determine patent record management responsibilities.**
In addition to EHRs being compatible, the parties need to determine who is responsible for inactive records and how they will be stored and maintained in accordance with HIPAA and other applicable laws and regulations. This issue is often overlooked.

**Set a closing date.** How long will the parties have to bring the deal to a close? Often, buyers want a commitment from the seller that they will not negotiate with anybody else during the due diligence period. However, these periods can last far longer than expected, and few LOIs contain a deadline. If a seller has expended resources through the due diligence process, and the buyer elects to walk away, this is an unfair outcome. An LOI should address the deposit of earnest money—or at least a promise to pay legal fees of the seller—if the buyer walks away without a material reason.

**Plan to get paid.** How will accounts receivable (AR) be handled? Many clients are very casual about this issue and assume it will be “figured out at a later date.” This can be a mistake. The parties need to decide how AR will be collected. Will the seller work on the weekends to collect AR? Will the seller pay the buyer’s staff to perform the work? Can the buyer’s staff do it during work hours? Will the buyer collect the AR and turn over the money to the seller for a fee?

The parties also need to confirm how their EHR systems will interface and how EHR records can be accessed for billing and collections.

**Verify party involvement.** Make sure the correct parties are identified, and it’s clear whether stock or assets are being sold. In many states, only physicians can own professional entities, so deals where non-physicians are involved need to be carefully reviewed. Additionally, certain types of corporations can only be owned by human beings, so the parties need to be aware that incorrectly structured transactions might cause unanticipated legal and tax consequences.

**Itemize what’s for sale.** Physician practices sometimes operate multiple locations and entities, which may or may not be part of the deal. The LOI should be very clear about what is being sold.

An essential part of the LOI is to also list the assets, equipment, service lines, and so forth not included in a deal.

Ericka L. Adler, JD, has practiced in the area of regulatory and transactional healthcare law for more than 20 years. Send your legal questions to medec@ubm.com.
could tell he is loved by many. I could tell he is a good man. His smile is kind and it has a quality that I cannot identify. He is thin with a full head of salt-and-pepper hair. He has a gentle and serene aura about him as he lays in his bed. As I talk to him, I realize that the serenity about him also comes from his stillness. It is subtle, his lack of motion—and also deceiving. Looking at him, he does not look “toxic” as we tend to call the really sick ones.

It is a random day, much like many before it, busy and demanding. By the time I get to Mr. T, it is evening and his family members have made their way to his hospital room, the young the old, the millennials and the baby boomers. I introduce myself as the hospitalist who will be the main doctor on his team. There is a hum of worry, dimly present behind the jovial hellos and the small talk.

It is the usual, community-acquired pneumonia that has failed outpatient treatment. His primary care doctor had tried a few antibiotics but nothing seemed to have worked; that was a clue to which I turn a blind eye. I simply do not see it. So, I give them hope. He should be out of here in the next few days I say. We are giving him stronger antibiotics I explain, “the big guns,” and they nod their heads. As I leave the room, I make a joke, and they all laugh. I am pleased because my jokes are usually off and rarely do I get a perfect setup where the joke is funny and there is a room full of people who get it and laugh. My biggest worry as I leave the room is that on the subsequent days when I see him during my daily rounds, they will realize that my jokes are really awkward and poorly timed and not that funny at all.

The days come and they go. Mr. T, who has been getting out of bed to his chair, now prefers to stay in his bed mostly. He tells me some days that he feels good, maybe even better, but lately he says he has been having rough nights. He is so short of breath, the only thing he seems to be able to do without losing his breath is think. His daughter, who happens to be a nurse, often tells me that until the time he started having the cough he was fit and that he played volleyball with his grandchildren on summer vacations.

The infectious disease specialist, Dr. P, a petite woman with probing eyes and one who does not sugarcoat things is the first to voice her concerns that the patient might have cancer. It takes my breath away. When I go into the room, I see Mr. T with yet another one of his many children. I cannot say the word and where I cannot give hope there is no replacement. I leave the room quickly.

Having mainly done the admission part of patient care for many years, I rarely have had the chance to make a claim on a patient the way I claimed this patient on the third floor of our small hospital. I had made a prediction that he would be well and I had worked every day towards that.
“Caring for Mr. T has made me realize I still have room to feel for strangers what I feel for my family, that I was still fighting the good fight with more passion than I knew I had.”

goal which had initially seemed attainable.

It has been over a week since I first met Mr. T and his family. I approach his wife as she stands outside his room with a nurse and the infectious disease consultant. All of a sudden, Mrs. T wails and puts her hand over her mouth. I assume that the biopsy result is back and that Dr. P has just given her the news before breaking it to Mr. T. The nurse hugs Mrs. T.

I hover, trying to give my support or answer questions. Nobody notices. The nurse is wrapped up in the moment, wrapping her arms around the wife’s shoulders and Dr. P is looking at them with those eyes, bracing herself for the consequences of her words.

Instead of hanging around them I step into Mr. T’s room. He is lying in the same position. He is weaker today than he was yesterday and weaker at this moment because he has just heard his wife’s anguish and he knows. His son who also now knows is holding his hand. Tears well up in my eyes and I have to leave right away.

Later I sit on the couch in our office and I tell our office manager, who also at times doubles as my unofficial therapist, about it all and my tears seem to surprise her. In the past my tears have come from telling her how my ten-month-old fell down the entire flight of stairs at my house. There was also the time when I announced my third pregnancy that had occurred a little too soon after my second pregnancy and I fretted about how I could be the breadwinner of my family and leave two babies at home while I work full time.

However, this time I cry not just because despite my armamentarium of medications and knowledge, death will win more times than I would care for it to but also because I had unintentionally crossed an invisible line. Over the years, I had put myself at a distance, given patients labels like “toxic” and did my best to make them feel better. When I walked into Mr. T’s world however, I had allowed myself to hope with the rest of his family, then after that, I had allowed myself to feel, to be caught up in the sadness and later on in the acceptance of the end. Caring for Mr. T has made me realize I still have room to feel for strangers what I feel for my family, that I was still fighting the good fight with more passion than I knew I had.

Editor’s note: The names of patients have been changed to preserve privacy.

Kaba Berhanu, MD, is an internist and hospitalist in Portsmouth, Va., where she has practiced for 10 years. “I fell in love with medicine from the day I stepped into my first med school class and two decades later I don’t see myself being happy doing anything else,” she says.

Berhanu particularly enjoys the “detective work” of medicine, treating each symptom and sign as a dot she strives to connect to form a diagnosis, and from there a treatment that she hopes will lead to a cure. On the other hand, she notes, the 24/7 demands of being a hospitalist pulls her away from her family, including on weekends and holidays.

When not working, Berhanu enjoys spending time with her family and jogging—her only regular “me time,” she says. Her favorite travel destination has been Cabo San Lucas in Mexico, but she’d like someday to visit Italy. When she retires, she adds, her hope is to live “off the grid.”

Her advice for new physicians? “You are entering a field with moments of great triumph and defeat. You may find yourselves on your knees battered, tired and wondering why you chose this path in life. There will also be moments of complete satisfaction when you realize that because of you somebody is suffering less or not at all.”
Managing asthma: Improve outcomes, boost payment

by LISA A. ERAMO, MA contributing author

HIGHLIGHT

Cost is the major barrier to adherence. Provide sample inhalers, look into the cost reduction programs offered by many pharmaceutical companies, and prescribe generic medications when possible.

Managing asthma:

By focusing on asthma management, physicians not only improve patient outcomes and reduce healthcare spending, they also earn more money. Asthma is a condition targeted under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the federal law that seeks to reform Medicare payments while improving population health and cutting costs.

Beginning in 2019, physicians in the Merit-based Incentive Payment System (MIPS), one of two participation tracks under MACRA, will be penalized if their costs exceed anticipated amounts or rewarded for keeping costs under the projected amounts. By helping patients control their asthma and thereby preventing costly hospitalizations and ED visits, physicians choosing to report on related MIPS measures may boost their quality scores and receive a financial bonus.

“The last thing you want is for a patient to be hospitalized because it’s such a high-cost place to receive care,” says Timothy Brundage, MD, medical director at Brundage Medical Group LLC in Tampa, Fla., a consulting company that helps physicians improve their clinical documentation. “Keeping the patient well and the asthma under control are the best ways to care for patients and reduce costs.”

Rex Mahnensmith, MD, an internist at Docs of CT in Milford, Conn., agrees. “The motivation behind value-based payments is keeping people well and safe, especially when they have asthma—a condition that can quickly become life-threatening.”

ASSESS ASTHMA SEVERITY

Assessing asthma severity helps physicians identify the proper course of treatment to ensure good outcomes, says Steven Kagen, MD, an allergy and immunology specialist in Appleton, Wisc. Kagen suggests asking patients these questions:

- Have you had problems with coughing, wheezing, shortness of breath, or chest tightness during the day?
- Do you wake up during the night due to coughing, wheezing, or other symptoms that don’t improve within 15 minutes of using the rescue inhaler?
- Do you have symptoms of asthma while exercising or playing?

Physicians can get credit under MIPS by using one of the following assessment tools:

- Asthma Control Test (ACT)
- Asthma Control Questionnaire (ACQ)
- Asthma Therapy Assessment Questionnaire (ATAQ)

Physicians can also ask patients diagnosed with asthma to record their peak expiratory flow rate daily and bring these...
measurements to their appointments, says Mahnensmith. “This is meaningful information, and it’s a good gauge of whether their inhaler is working,” he adds.

**PRESCRIBE CONTROLLER MEDS**

Prescribing a rescue inhaler may be sufficient for patients with mild intermittent asthma; however, those with more severe forms of asthma—those who use their rescue inhaler more than once a day two times per week—may also require a controller medication to continuously relax and dilate their airways, says Mahnensmith. Physicians may overlook adding the controller medication if they aren’t aware of the severity of the patient’s symptoms. This happens either because they don’t ask detailed questions or because patients don’t provide the information, for example if they forget or if they simply dismiss their own symptoms, he adds.

Pharmacists can provide insight into how often patients use their rescue inhaler so physicians know when a controller medication may be necessary, says Mahnensmith. For example, when prescribing an inhaler, physicians should consider starting with one refill only. They may also include a note to the pharmacist asking them to call the physician’s office when the patient requests the refill. Each inhaler typically includes 120 inhalations and should last for at least three months. If the patient refills the script in one month, that means they’re using the inhaler four times a day and require a controller medication immediately, he adds.

**IDENTIFY ASTHMA TRIGGERS**

Raising patient awareness of the environmental factors that trigger their asthma is critical because, in some cases, they may be able to avoid the triggers entirely (e.g., by staying inside on days when pollen counts are high), says Kagen. Physicians should ask patients to record when and where asthma attacks occur as well as the symptoms they experience, he adds.

There are also a variety of mobile apps available that can help patients log their symptoms. Kagen created one that correlates self-reported symptoms—wheezing lungs, itchy eyes, cough, and runny nose—with various weather elements, helping patients identify the environmental triggers that make them feel worse. Patients can also

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**ASTHMA MIPS MEASURES**

These two asthma-related MIPS quality measures can help physicians gain points and potentially boost revenue:

1. **Medication management for patients with asthma**: Percentage of patients ages 5-64 with persistent asthma who were dispensed appropriate medications on which they remained for at least 75 percent of the treatment period during the performance year. The measure includes the following controller medications:

   - **Antiasthmatic combinations** (Dyphylline-guaifenesin or Guaifenesin-theophylline)
   - **Antibody inhibitor** (Omalizumab)
   - **Inhaled steroid combinations** (Budesonide-formoterol, Fluticasone-salmeterol, or Mometasone-formoterol)
   - **Inhaled corticosteroids** (Becloethasone, Ciclesonide, Fluticasone CFC free, Budesonide, Flunisolide, Mometasone)
   - **Leukotriene modifiers** (Montelukast, Zairirlukast, Zileuton)
   - **Methylxantines** (Aminophylline, Dyphylline, Theophylline)

2. **Optimal asthma control**: Composite measure of the percentage of pediatric and adult patients ages 5-40 whose asthma is well-controlled as demonstrated by one of three age-appropriate patient-reported outcomes tools and who are not at risk for exacerbation. Clinicians submitting this measure must use one of the following assessment tools to determine whether the asthma is well-controlled:

   - **Asthma Control Test (ACT)**
   - **Asthma Control Questionnaire (ACQ)**
   - **Asthma Therapy Assessment Questionnaire (ATAQ)**

   “Without risk of exacerbation” is based on the following data collected during a 12-month period:

   - **Number of ED visits not resulting in a hospitalization due to asthma**
   - **Number of inpatient hospitalizations requiring an overnight stay due to asthma**

To receive credit for this measure, patients must have had no more than a total of two ED visits, two hospitalizations, or one of each.

Source: CMS Quality Payment Program Resource Library (bit.ly/QPP-library)

(See technical specifications for claims registry measures 398 and 444).
use the app to predict symptoms based on a four-day weather forecast. In addition, the app locates the closest board-certified asthma and allergy specialist so patients can seek help immediately.

Allergy testing using a simple skin test is another option to identify asthma triggers. The test takes fewer than 10 minutes, and it identifies approximately 60 airborne allergens, says Mahnensmith. Once patients are aware of the allergens that trigger their asthma, they can receive allergy desensitization therapy that weakens allergic reactions by exposing them to gradually increasing doses of allergens, he adds.

**FOCUS ON ADHERENCE**

Cost is one of the most common barriers to medication adherence, and physicians can overcome it by simply asking patients whether they can afford their inhalers, says Brian Boyce, CEO of ionHealthcare LLC in Richmond, Va., a healthcare consulting company that specializes in risk adjustment. Provide sample inhalers, look into the cost reduction programs offered by many pharmaceutical companies, and prescribe generic medications when possible, he adds. There are also high-tech, low-cost inhalers available with global positioning systems that measure location-specific air quality.

Helping patients adhere to their medications also requires frequent patient monitoring (i.e., every three months), says Mahnensmith. If I’m really concerned about someone, I’ll tell them [all patients at risk of an exacerbation] I want to see them next week so I can see how they’re doing, listen to their lungs, and do a peak expiratory flow ratio,” he adds.

Patients with uncontrolled asthma should return to the office every two to four weeks for repeat education and ongoing monitoring, says Kagen. Kagen provides a demonstration and then asks a nurse to reiterate the same information to patients. “Each inhaler may be different in terms of the technique that’s required, and each patient may have different skills,” he says. For example, a patient with

Five documentation tips to master asthma under MACRA

Helping patients control their asthma not only improves outcomes, it can boost physician payments under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and in risk-adjusted payment models. However, proper documentation is critical for payment. Here are five documentation tips:

1. **Document asthma, when applicable.** Physicians receive risk adjustment credit when they document asthma in the current problem list—not the patient’s past medical history, says Brian Boyce, CPC, CEO of ionHealthcare LLC in Richmond, Va.

2. **Focus on asthma severity.** To accurately reflect asthma severity, physicians should document the following details:
   - **Type (e.g., mild, moderate, or severe)**
   - **Character (e.g., intermittent or persistent)** (Note: Persistent asthma is what triggers the related

3. **MIPS measure for medication management.**
   - **Complications (e.g., acute exacerbation, status asthmaticus, or acute respiratory failure)**

   All of these asthma descriptors are meant to help payers understand severity and risk, says Boyce. This information helps define capitated payment rates, and it helps payers identify patients who could potentially benefit from asthma education and outreach, he adds.

   In capitated payment models, payers expect to pay more for patients whose asthma is uncontrolled or exacerbated, says Raemarie Jimenez, CPC, vice president of membership and certification solutions at AAPC in Salt Lake City, Utah. “If you’re not indicating the severity of the asthma, then it looks like these patients are using more resources even though they’re not that sick,” she says.

   Capturing asthma severity may also help practices in an Accountable Care Organization (ACO) achieve shared-savings bonuses, says Timothy Brundage, MD, medical director at Brundage Medical Group LLC in Tampa, Fla.

   When physicians capture asthma severity—and then keep patients with severe asthma well-controlled and out of the hospital—the ACO gains revenue that it may share with practices for keeping costs lower than expected, says Brundage. When physicians don’t capture severity—and
rheumatoid arthritis can’t generally use an inhaler that requires them to squeeze the device, but they can use one that employs a “click and inhale” technique.

Physicians must observe patients using the inhaler, says Mahnensmith, adding that coordination, timing, and direction of the spray is often incorrect. For example, do patients pump and inhale into the lungs, or do they pump onto the tongue and upper palate with no inhalation? If the patient is unable to inhale into the lungs due to lack of coordination, do they need a spacer to guide the medication directly into the lungs?

Physicians should consider providing patients with written instructions on how to use the inhaler properly. The CDC also provides a video that instructs patients on proper inhaler use (bit.ly/CDC-inhaler).

“Every patient is unique,” Kagen says, “and every patient must be managed according to their own needs, immune system, autonomic nerve system, home and work environments, and underlying inflammatory pathways.”

Patients with unspecified asthma are subsequently admitted to the hospital—poor clinical management is the suspected culprit. As a result, the ACO doesn’t generate savings, and the practice doesn’t receive a bonus, he adds.

1. Include additional narrative details to help payers understand the clinical picture. Boyce provides these examples:

- Any nighttime awakenings due to asthma
- Number of daily or weekly exacerbations
- Patient education on proper use of the inhaler
- Recent urgent care or emergency department visits
- Type and frequency of symptoms
- Whether the asthma interferes with the patient’s normal activities and, if so, to what degree (e.g., with minor limitation, noticeable limitation, or extreme limitation)
- Whether the asthma is controlled on current medications
- Whether the patient uses their inhaler correctly

All this information helps paint an even more detailed picture of the patient’s asthma and what the physician is doing to manage it, says Boyce.

2. Know when to assign additional codes. The following codes can help payers understand why the cost of caring for patients with asthma may be higher than expected:

- Exposure to environmental tobacco smoke (Z77.22)
- Exposure to tobacco smoke in the perinatal period (P96.81)
- History of tobacco dependence (Z87.891)
- Intentional underdosing of medication due to financial hardship (Z91.120)
- Intentional underdosing of medication for another reason (Z91.128)
- Occupational exposure to environmental tobacco smoke (Z57.31)
- Tobacco dependence (F17.-)
- Tobacco use (Z72.0)
- Unintentional underdosing of medication due to age-related debility (Z91.130)
- Unintentional underdosing of medication for another reason (Z91.138)

3. Results of the asthma control assessment. Physicians boost MIPS scores when they document the following:

- ACT score of 20 or above
- ACQ score of 0.75 or lower
- ATAQ score of 0

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### Asthma diagnosis codes to know

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J45.20</td>
<td>Mild intermittent asthma, uncomplicated</td>
</tr>
<tr>
<td>J45.21</td>
<td>Mild intermittent asthma with (acute) exacerbation</td>
</tr>
<tr>
<td>J45.22</td>
<td>Mild intermittent asthma with status asthmaticus</td>
</tr>
<tr>
<td>J45.30</td>
<td>Mild persistent asthma, uncomplicated</td>
</tr>
<tr>
<td>J45.31</td>
<td>Mild persistent asthma with (acute) exacerbation</td>
</tr>
<tr>
<td>J45.32</td>
<td>Mild persistent asthma with status asthmaticus</td>
</tr>
<tr>
<td>J45.40</td>
<td>Moderate persistent asthma, uncomplicated</td>
</tr>
<tr>
<td>J45.41</td>
<td>Moderate persistent asthma with (acute) exacerbation</td>
</tr>
<tr>
<td>J45.42</td>
<td>Moderate persistent asthma with status asthmaticus</td>
</tr>
<tr>
<td>J45.50</td>
<td>Severe persistent asthma, uncomplicated</td>
</tr>
<tr>
<td>J45.51</td>
<td>Severe persistent asthma with (acute) exacerbation</td>
</tr>
<tr>
<td>J45.52</td>
<td>Severe persistent asthma with status asthmaticus</td>
</tr>
<tr>
<td>J45.990</td>
<td>Exercise-induced bronchospasm</td>
</tr>
<tr>
<td>J45.991</td>
<td>Cough-variant asthma</td>
</tr>
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</table>
Financial Strategies

Cracking the code behind the patient revenue cycle

The rules of other consumer commerce sectors somehow do not apply to medical billing. Stop and think about this for a moment. It’s easier to make sense of how much we spend for goods and services such as groceries, clothing, and gasoline because we know how much it costs up front. No smoke and mirrors. No hidden expenses we are billed for days, weeks, or even months later. Imagine buying gasoline and two weeks later receiving a bill from the station owner because he didn’t include the excise tax on the pump price. Would you pay that?

Yet that kind of scenario is exactly what healthcare consumers have learned to expect when it comes to their medical bills. Medical billing and collection is a broken system with far-reaching negative consequences—it’s about time we got down to fixing it.

What we don’t know CAN hurt us

Lack of timely payment or no payment at all is leading to a crisis in healthcare. The simple fact is that in comparison to other products and services, people do not understand how much healthcare costs.

In fact, a recent report by the research company West stated that 75 percent of patients don’t know what they’ll owe until they see a bill. Seventy-five percent! Imagine if you went to the store and purchased a gallon of milk but had no idea what it cost until a bill came later. Oh, and add to that the fact that the price of milk would vary wildly from store to store.

In all likelihood, people would stop purchasing a product with such an unpredictable cost structure. Perhaps we’re onto something here. If people know prices upfront, they are more likely to pay them.

The need for clear and understandable statements

How many times have you tried in vain to decipher an Explanation of Benefits (EOB) from your insurance company?

Sometimes it seems these things are written in a kind of code, seemingly with the intent to obscure benefit information from patients. It’s no surprise to many that trying to understand the healthcare billing system, how benefits are applied, and what balance patients are ultimately responsible for paying has traditionally been as confounding as trying to understand a garbled voicemail—if the message is unclear, it is impossible to take the appropriate action. No wonder so many patients struggle to meet their medical financial responsibilities.

Lack of price transparency killing private practice

As the proportion of patient financial responsibility grows with the rise in high-deductible health plans, profit risks become greater for independent practices. Small practitioners are seeing larger write-offs, higher costs to collect, and longer revenue collection cycles. We seem to be in the midst of a healthcare payment system crisis that is squeezing these small practitioners the most, forcing them out of independent practice.

Consider these statistics:

- In 2016 33 percent of physicians were in independent practice compared to 48.5 percent in 2012
- In 2016 20 percent of doctors worked in groups of 100+ compared to 12 percent in 2012
- 73 percent of those in independent practice would remain so if they could maintain stability and profitability, but 44 percent expect to sell their practice in the next 10 years
- Research shows that small practices deliver better care, especially where high-quality primary care makes a difference: lower hospital readmission rates, better outcomes for patients with diabetes, etc.
Financial Strategies

**Percentage of physicians in private practice**

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>33%</td>
</tr>
<tr>
<td>2012</td>
<td>48.5%</td>
</tr>
</tbody>
</table>

These numbers paint a distressing picture—one that shows an erosion of independent practice that ultimately leads to worse overall health outcomes for everyone.

**What can we do?**
The solution to this problem is lies in taking a price transparency cue from the retail sector by helping patients more clearly understand the why and what of payment responsibility so they can make smarter decisions about healthcare consumption and budget accordingly.

Here are additional suggestions for how medical providers can move toward more effective solutions to the pressing issue of poor revenue cycle management:

**Talk money:** Have frank discussions with patients about ability to pay before care is delivered. Only a quarter of healthcare providers do this now.

**Embrace technology:** Revenue cycle management technology solutions can make it easier for patients to understand and make payments upfront and on-time. This will lead to greater rates of patient engagement, participation, and bill payment. Seventy-seven percent of healthcare consumers say it’s important or very important to know costs before treatment, but just one in five physicians currently send reminders about payments on or near due dates.

**Join forces:** An independent physician association (IPA) or similar organization can provide some of the benefits of being part of a larger group of physicians without sacrificing independence, allowing the opportunity to:

- Negotiate with payers
- Enjoy bulk rates on malpractice insurance
- Leverage billing companies to ensure timely and accurate

More broadly, the healthcare industry needs sounder infrastructure to support independent physicians. In turn, medical practices must be more proactive about researching and adopting innovative technology tools that can simplify and streamline both time-of-service and residual balance patient payments.

We know the demand is already there—49 percent of physicians expect they will have to develop innovative billing and payment models to remain independent.

**Healthcare price transparency and payment convenience pays dividends**

One of the core faults of our healthcare pricing system is that patients aren’t required to pay for healthcare in any consistent way.

As a result, one of our most pressing needs is to implement technology solutions that push healthcare providers to think less like an institution and more like a small business. The simple fact is, if you make the payment process cleaner and more convenient, more patients will fulfill their financial obligations.

Medical providers must tailor their billing and payment processes to patient needs and desires, by implementing tools and resources the modern consumer has come to expect—such as the ability to pay online or via a smart phone app. Providers should seek to create more of a convenient patient experience than an unpleasant episode.

By implementing patient revenue cycle solutions that promote price transparency and offer payment convenience, patients will experience higher levels of satisfaction, peace of mind, and trust. Remember, members of the next generation of healthcare consumers are watching you more closely than ever, are eager to share their experiences via social media and review sites and have a virtual global peer-to-peer network right at their fingertips.

If we don’t proactively tackle the growing fiscal problems that are essentially forcing many smaller medical practitioners to fold their tents, we can’t realistically expect our healthcare system to evolve into a leaner entity with better outcomes.

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Lance Goudzwaard is president of the Center for Transformative Coaching and has more than 20 years of experience as a healthcare operations and financial management professional. Send your financial questions to medec@ubm.com.
How physicians can take vacation

by DAVE SCHAFER Contributing author

T
ime off? Surely you jest,” wrote C.K. Hebdon, MD, in response to a query about going on vacation. Hebdon is the owner and sole physician at the Center for Performance & Longevity in Salt Lake City. An addiction medicine specialist, he says no other nearby specialist can cover his clinic when he leaves, so he rarely takes time off from his practice.

“And if I take a day off, I’m punished by having to fit in that day’s patient load into the surrounding days,” he notes. “Monthly visits and prescriptions must be maintained.”

In Physicians Practice’s 2018 Great American Physician Survey, 29 percent of respondents reported they’re the only physician at their institution. Those doctors are opting for the flexibility and increased freedom to spend more time interacting with their patients, a perk that often comes with a small private practice. (Editor’s Note: Physicians Practice is a sister publication of Medical Economics).

Matthew Bates, MPH, managing director of healthcare practice for Huron Consulting Group, a management consulting firm, relates the story of a solo practitioner who drives to all of his vacation destinations. The doctor plots his course so he has cell phone coverage in case someone at his office needs something.

“That’s incredible dedication. But he’s 40-something, and he says he’s burning out,” Bates says. “His marriage is struggling, and he’s disconnected from his family. He’s not sure how much longer he can keep going with that lifestyle.”

On the rare occasion Hicks goes on vacation, he carries two cell phones and two smart watches that can make and receive phone calls. That way, he’s always accessible. “I never go anywhere without them,” he says. “Not that they ever ring, but if they do, I have them. They’re just part of me.”

Being completely unavailable to the office isn’t an option for most solo practitioners. Even so, they can strategize ways to physically escape the daily grind and maximize the mental break they get while away. It all comes down to a foundational strength of solo practices: relationships.

“WORKING HARD ON BOTH ENDS”

Erinn Harris, MD, is the entire office staff at Har-
As a solo practitioner, she maintains regular clinic hours, but when she’s not in the office, it’s closed. Because she and her patients have a relationship built upon one-on-one interactions, they understand her need to take time off. They’re even forgiving when she has an emergency and has to close the office suddenly.

That type of patient relationship is common in traditional payer-based practices, too. Because they’ve gotten to know each other over time, patients see those physicians as people with a personal life. Patients recognize they can often place demands on their physician’s personal time, so they’re usually understanding when their physician wants, or needs, to take time off.

Deborah Winiger, MD, who runs North Suburban Family Healthcare in Vernon Hills, Ill., says the relationships she has built with patients cause them to be more respectful of her time when she’s out of the office, so they tend to avoid calling her outside of office hours. When they do, they keep the call brief.

Partly it’s the nature of a solo practice. Patients know that if they leave a message with a solo practitioner’s office, they’ll get a call back the next morning, which isn’t always the case with larger group practices.

Most solo practitioners work hard to accommodate their patients before they leave the office for an extended time. They give patients plenty of notice that they’ll be out of the office, and they often load up extra patients in their schedule before and after vacation.

“Even if I’m gone for the week, revenue for the practice tends to not be down that much, because I end up working harder on both ends of the vacation,” Winiger says.

Life goes on even if a doctor isn’t in the office seeing patients. In his experience working with healthcare practices, Bates says the majority of phone calls to medical practices don’t require physician attention. The most common reasons for calling are about scheduling, billing, or the nurse desk—matters staff can handle. But for those that require a medical professional, physician assistants (PAs) or nurse practitioners (NPs) play a crucial role.

“Most of my patients are used to seeing the NP or PA, so it’s not a big deal for them, and it works out really well for me,” Hicks says. “If I want to go on vacation, they have full licensure and the ability to write all the scripts, so I don’t have to worry about that.”

Instead of seeing about 70 patients a day, of which Hicks would see close to half, the office cycles through about 50 when he’s away, meaning the practice can still earn revenue during that time. It’s less than normal, but a more manageable loss of income than if the practice were closed. That also means fewer patients have to wait to be seen or referred elsewhere for care.

But there are limitations to what an NP can handle, Winiger says. “Invariably, something always happens when you’re gone. That’s just the nature of medicine.”

And when those “somethings” happen, solo practitioners need a plan in place. That’s where other local physicians can help.

**FIND FILL-IN PHYSICIANS**

If Harris leaves the country for vacation, she tells her patients about another direct primary care physician nearby who they can see for urgent needs.

That’s another strategy for temporarily cutting ties with the office: If there are other physicians in the area who provide the same services, solo practitioners can ask them to cover urgent cases.

“In markets where there are other doctors who can cover, what we typically see is an on-call/emergency reciprocal setup,” Bates says. “They’ll refer their patients to another doctor in town who they’ve built a relationship with while they’re gone. Many solo practitioners share call schedules. Then they might agree to use that same structure of sharing patients to help support time off.”

That means the solo practitioner going on vacation now will have to take on more patients when their coverage doctor goes on vacation later. That can make for some busier than normal days as payment for taking a vacation.

But solo practitioners understand that cost, and because they are usually able to give plenty of notice about a pending vacation, patients don’t expect to be seen while they’re gone. The result is that the additional load isn’t too heavy for the covering doctor. Instead, it tends to be emergency cases or patients who insist they can’t wait until their physician returns.

Before Ronald Krauser, MD, retired from Arthritis Associates of the Main Line in Paoli, Penn., he shared weekend call duty with a local rheumatologist group. The two rheumatologists from that group also covered for him when he took vacations.

The key to a good coverage relationship is flexibility, Krauser says. “I could call them at 5 o’clock...
“Plan ahead and make it happen.

The world won’t fall apart, even though sometimes it feels like that.”

— DEBORAH WINIGER, MD, NORTH SUBURBAN FAMILY HEALTHCARE, VERNON HILLS, ILL.

and say, ‘Listen, I have to be out of the office the next two days,’ and nobody ever said anything except, ‘OK, we’ll take care of it.’

Electronic health records now allow doctors who cover for a practitioner to have basic patient information at their fingertips.

“In the old days, if I was a paper-based doctor, there was no way to get that chart unless I give them the key to my office,” Bates says.

Figuring out how to enable EHR access for the covering doctor should be part of any vacation planning, he says.

WORKING REMOTELY
Technology can assist solo practitioners who want to take time off in several other ways.

When Harris took off four weeks for maternity leave, patients continued calling her for lab orders or prescription refills. She says fulfilling those needs wasn’t as difficult as she thought it would be.

Physicians can access medical records remotely via cloud storage, so they can order prescription refills and specialist referrals remotely. They can also order X-rays—or even have a patient send a picture of a rash via text or email for a quick telehealth visit.

Harris estimates she can handle 90 percent of patient needs over the phone.

“It works out pretty well. I’m able to handle a lot of things while I’m out of the office, Harris says.”

Working remotely is still working, but it gives providers the freedom of not having to come into the office. Telehealth visits allow physicians to quickly process the one or two urgent items that come in rather than having to go into the office for a full slate of patients.

USE LOCUM TENENS
If all else fails, there are locum tenens physicians. The obvious problem is that the solo practitioner must pay them, which eats into the bottom line. Plus, it costs time to train locums on office processes.

“Getting a locum tenens is sometimes a pain in the rear because you have to train them on your EHR system,” Hicks says.

Relationships on this smaller end of the practice-size spectrum are especially important, says Alexi Nazem, MD, MBA, a hospitalist with Weill Cornell Medicine in New York City and CEO and co-founder of Nomad Health, an online platform that allows doctors to interact directly with the people who are considering hiring them. “If you can build a great relationship with a locum tenens, that doctor can repeatedly cover for you.”

But solo practitioners are often priced out of the traditional locum tenens market, Nazem notes. There aren’t many solutions to that, except perhaps using less expensive agencies or online tools to find a locum tenens.

Another possibility: Hire a retired or semi-retired area physician to cover for you. Ward Paine, MD, is one of the rare solo practitioners who doesn’t answer the phone on vacation. He says he takes vacations to spend time with his family, so he stays away from the phone and office work.

Besides running his own clinic in Morgantown, W.Va., Paine provides services at the local hospital and a nursing home. When he leaves for more than three days, he hires a semi-retired doctor to help cover the nursing home patients on a locum tenens basis.

“He’s someone I know and trust, so I feel comfortable with him,” he says.

REGULAR VACATIONS
In a facility with 12 other doctors, taking time off is easy. In a solo practice, you have to be more purposeful, Bates says. “It can’t just be, ‘I’m not feeling good today. I’m going to call in sick.’ You have to plan.”

Let your patients know that you’re planning on being out of the office by posting messages on your front door, on social media channels or practice website, and on the voicemail system. Block out your schedule for that period of time as far in advance as possible and figure out an on-call process and emergency coverage.

It’s more likely that communities with only one provider will be in a rural area, and for those residents, it’s not unusual to drive to the next town for any number of reasons, including seeing a doctor. Referring them to a physician in another town while you’re out of the office is part and parcel of living in a remote area, Bates says.

“Telling patients that they will have to drive to the next town over is OK in rural America,” he says. “I think rural Americans are comfortable with that, and they adjust to that.”

In the end, you just have to plan to take time off, and then do it, Winiger says.

“Plan ahead and make it happen,” she says. “The world won’t fall apart, even though sometimes it feels like that.”
The technology patients want

The PwC Health Research Institute recently conducted a widespread study to look at the defining issues of the healthcare industry in 2018 and the years to come. This report advised, “Organizations need to educate both patients and clinicians how to use available tools and integrate them into care.”

Adding technology to your practice will strengthen your patient relationships and improve patient retention, ultimately increasing your bottom line. Including funds in your budget dedicated to technological investments that improve the patient experience will be worth it in the long run.

The following are the most popular technologies patients are seeking.

**Digital self-scheduling.** Research shows that 77 percent of patients want to book their own appointments. Online self-scheduling tools allow patients to view the physician’s availability and select an appointment time that best suits their schedules at their convenience. This minimizes the need for rescheduling, eliminates phone calls, and reduces frustration for patients and staff members.

**Online billing and payment.** Patients are looking for digital options when it comes to both billing and payment. Around 80 percent of patients say they want to pay their healthcare bills online. Unfortunately, 90 percent of surveyed providers still use paper patient statements and as a result only 20 percent of patient make any online healthcare payments.

**Mobile communication.** Patients are looking for digital access to their doctors’ offices and want to remove the need for a phone call. They want to be able to request a prescription refill or ask a health question in a more convenient manner. A recent Harris Poll found that 59 percent of insured patients and 70 percent of millennials would choose a primary care provider who offered mobile options over one who did not. Enabling practice texting (especially two-way texting) is an easy way to meet this demand.

**Access to medical records.** Easy access to medical records is one of the top requests of today’s patients. While health information is now available electronically more than ever before, over half of patients (55 percent) say that they have little to no access to or control over their medical information. If you haven’t given your patients’ electronic access to their medical records, now is the time to do so. If you choose to make the switch to online patient medical records, be sure to educate your patients how to access these records, because there is a good chance your patients will not know how to access their records without initial instruction.

Running a business successfully, regardless of industry, is all about creating strong, long-term relationships by meeting the demands of your market. And the healthcare market is demanding additional technology. So as you create your budget for the upcoming year, take an assessment of your practice. Are you offering the digital experience today's patients demand? If not, see where you can make some changes. A small investment in those patient relationships now can lead to great dividends in the future.

Josh Weiner is the chief operating officer of Solutionreach. Send your technology questions to medec@ubm.com

**Tech Talk**
EHR certification: Is the latest standard attainable?

by MARY K. PRATT Contributing author

The Centers for Medicare & Medicaid Services (CMS) wants physicians to use 2015-certified EHRs, an upgrade that CMS officials believe will help providers more easily share patient information.

Requiring the use of these up-to-date EHRs comes after CMS redesigned its incentives under the Merit-based Incentive Payment System (MIPS), which is part of Medicare's value-based-pay program affecting many physician practices.

Yet CMS and health IT experts estimate that thousands of physicians have yet to switch to 2015-certified EHRs. This scenario could leave those physicians scrambling in the coming months to make potentially costly and complex EHR upgrades. The alternative is to risk lower MIPS scores for 2019, which could mean lower Medicare reimbursements.

As a result, some health IT experts see the government’s push for physicians to update their systems as unduly burdensome.

“There’s a big group of physicians who haven’t made a switch to the new software, and those who aren’t on the 2015-certified EHRs are usually the small and independent practices,” says Robert Tennant, MA, director of health IT policy for the Medical Group Management Association, headquartered in Englewood, Colo. “We don’t want to impose such a hardship on these practices just to get them on some arbitrary standards with their EHRs that may not even produce higher quality of patient care.”

FEDERAL REQUIREMENTS DRIVE EHR UPGRADES

MIPS mandates physicians to use EHRs certified to have specific features and functions established under the federal government’s 2015 Edition Health IT Certification Criteria.

After months of discussion, CMS is finalizing its 2019 Medicare Quality Payment Program rules and is expected to approve the requirement for physicians to use 2015-certified electronic health records (EHR) systems in order to be eligible to receive the maximum MIPS score.

Many vendors have their 2015-certified EHR updates ready for physicians to implement, according to healthcare IT experts. And many medical facilities and physician practices already have implemented these updated systems.

In fact, the Office of the National Coordinator for Health Information Technology reports that 80 percent of clinicians have access to 2015-certified EHRs, with experts explaining that many EHR vendors don’t yet have certified EHRs ready for the physicians using their technology.

But access to 2015-certified EHRs is not the same as having those upgraded systems implemented and in everyday use, says Jeff Coughlin, MPP, senior director of federal and state affairs at the Healthcare Information and Management Systems Society (HIMSS), a nonprofit health IT advocacy organization.

Indeed, the estimated number of upgraded EHRs actually implemented is lower: ONC earlier this year reported that at least...
66 percent of clinicians eligible to participate in MIPS have 2015-certified EHRs.

Health IT leaders say that’s a healthy track record of adoption, but they stress that the ONC figure means that one-third of the roughly 750,000 physicians in the United States don’t have the updated EHRs they’d need to meet these new CMS requirements.

Health IT experts say that physicians with EHR vendors who have yet to receive certification for their products (mostly the smaller and niche companies) and small practices without strong IT support services will be more likely to face such struggles than practices using EHRs from the bigger vendors and/or those practices affiliated with medical centers with IT departments handling the work.

INTEROPERABILITY BEHIND PUSH FOR NEW CERTIFICATION

Physicians will still be able to practice without the 2015-certified EHRs; in fact, CMS is expected to require physicians use the updated version for only a 90-consecutive-day reporting period in 2019, which CMS officials say gives physicians time to implement the upgrades.

But Tennant says physicians will be hard-pressed to meet some of the anticipated reporting requirements for 2019 without a 2015-certified EHR in place and they will not be able to optimize their MIPS scores without having the upgraded version in place and fully utilized for at least one quarter of the upcoming year.

He says physicians could miss out on meeting requirements under Promoting Interoperability—one of four categories that make up the MIPS score—by not having a 2015-certified EHR in place. Moreover, physicians also might not be able to meet all the requirements under the Quality category without an updated EHR in place for the entire year.

Tennant says CMS should recognize that requiring this EHR upgrade is a hardship for many practices, pointing out that some physicians can’t afford the costs associated with implementing updated software while those whose vendors have yet to release a 2015-certified version are struggling to decide whether to wait or go the more costly route of finding a new EHR vendor. He says his organization suggests CMS continue encouraging practices to move to 2015-certified EHRs while still allowing physicians to use their current versions without risking lower MIPS scores.

Still, many health IT leaders say they support the goals of the 2015 certification. “We’re big boosters of the 2015-CEHRT,” Coughlin says. “We talk about interoperability, and the steps and benefits included with the 2015 changes really promote greater data exchange.”

SIGNIFICANT WORK REQUIRED FOR UPGRADES

Physicians should anticipate a lot of work and potential extra costs associated with that work.

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Questions physicians should ask their EHR vendors

Health IT consultants say physicians upgrading their EHRs to 2015-certified versions should ask their vendors to:

Create a written timeline for when the implementation, testing and training will take place to ensure that the vendor has the physician in queue for work and commits to getting the work done in a timely manner.

Detail how they’re securing the upgraded system against breaches and cyberattacks.

Break down the costs associated with the upgrade, particularly justifying any charges beyond the regular maintenance fees that cover upgrades as set by the physician’s existing contract for EHR software.

Provide consulting services and training to ensure that the upgraded EHR is fully functional and completely integrated with other office technology and that the practice staff can quickly master its new features and maximize its benefits.

Share what planned upgrades they have in the works along with the timeline for delivering those to help physicians better prepare for such projects moving forward.
“An upgrade always takes longer than anyone anticipates, because there’s never anything seamless about something like this. And this is a major upgrade,” says Mari Rose Savickis, MPA, vice president of federal affairs with the College of Healthcare Information Management Executives (CHIME).

Tennant says the work involved in an upgrade varies based on numerous factors. Physicians with an EHR using an on-site server will likely need their vendor to come on-site to update the systems, while vendors offering cloud-based EHRs will be able to remotely upgrade the systems of their physician customers.

Physicians also will find that whether, and how much, a vendor charges for its 2015-certified EHR updates can vary, depending on their contracts, whether they’re on the most current version of their vendor’s EHR software or have skipped previous upgrades, and other factors, Tennant adds. They should expect moving to 2015-certified EHRs possibly to require re-working certain processes or adjusting to new user interfaces.

As a result, physicians need to build in time to train themselves and their staff on their upgraded EHRs, which could mean everything from learning how to navigate new screens to tweaking workflows, says Brooke Rockwern, MPH, an associate of health IT policy at the American College of Physicians.

Experts advise that physicians also plan for a reduced number of patients following implementation as they get accustomed to their new systems in addition to the downtime scheduled for actual training.

A SENSE OF URGENCY

Physicians who don’t yet have a 2015-certified EHR in place need to determine if their existing EHR vendor has one available, Savickis says, noting that the government provides an online list of certified health IT products at https://chpl.healthit.gov/#/search.

If a vendor doesn’t yet offer a 2015-certified EHR, the physician needs to find out whether it will soon have one available. If the vendor doesn’t, the physician will need to find a different vendor and plan to take out the existing EHR and replace with a new one—a significant undertaking, Savickis says.

Some physicians might find, for example, that they need to upgrade some hardware; they might need new servers if they’re using server-based EHRs, or they might need new computers powerful enough to handle the upgraded software.

Savickis says physicians need to ensure their 2015-certified EHRs are fully tested to ensure everything works properly and securely. This process could reveal that the EHR doesn’t work well with other software systems, a glitch that will require additional technical work and testing to solve.

Additionally, physicians should anticipate a possible time lag in implementing the upgraded version of their EHRs, Rockwern says. Even if a physician or practice is ready to implement upgrades, the vendors, IT consultants and technical workers it needs might have a backlog of work as other providers get ready for the new CMS requirements.

However, health IT experts say they expect CMS to provide hardship exemptions for physicians who aren’t ready in time.

Still, Tennant, Rockwern and others say that despite physicians’ frustrations over the years about their EHRs and government mandates around the use of technology, they believe the requirements for 2015 certification will bring improvements through improved interoperability capabilities, increased security features, a greater ability to incorporate patient-generated health information and more capacity to analyze patient demographic data to identify trends.
Hoff notes that another effect of consolidation among hospitals is to limit patient choice. He cites the Boston region, which is dominated by the Beth Israel Deaconess and Partners HealthCare systems. "If you don’t want to go to one of these systems to get care, the options become very limited," he says.

And while growth sometimes enables hospital systems to reduce their operating costs through economies of scale, those reductions don’t always result in lower prices for insurance companies or patients, Hoff says.

The same dynamic occurs among insurance companies, according to Eric Schneider, MD, FACP, senior vice president for policy and research at The Commonwealth Fund, a healthcare policy research foundation.

Although their growth often enables them to negotiate price discounts with providers, "there’s very little evidence that they are passing those savings along to consumers in the form of lower premiums or copays," he says.

Along with higher costs, an additional—and often overlooked—impact of consolidation among providers is the transportation problems it causes patients, says Caitlin Donovan, a spokeswoman for the Patient Advocacy Foundation.

“If your doctor’s office closes you have to find a new site of care, and especially for people in rural areas or the elderly, it can be a really big problem, especially if there’s no public transportation,” Donovan says.

**THE IMPACT ON DOCTORS**

But if consolidation, broadly speaking, is not benefiting patients, its impact on doctors appears to be more mixed, and often determined by individual circumstances.

For Howard Mandel, MD, an independent ob/gyn physician practicing in Los Angeles, it has meant a nearly two-thirds decline in annual income since the mid-1990s. That’s largely because most of the independent primary care doctors who used to be his main source of referrals have joined Cedars Sinai Medical Center, a regional hospital system, and refer their patients to Cedars Sinai-affiliated specialists.

Mandel notes that although the Stark Law forbids hospital systems from requiring their doctors to refer patients to others in the system, they can offer other incentives, such as tying financial bonuses to how much revenue the doctor generates for the system, including through referrals to specialists.

Sometimes the penalties for not being part of a hospital system can take subtler forms, such as getting less desirable surgery times or having surgery privileges linked to the number of procedures the doctor performs.

“If you work for a hospital system, that’s really easy because they’re constantly feeding you patients,” Mandel says. “I’m someone who wants to only operate when necessary, so what do I do now? Either I change my practice style and start doing surgeries more liberally, or I lose my privileges for doing certain types of surgeries.”

In contrast, Fred Nichols, DO, is expecting a substantial bump in income as a result of consolidation. He is affiliating his Hamburg, New Jersey-based ob/gyn practice with Atlantic Health Partners (AHP), a network of specialty physicians.

“I think we’re going to see some pullback to a model that’s not as big, where patients get more of a personal touch and are able to interact more humanely with their providers.”

— TIMOTHY HOFF, PHD, PROFESSOR OF HEALTHCARE SYSTEMS AND HEALTHCARE POLICY, DAMORE-MCKIM SCHOOL OF BUSINESS, NORTHEASTERN UNIVERSITY
Why one hospital system is seeking a partner

In early 2018 Summa Health, based in Akron, Ohio, announced it would begin looking for another health system for a partnership or merger. With four hospitals, 10 health centers, and about 7,000 employees spread over two counties, Summa has faced mounting financial challenges in recent years, culminating in a $28 million operating loss in 2017 and an announced plan to eliminate 300 jobs.

In its announcement, Summa acknowledged that changes in the healthcare industry “have put pressure on hospitals and healthcare systems to expand access to care while minimizing costs,” and that Summa would need a partner to achieve those objectives.

Summa’s experience is a useful lens through which to view the financial and economic forces behind hospital consolidation. Summa President and CEO Cliff Deveny, MD, explains that a major catalyst for its decision to seek out a merger or affiliation partner is the reimbursement cuts it is facing from government payers: a half percent from Medicare, and five percent from Medicaid.

The latter program, he adds, covers 22 percent of the system’s patient population. Reimbursements from commercial payers and private employers are expected to be no better than flat.

“Meanwhile, we know we have expenses that will continue to go up, whether it’s pharmaceuticals or medical supplies or making sure our people get appropriate salary increases,” he says. Summa has responded by cutting expenses over the last five years or so, while adding or expanding some clinical services.

As a result of these efforts, Deveny says, the system expects to end 2018 in the black. “Now we’re at a point of strength and we want to see if there’s an opportunity to kind of supercharge our success and bring certain services and more access points and all kinds of other things we need to invest in,” he says.

At the same time, Summa faces growing competition for patients and revenue. In 2015 the Cleveland Clinic, one of the nation’s largest healthcare systems, purchased nearby Akron General Hospital. More recently Portage Medical Center, another Akron-area hospital, was acquired by University Hospitals Health System, which is based in the same neighboring county as the Cleveland Clinic.

“We had essentially been the tertiary health system for Portage, but since University took it over, we’ve seen a 70 percent reduction in transfers from them. Now they’re all being sent to Cleveland,” Deveny says.

Meanwhile commercial payers, faced with resistance to spiraling health insurance premiums, are growing increasingly hard-nosed in their contract negotiations with providers, including Summa.

So another benefit of merging or partnering, Deveny says, is enhanced ability to attain what he terms “appropriate reimbursement” from insurance companies and self-insured employers.

Responding to concerns that Summa’s decision could lead to facilities being closed and/or patients having fewer choices among providers, Deveny predicts that, if anything, the opposite will occur.

“You’ve got to embrace change, and know that you’ve got to continue to find avenues to grow.”

“In fact, what we want to do is expand and grow. We feel like there’s a significant amount of demand for our services, especially in the ambulatory area,” he says, citing services such as women’s healthcare, behavioral health and treating opioid addiction.

“Those things aren’t sexy, or as profitable as some other services, but we want to make sure we continue focusing on services that are important to our charter as a community hospital,” he says.

Asked what lessons Summa’s experience might hold for other health systems, Deveny says, “You’ve got to embrace change, and know that you’ve got to continue to find avenues to grow.”
practices operated by Atlantic Health System, which owns six hospitals in the northwest corner of the state.

Nichols will continue to run the practice, but bill at the higher reimbursement rates AHP has been able to negotiate with payers because of its size. Had he been part of AHP for 2018, he would have been reimbursed an additional $265,000. “Obviously I can’t ignore that type of difference,” he says.

In addition, AHP will take over the practice’s billings and collections and provide IT support, for which Nichols will pay an amount equal to 12 percent of his collections, compared to the 16 percent he now pays for those services.

A further benefit comes from implementing Atlantic Health System’s EHR. “If I send a referral to one of their affiliated physicians, I can look up their consult, look up the results, really get that seamlessness of information they [EHR manufacturers] talk about. I see that as a plus,” he says.

As to whether being part of AHP will limit the choice of nearby doctors to whom he can refer patients, Nichols says, “In theory that’s true, but in practice Atlantic Health’s penetration in this area is around 90 percent, so most of the doctors I’m referring to are already part of the system.” Moreover, the nearest hospital not part of Atlantic is 40 miles away. “That distance is prohibitive for most people around here,” he says.

THE LIMITS OF CONSOLIDATION
Are there limits to how far consolidation in healthcare can go?

One possibility is the federal government stepping in to block mergers or acquisitions on anti-trust grounds.

“I think the main countervailing trend is just regulatory oversight,” says Christopher Whaley, PhD, an associate policy researcher at the RAND Corporation. “We see the Federal Trade Commission taking a bit more active role in thinking about hospital and physician mergers and the Department of Justice has been pretty active in looking at insurance mergers.”

Regarding the latter, Whaley cites the Justice Department’s role in blocking the proposed mergers between insurance giants Aetna and Humana and Cigna and Anthem.

Over the long term, however, a more powerful constraint—among hospital systems, at least—may be the unwieldiness and diminished efficiency that often results from getting too large.

“Just because you’re big doesn’t mean you’ll figure out how to do things in a way that will keep you successful,” says Hoff. “Over time, it gets really difficult to manage a multi-layered organization. And in some ways it’s even worse with a hospital system because they are highly siloed organizations and you can only integrate so much across the different care delivery streams.”

“You had a pushback sentiment [from providers] that said, ‘the reason [payers are] able to get away with that is I’m sitting out here by myself. But if I become part of a larger entity, then it shifts market power from the payer back to the provider.’”

—J.B. SILVERS, PHD, PROFESSOR OF HEALTHCARE FINANCE, CASE WESTERN RESERVE UNIVERSITY CLEVELAND

In addition, Hoff says, large consolidated hospital systems could face pushback from patients who don’t want care from what they perceive as a faceless, bureaucratic institution.

Instead, he says, “I think we’re going to see some pullback to a model that’s not as big, where patients get more of a personal touch and are able to interact more humanely with their providers.”

 MORE MERGER COVERAGE IN THIS ISSUE

Physician employment: Red flags to watch for
PAGE 25
Opinion: Physicians must fight healthcare consolidation
PAGE 4
here are two big differences between a traditional and a direct primary care (DPC) practice:

- The doctor is paid directly by patients, not insurance (or other third-parties)
- The patient doesn’t pay for office visits, instead paying a low monthly fee (typically about $50 per month).

The monthly payment is enabled by the freedom from insurance billing and codes, so the two changes are tied closely together. This article will focus on the ways in which the monthly payment changes the experience for doctors and patients.

First, I want to address certain hybrid practice models and their use of monthly fees. Many “concierge” practices (and even some who label themselves DPC) use the monthly fee in addition to traditional insurance billing. This practice can only legally be done if the monthly fees are for “uncovered services,” those not covered by third party billing codes. This practice can only be legal if the services are for uncovered services and not covered by insurance.

The value of the direct pay monthly fee to physicians and patients

“I have this freedom is because I am no longer tied to the office visit as the only profitable means to give care.”

THE FEE ITSELF

The ”ideal” patient for a subscription-based practice is one that doesn’t use your services frequently, but also sees value in paying your monthly fee. This is why I set my fees based on age, starting at $30 per month for children, and increasing incrementally by age to a maximum of $75 per month for seniors.

Any practice is much more likely to have frequent visits from a 70-year-old than a 30-year-old. Furthermore, if you set your prices too high for the younger patients, you select against the very patients you are seeking—generally healthy people who need you on occasion. I’ve been satisfied with the income I can generate from my practice with our current fee schedule and with the level of medical need of my patient population. I’ve been able to grow my practice above 750 patients and still not feel overwhelmed, and I have very little loss of patients on a monthly basis.

Financially, one of the greatest benefits of having a practice based on monthly fees is the predictability of revenue. Not only is overall income predictable, but the flow of revenue is steady throughout the month, making cash-flow easy to navigate. While there is no such thing as a “big month” in a subscription practice, neither are there “slow months,” which is a trade I am happy to make. Plus, I’ve twice adjusted my price up by $5 per month, which caused very little loss in patient numbers but generated a substantial gain in revenue (which is nice with kids in college).

THE EFFECT OF MONTHLY FEES

Fewer pointless visits.

Before leaving my old practice, I tallied the reasons for office visits to see what percentage of patients actually needed to be seen for their care. I looked at the data and thought: “Could this care be done via phone call or text message?” The actual portion of patients who needed to be seen was stunning: it was less than 25%. Many of the visits were to touch base about medication changes, many were for minor acute problems (URI’s, stomach bugs, etc.), patients needing work/school excuses, or problems that could easily be handled remotely (Otitis Externa, conjunctivitis, etc.). In truth, the main reason they were coming to the office was financial:
I didn’t want to work for free. The monthly payment removes that pressure, and so lets us care for people in the way that makes most sense.

2 **Alternative care vehicles.** I give much of my care via secure text messaging. There are many questions people have about smaller health problems. There are simple things (like rashes, acute illnesses) that can be communicated easier by this means. I also follow-up by sending a quick message asking how they are doing. My patients love this. They love the fact that they don’t have to wait forever and get passed around the phone system to contact a human. They reach out to me or my staff and quickly get the help they need. This takes a huge burden off of our phones, so the wait for those who do choose to call is much shorter.

3 **An open schedule.** Having a greatly decreased volume of unnecessary visits opens up the schedule. There is no benefit to being fully booked. In fact, you are more rewarded for having a relatively open schedule at the start of the day. This took me some time to get used to, finding myself worried when my office was quiet, and even getting bored when nothing was happening. But two facts kept me from freaking out when things slowed down: First, I am paid just as much on a slow day as a busy one and, second, my patients are paying me monthly so they get access to my care, not necessarily for the care itself. The second point was harder to wrap my brain around. One of the big universal complaints about doctors is that they are difficult to get any time with. Appointments are hard to get, and are often too short. With an open schedule, patients easily get same-day appointments. My busiest schedule in the past 5+ years was 15 patients, and my average day is between 8 and 11 patients.

4 **Longer appointments.** I mentioned this earlier, but it needs to be emphasized, as it is a huge benefit. New patients get 60 minutes of my time, and established patients get 30 minutes per visit. This means I have time to explain, education, listen, and think about things. I don’t have to limit the patient to “just one problem” (as many doctors do). And, most importantly, I can be careful and give better care. Now, I don’t spend 30 minutes on a strep throat or ear ache, but I can check preventive care on these while they are here, making sure I am giving the best care possible. Overall, patients love the fact that they aren’t rushed and that they get my full attention in their office visits.

5 **Running on time.** In the more than 5 years I’ve been in business, the longest I’ve made someone wait for a visit is 20 minutes (aside from when they come early for appointments). Most patients go immediately to the exam room and I see them within 5 minutes of them showing up.

Again, the reason I have this freedom is because I am no longer tied to the office visit as the only profitable means to give care. Healthy patients are no less profitable to my business, in fact they are beneficial in that they leave the schedule more open than do sick patients.

So what keeps me from “cherry picking” healthy patients (as some have suggested occurs with DPC)?

First, I don’t have a good means of determining ahead of time which patients will be “easy” and which will be more complex. Second, and more importantly, with my schedule free I have time to give good care for complex patients, eventually turning them into “easy” patients, as their problems are finally under control. I enjoy taking care of complex and difficult patients if I have the time to do so. The time demanded by government regulations and insurance compliance is now given back to the patient so I can give quality care.

And that is the main benefit: I get to be a good doctor again.

Rob Lamberts, MD, is a board-certified internist and pediatrician who runs Dr. Rob Lamberts, LLC, a direct primary care practice in Augusta, Ga. He also recently gave a TED talk on the DPC model. Have questions about DPC? Email medec@ubm.com.

**“New patients get 60 minutes of my time, and established patients get 30 minutes per visit.”**
Best thing said / advice given by a patient

Maria Young Chandler, MD, MBA
Business of Medicine / Pediatrics
Irvine, Calif.

“I feel like you’re my sister, not my doctor.”

George G. Ellis, Jr., MD
Internal Medicine
Boardman, Ohio

“Listen to your patients to truly understand them.”

Antonio Gamboa, MD, MBA
Internal Medicine / Hospice and Palliative Care
Austin, Texas

“Take a good vacation every year (not that I do).”

Jeffrey M. Kagan, MD
Internal Medicine / Hospice
Newington, Conn.

“Take time to go boating.”

Melissa E. Lucarelli MD, FAAFP
Family Medicine
Randolph, Wis.

“You’re already helping me by just being here.”

Joseph E. Scherger, MD
Family Medicine
La Quinta, Calif.

“Attitude makes all the difference.”

Salvatore Volpe, MD
Pediatrics/Internal Medicine / Pediatrics
Staten Island, N.Y.

“Spend more time with your family.”

The board members that contribute expertise and analysis to help shape content of Medical Economics.
“You’ve got to embrace change, and know that you’ve got to continue to find avenues to grow.”

CLIFF DEVENY, MD, PRESIDENT AND CEO, SUMMA HEALTH, AKRON, OHIO

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“There’s a big group of physicians who haven’t made a switch to the new [EHR] software.”

ROBERT TENNANT, DIRECTOR OF HEALTH IT POLICY, MGMA

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“...said they were the only one at their office...”

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JILLYN FROMMER
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(720) 116-3007 / jillyn.frommer@ubm.com

AUDIENCE DEVELOPMENT

JOY PUZZO
VP, Marketing & Audience Development

CHRISTINE SHAPPELL
Director, Audience Development

WENDY BONG
Audience Development Manager
218-740-7244 / wendy.bong@ubm.com

PUBLISHING & SALES

THOMAS W EHARDT
Executive Vice-President, Senior Managing Director, UBM Life Sciences Group

ERIC TEMPLE-MORRIS
VP, Business Solutions Sales
503-203-1060 / eric.temple-morris@ubm.com

ANA SANTISO
Associate Publisher
732-346-3032 / ana.santiso@ubm.com

HEATHER SHANKMAN
National Account Manager
732-346-3054 / heather.shankman@ubm.com

JOHN CURRID
Director of Sales, Business Solutions
212-600-3134 / john.currid@ubm.com

JOANNA SHIPPOLI
Account Manager, Recruitment Advertising
440-891-2615 / joanna.shippoli@ubm.com

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“A good bedside manner is important, but to get paid now it’s just as important to have a good computer-side manner.”

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