Navigate HIPAA
Secure your practice to avoid disaster
When you ignore a patient’s cry for antibiotics

I listened intently to her history—her symptoms, how long they’d been going on, how they’d had an effect on her sleep and activity, and the failure of over-the-counter medications to ease her suffering.

Next, I completed a careful exam, looking for clues as to the cause of her ailment. Once finished, I touched her lightly on the shoulder and indicated that she could take her seat. Taking an imperceptible sigh, I mentally prepared myself for the news I had to deliver. She would not like it. She may even express denial and anger. It was entirely possible she would seek a second opinion since I wasn’t going to be able to give her the treatment she specifically requested at the opening of our visit.

Steeling myself against her probable disappointment, I began, “You have bronchitis which is usually viral. You do not need antibiotics.”

The no-antibiotics talk with patients is one of the most challenging ones that I face. So much information needs to be conveyed before their minds close and they decide you are a quack. First, I need to reassure my patient that I’ve heard the history clearly. It is imperative that I express empathy. Even though a sore throat is minor on the list of medically bad things that can happen to you, we’ve all been there when our throat is so painful that each breath and swallow is a constant reminder of our suffering. Next, I explain my physical exam findings with both the important negative and positive aspects. Then I will discuss the lack of a role of antibiotics to treat viral infection. Finally, I will list the possible consequences or side effects associated with inappropriate antibiotic prescribing and describe what we can do to help with symptoms.

Reaction is usually mixed. Some patients express relief that you’ve made the diagnosis and have a clear treatment plan. An increasing number of patients have already heard the message that antibiotics have no role in the treatment of viral infections and start nodding before you’ve even completed your explanation. Some will narrow their eyes into slits, silently questioning your competence. A few will become angry, demanding antibiotics or threatening to seek them elsewhere.

Thinking about the difficult conversations I have with patients about cancer diagnoses, congenital anomalies in pregnancy or end-of-life discussions, it is somewhat surprising that the one most likely to cause my stomach to flip-flop is one in which I decline to prescribe inappropriate treatment for a patient who is convinced that is what they need. These conversations can be easier, here are a few important tips.

1. Make sure to listen and complete the examination carefully both to provide good medical care and to demonstrate to the patient that you are being thorough.

2. Express empathy for their experience. While not life-threatening, colds make us feel rotten.

3. Explain your reasoning with confidence.

4. State what you can do to help them feel better.

5. Discuss the potential negative impact of inappropriate antibiotics for them personally (most ill people do not really care all that much about the threat of antibiotic-resistance in the larger population).

6. Above all, do the right thing, so that none of your patients will say to another doctor, “But, Dr. Frank always prescribes me antibiotics for bronchitis.”

Jennifer Frank, MD, is a family physician in private practice in northeastern Wisconsin. This article was first published in our partner publication, Physicians Practice. How do you handle antibiotic requests when you don’t think its warranted? Tell us at medec@advanstar.com
Physicians are more than quality metrics

Quality metrics are assuming an ever-greater role in healthcare delivery, and many physicians are angry about it. They cite the vast increase in the number of metrics they must track, the lack of standardization among them, and the fact that payers are increasingly using them as a tool in setting compensation for medical practices and individual physicians.

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“In the event of an audit, good intentions aren’t enough.”
JEFFREY ZESKIND, MS, CHIEF EXECUTIVE OFFICER, HIPAA-CONSULTANTS.COM

“28% of physicians surveyed believe the ACA should be repealed, but only if an alternate plan is in place”

“‘I refuse to be a fee-for-service provider.’”
CHRIS LARSON, DO, AUSTIN, TEXAS

READ MORE ABOUT THE RISE OF DIRECT PRIMARY CARE ON PAGE 42

MORE ON NAVIGATING HIPAA ON PAGE 18

MORE RESULTS ON PAGE 30
Certifying boards don’t serve physicians’ needs

After reading the letter sent by Edward Volpintesta, MD (“Family docs have MOC concerns,” February 10, 2016) I disagree that family physician criticism is rare concerning maintenance of certification (MOC). I believe that we are very vocal.

At most meetings where the subject comes up, no one is happy with the current system. In a world of wanting to practice “evidence-based” medicine, there is no evidence that MOC produces better physicians. Why this fact is ignored, I don’t know. Why does ABMS ignore what physicians are speaking out about, I don’t know.

Three years ago, when my certification expired, I chose to not follow the MOC path. I practice excellent medicine for my patients. I stay up on CME. My patients and local hospital are happy with my efforts. So, it appears according to ABMS, that since I don’t have my current MOC, I am less of a physician. Where is the evidence of that?

I believe that all of us who are now being falsely labeled need to stand up and make a choice. Either ABMS represents what we as a large group of physicians believe is fair, or ABMS is dissolved and a new Board system is put in place.

Lawrence Voesack, MD
ODESSA, TEXAS

As an older, grandfathered-in doctor, I can tell you that we were grateful but all felt it was unreasonable for anyone to have to retake a meaningless exam every 10 years with all the time and expense involved. It was our colleagues in our professional societies, mostly academics, who jumped on the bandwagon.

When MOC first hit the fan, the American College of Cardiology gleefully sent us mailers telling us that we were no longer protected by the grandfather clause and that they would be right there to provide us with all the expensive courses and paperwork that we would need to navigate the MOC requirements.

Congress was behind them and included MOC in the PQRS requirements. Committees manned by ACC academics even said it didn’t matter if this helped push some of us into retirement. Even our AMA didn’t have the guts to come out against MOC because it would have been a bad PR move to come out against “quality.”

I am happy to see people revolting, but believe that revolting will ultimately fail. The ABIM will ride their time and over the next five years will ultimately prevail.

Allan Shiener, MD
THOUSAND OAKS, CALIFORNIA

Evidence-based guidelines aren’t always reliable

Mr. Bendix states: “A doctor might genuinely believe, for example, that he or she orders mammograms for all patients who need them according to the latest guidelines.” (“Quality metrics: A payer’s perspective,” March 10, 2016.) Yet frequently, the “latest guidelines” are either obsolete or based on poor quality evidence.

“Another problem is that guidelines rarely take patient preferences into account”

Another (major) problem is that guidelines rarely take patient preferences into account. Mammograms are a perfect example. As stated by Dartmouth’s Dr. Gilbert Welch, “half [of women state] they would not choose to start screening if [mammograms] resulted in more than one over-treated person per one cancer death averted.....that implies that millions of Americans might choose not to be screened if they knew the whole story — that overtreatment is typically more common than avoiding a cancer death.”

Healthcare “quality incentives” are unethical. They often force doctors to choose between implementing the incentivized measure or doing what is in the patient’s best interest. Dr. Salmon might want to review the Hippocratic Oath.

Peter C. Cook, MD, MPH
LEE, NEW HAMPSHIRE
Negotiating health IT contracts

You likely get notifications from Apple or other consumer tech companies that their terms and conditions have changed. You can either read nearly two dozen pages of legal language or simply click “I agree” and move on with your day. Most of us choose the latter option.

However, that is probably the worst decision when it comes to the contracts your practice makes with its health IT vendors, according to attorney Steven J. Fox, JD, who represents hospitals and health systems in contract negotiations. Fox provided insight on negotiating health IT contracts during a session at this year’s Health Information and Management Systems Society (HIMSS) conference in Las Vegas.

Since the products you eventually agree to use are ones you’ll likely continue using for a decade or even longer, Fox said that you can be a tough negotiator, but you want to be certain that the end result is one mutually agreed upon for a long-term professional relationship.

“You want to get the best deal, but also one that is a win-win for both parties,” Fox said.

1. **Assemble the right team members for a successful contract negotiation.**

   There are negotiators and then there are non-negotiators. “What you want on your team are those who know how to negotiate, are not afraid to and like to,” he said. Fox noted that you don’t want those who don’t understand that negotiations are a process and involve reviewing details multiple times and who might get frustrated and accept language simply to speed up the process.

2. **Have a solid foundation.**

   Most of the “spectacular failures” Fox has seen with big vendors and big hospitals and health systems were due to the organizations lacking solid ground. Important elements here are having organizational consensus involving key stakeholders, recognizing your organization’s capabilities, and understanding the limits of the technology.

3. **Know your budget … but don’t share with the vendor.**

   “The surest way to get a high-priced contract is when the vendor asks your budget, that it is amazingly priced within a few dollars of that amount,” he said. “Or you say your board has approved the pricing so let’s start negotiating. Now you are starting down from a pre-approved price [and the vendor now knows that].”

4. **Be prepared to walk away – really.**

   The only true leverage practices have when they’ve selected the technology they feel is best for them is the willingness to walk away. “You must make it clear … [you] will walk away and go to plan B,” he said. “We’ve had cases that there are no plan B and the vendor knows it. That might be because there are no good second choices [for your specific situation] or the vendor is in so deep with that hospital, they realize there is truly no plan B.”

5. **Read the definitions in the contract.**

   To truly know what you are agreeing to, Fox said, understand who the “customer” is, who are the “affiliates” that may also use the product, and be sure those definitions meet the intent of what you are negotiating.

6. **Beware ‘unusual limitations’ on licensing software.**

   An example is agreeing to the use of a product based on the number of computers the software is on versus the number of actual users. If, by default, you put the software on all practice computers as part of prepping your staff machines, this can wind up being a costly mistake if your practice has 50 employees, but only two use the software.

7. **Tie payments to milestones.**

   Don’t tie payments to dates or timelines, Fox said, because vendors love to collect 50% upon finalizing the contract and the rest among implementation—which is likely the next day. Instead, you might consider a schedule such as 20% due upon contract execution, 25% due upon installation, 25% due upon “first productive use” of the product, and the final 30% due upon acceptance.

8. **Keep your head out of the ‘cloud.’**

   Yes, cloud systems are a hot topic and very appealing, Fox noted, with no infrastructure needed in your practice. However, just because your data doesn’t live on your hardware doesn’t mean it isn’t on any hardware. Practices need to consider the dangers that could harm that system, from inclement weather, a failed recovery system, and other details. Fox advises checking vendor references.

Editor’s note: This article was first published in our partner publication, Physicians Practice.

*The Vitals is continued on page 17*
HHS announces pledges on health data interoperability

The federal government may finally be getting serious about promoting interoperability in health records. Sylvia Burwell, secretary of the U.S. Department of Health and Human Services, says that electronic health record (EHR) vendors that provide more than 90% of the EHR technology used in U.S. hospitals—along with five large, private healthcare systems, and numerous professional associations and stakeholder groups—have promised to implement four “core commitments” designed to improve the flow of health information to and between consumers and healthcare providers.

Burwell made the announcement during her keynote address to the 2016 conference of the Health Information Management Systems Society, held February 29 through March 4 in Las Vegas, Nevada.

The commitments include:

- Helping consumers to easily and securely gain access to their electronic health information, direct it to any desired location, learn how their information can be shared and used, and be assured that this information will be effectively and safely used to benefit their health and that of their community.
- Many of the biggest health IT developers, including Cerner, Epic, and Meditech, have committed to using standardized application programming interfaces and a single shared standard for communicating with one another, so that user-friendly resources, like smartphone and tablet apps, can quickly come to market and be compatible with one another.
- Helping providers to share individuals’ health information for care with other providers and their patients whenever permitted by law, and not block electronic health information (defined as knowingly and unreasonably interfering with information sharing).
- Implementing federally recognized national interoperability standards, policies, guidance, and practices for electronic health information, and adopting best practices, including those related to privacy and security.

“Unlocking data is a key part of our efforts to transform healthcare system into one that works better for all Americans,” Burwell said. She called the pledges “a major step forward in our efforts to support a healthcare system that is better, smarter, and results in healthier people.”

New rule would give ONC power to better enforce EHR certification

The federal government has announced proposed rules that would give the Office of the National Coordinator for Healthcare Technology (ONC) greater oversight to ensure that certified electronic health records (EHR) can actually fulfill the functions physicians need them to, especially when it comes to interoperability.

Physicians know a gulf exists between what a system is certified to do and what it can do in practice. Especially when it comes to interoperability—exchanging records with other providers or getting notified when a patient has been released from the hospital—many EHRs can’t really do what their certifications say they can.

The proposed rule, which is open for comments until May 2, gives ONC the power to review certified EHRs to ensure they meet the standards. It would also provide more regulatory oversight over the certifying groups, and pushes for greater transparency by releasing surveillance and testing results to provide physicians with “valuable information about the overall performance of certified health IT,” according to an ONC news release.

The goal is ensure that when EHR products go to market, these “products are actually working as billed,” Karen DeSalvo, MD, the national coordinator who runs ONC, said during a Tuesday media event at HIMSS 2016 in Las Vegas.

“The proposed rule furthers our ability to address and correct non-conformities found in certified health IT products from the initial testing phase through implementation in healthcare settings,” ONC says. These non-conformities—essentially the system issues that hinder usability for physicians and other providers—would be better addressed under the proposed rule by allowing ONC to work with the vendors on an action plan to address the issues or, if necessary, suspend or revoke certification. But that punitive action is not the goal, said Elise Sweeney Anthony, JD, acting director of ONC’s office of policy.

“Our goal is to work with developers,” Anthony said. “Our goal is not to get to decertification.”

Farzad Mostashari, MD, the former ONC coordinator, weighed in on the proposed rule during a talk at HIMSS later on Tuesday, calling it a major tool for ONC to use to ensure EHR systems do what physicians need and what they are actually certified for.

“Do we need government regulation? I would say we certainly need enforcement of the regulations we already have,” Mostashari said. “That’s why the rule that dropped today from ONC is so important. … If there is a vendor not doing the right thing, we can reach directly. We don’t need to go through the certification body or the testing body. This is a big deal.”
10 HIPAA mistakes practices must avoid

A breach or poor audit result can undo years of a physician’s hard work

by SHELLY K. SCHWARTZ Contributing author

HIGHLIGHTS

As more audits are conducted and penalties grow more severe, practices must put safeguards in place to protect not just their patients but themselves.

All practices should require user authorization, and protect workstations with passwords and PIN codes, that get changed regularly, to prevent unauthorized access.

PRACTICES THAT send e-mail appointment reminders, upgrade their technology, or contract with third party vendors should beware. Absent proper protocols, such actions can expose providers to risk.

Indeed, compliance with the Health Insurance Portability and Accountability Act (HIPAA) is now far more complex than it was before regulators cracked down, delivering bigger fines and aggressive enforcement.

“I think many practices are looking at HIPAA as it used to be and enforcement as it used to be and we don’t live in that world anymore,” says Jeffrey Zeskind, MS, chief executive officer of HIPAA-Consultants.com, a privacy compliance consulting firm in Miami, Florida. “There are a lot of hospitals, clinics and medical groups out there hoping they don’t get any attention from the government and that’s foolhardy. In the event of an audit, good intentions aren’t enough.”

Despite widespread awareness of the need to store and send sensitive patient data securely, physicians and practices run afoul of HIPAA rules on a regular basis, which opens the door to both civil and criminal penalties. Others invite formal complaints by failing to communicate with patients effectively and undertraining their staff.

Indeed, as more audits are conducted and penalties grow more severe, practices must put safeguards in place to protect not just their patients but themselves. To that end, it helps to explore the HIPAA mistakes that ensnare healthcare providers most often, but are easy to avoid.

1/ Outdated polices

Failure to keep current is first among the major HIPAA mistakes, says Robert Tennant, director of health information technology policy for the Medical Group Management Association in Englewood, Colorado.

For practices that have moved to an electronic health record in particular, he notes, the changes in data capture, storage and transmissions requirements have been significant.

“I would argue it’s an excellent time to review and update your privacy policies.”
HIPAA requires healthcare providers to develop and follow procedures that ensure the confidentiality and security of protected health information, or PHI. But the rules have changed dramatically since 1996 when they were first enacted by Congress. The Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009, for example, not only toughened breach notification laws, but applied HIPAA standards to healthcare provider’s business associates (BAs), including software vendors, data analysts and claims processing firms.

To ensure compliance, providers must now generally get a signed business associate agreement from third-party vendors that process PHI. The contract should spell out explicitly how a BA should report and respond to a data breach, including those caused by a subcontractor.

More recently, the HIPAA omnibus rule of 2013 increased penalties for violations, strengthened enforcement strategies and gave patients the right to withhold information from their health plan if they pay for a test or procedure out of pocket. As a result, practices must now have processes in place to redact those documents in the event that a health plan requests a copy of that patient’s medical record, says Tennant.

Because the omnibus rule now permits patients to review and request copies of their electronic medical record, practices must ensure that they are able to produce such records in the required 30-day

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**Does HIPAA hit its mark?**

Despite the HIPAA rules and improved safeguards to PHI, more than 40 million Americans suffered a breach of their personal health information from 2009 through the end of 2014, not including the 80 million record breach that Indianapolis-based insurer Anthem revealed in 2014, according to health IT security firm Redspin of Carpinteria, California. In 2014 alone, 164 incidents of PHI breaches were reported to the Office of Civil Rights, impacting nearly 9 million patient records, a 25% increase over 2013. More than half were caused by hackers.

Such breaches beg the question: Is HIPAA doing its job? Rebecca Herold, CISM, president of The Privacy Professor, an information security and privacy consultant in Des Moines, Iowa, thinks the answer is yes. “You can’t prevent all breaches, but I believe that without HIPAA there would have been many, many more,” she says. “And, because of the reporting requirement of HIPAA, we wouldn’t know about them because the entities covered by HIPAA would not report them.” Others say the omnibus rule that broadened patients’ rights to request electronic PHI paved the way to patient-centered care, empowering patients to take a more active role in their own care.

Not everyone agrees. As health information technology facilitates a more fluid exchange of sensitive patient data, it also opens the door to bigger potential breaches that not even HIPAA can prevent, says Peter Dixon, MD, an internist and solo practitioner in Essex, Connecticut. “We need privacy laws, but I am dubious about its ability to protect patient data,” he says, noting technology is always two steps ahead of legislation. “With paper records, privacy used to be sacrosanct. Now everything is on computers and it’s fair game for hackers.”

All the more reason that practices should enact internal policies that protect their patients and their providers, says Robert Tennant, director of health information technology policy for the Medical Group Management Association in Englewood, Colorado. HIPAA is here to stay and must be part of the conversation. “HIPAA updates should be discussed in meetings and staff emails,” he says. “Talk to your staff about cases that illustrate broader policies and remind them how to handle it.”
“I think many practices are looking at HIPAA as it used to be and enforcement as it used to be and we don’t live in that world anymore ... In the event of an audit, good intentions aren’t enough.”

— JEFFREY ZESKIND, MS, CHIEF EXECUTIVE OFFICER, HIPAA-CONSULTANTS.COM, MIAMI, FLORIDA

Operations

HIPAA

time frame, and to do so in the format requested (PDF, Word file, etc.) ”The bottom line here is that practices should review and update all of their policies and procedures every year to be sure they remain compliant,” says Tennant.

2/ Inappropriate access
Under HIPAA, access to PHI is limited to those who need it to do their job. That includes clinical staff. (That standard does not apply to exchanges among providers for treatment purposes.)

According to Steven Waldren, MD, director of the American Academy of Family Physician’s Center for Health Information Technology, the most common HIPAA violations, he says, come from within. Indeed, a 2011 survey by data security firm Veriphyr, in Los Altos, California, found that more than 70% of the organizations studied experienced at least one breach of PHI during the previous 12 months, and that employees were responsible for a majority of them.

Some 35% viewed the health records of fellow employees and 27% accessed records of friends and relatives. All practices should require user authorization, and protect workstations with passwords and PIN (personal identification number) codes, that get changed regularly, to prevent unauthorized access, says Waldren.

3/ Volume violations
Practices frequently become lax when it comes to verbal communication, says Michael Mirro, MD, a cardiologist in Ft. Wayne, Indiana, and past chair of the American College of Cardiology’s Informatics and Health IT Task Force.

“Conversations about patients in the office are not permitted where other patients and even staff can hear what you’re saying,” he says. “If someone in the waiting room overhears that Mrs. Jones has metastatic breast cancer, that’s a violation of her privacy, and in a smaller community where everyone knows each other that’s particularly not good.”

Oral communications, like any other, are subject to the ”minimum necessary” standard. As such, practices should develop and implement policies that reasonably minimize the amount of PHI used, disclosed and requested. Specifically, a policy should identify the persons within the practice who require access to PHI to perform their jobs, the categories or types of PHI needed, and the times when it is appropriate to access that information.

Standard protocols are generally sufficient for regular or recurring requests, but non-routine disclosures and requests for PHI should be considered on a case-by-case basis.

4/ Failure to choose a privacy officer
Practices are considered non-compliant if they haven’t designated both a privacy and a security officer (who may be one and the same) among their current staff, a detail many smaller healthcare practices overlook.

Under HIPAA, the privacy officer—often the business manager—is responsible for overseeing all activities related to the development, implementation and maintenance of your practice’s privacy policies. Similarly, the security officer must take steps to protect patient data that is held or transferred in electronic form by establishing both technical and non-technical safeguards. The security officer also should help educate staff on any changes to HIPAA rules.

Security and privacy officers, however, need not work directly for your practice. They can be outside consultants, attorneys or other qualified third parties. Zeskind notes that contracts with third party officers should spell out the effective dates of their service and describe their job responsibilities in detail, including whether they will provide a full security risk analysis (SRA), corrective action plan, and customized policies and proce-
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To protect themselves further still, practices should ensure that all consultants have errors and omission professional liability insurance in case they make a mistake, he says.

It’s worth noting that several organizations, including the Healthcare Information and Management Systems Society (HIMSS) and the American Medical Association, provide free privacy and security toolkits to help officers meet HIPAA compliance. The toolkits help explain the revised rules, provide guidance on best practices for updating their existing HIPAA policies and procedures, and contain templates of documents practices will need to update and distribute.

5/ Unencrypted devices

Medical practices must also secure their digital devices. Laptops get hacked. Smartphones get stolen, and tablets go missing. These things happen, but if they happen on an unsecured device and PHI is involved, the provider can land in hot water. Such offenses can result in hefty fines, depending upon the degree of negligence involved.

The easy way around that is to ensure that all company-owned devices and mobile devices are encrypted to prevent unauthorized access. That way, even if your device is lost or stolen, it won’t be considered a HIPAA privacy breach. “Encryption is your ‘get out of jail free’ card,” says Tennant, noting that this is an area where most practices still fall short. “We strongly recommend that mobile technology either not contain PHI or if it must that it be encrypted.”

Encryption is the process of converting data into an unreadable format by the use of algorithms. HIPAA has long required that data in transit be encrypted, but now requires the same security controls for data at “rest,” too—meaning data stored on their server, computer databases and flash drives.

It’s not technically difficult and costs less than $100 a year to encrypt a hard disk, but many practices prefer to hire an IT specialist. “It’s fine to use a consultant, but make sure they’re well-vetted,” says Zeskind. “To save money, many small firms go with Uncle Bob, who knows how to put together a network, but knows nothing of security and privacy.”

6/ Mobile mishaps

Email and text messaging are a major source of HIPAA violations. Email messages sent to patients, says Mirro, should never contain personal health information. They may, however, notify patients that a message awaits them in the practice’s secure portal.

Before hitting send, however, keep in mind that employers have the right to read any email sent or received from a work email account. A seemingly benign message from an oncology center that confirms the patient’s appointment may be enough information to compromise their employment, says Mirro.

Practices should never send PHI via email in response to a patient’s request, because the patient’s identity cannot be confirmed. “My nurse or I always reply, ‘I will call you,’ so we can be sure we’re actually talking to the patient and not someone who jumped onto their email,” says Mirro.

Providers should ensure that e-mail contains the minimum amount of information needed, should verify the e-mail address of the recipient, and confirm that the patient wants to receive emails from their office.

Text messages, while efficient, are more problematic still. Nurses who text status updates on patients to doctors are violating HIPAA rules. So, too, is the physician who sends protected patient information to other doctors via an unsecured service—doubly so if they peck out a message where others can see. HIPAA-secure messaging exists through vendors such as Doximity and TigerText, which also enable users to remotely delete text messages in the event they are sent to the wrong person or a mobile device is lost or stolen.

7/ Sloppy security risk assessments

HIPAA security rules require healthcare organizations to conduct a security risk assessment (SRA) to ensure compliance with administrative, physical, and technical safeguards. Some practices, however, perform the assessment once and consider it done.

That’s a mistake.

The rules require healthcare organizations to conduct an SRA at least annually, and more often if they’ve upgraded their technology, executed a spinoff, or otherwise exposed their practice new potential risks. Waldren says practices must perform an assessment annually, update their procedures for maintaining security, identify any security risks found, and document what
The adoption of electronic health records (EHRs) presents doctors with a dilemma when it comes to protecting patient health data.

On the one hand, Medicare provides incentive payments for meaningful use of EHRs, which requires doctors to capture, store and securely share protected health information with their patients and other providers. On the other, HIPAA makes healthcare providers accountable for keeping protected health information (PHI) confidential, delivering hefty fines for those who fail to comply.

The Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009 raised the maximum fine per violation to $50,000 from $100, and the annual cap for all violations of a specific provision climbed to $1.5 million from $25,000. Criminal penalties under the HITECH Act also now range from $50,000 to $250,000, with up to 10 years in prison, depending on the degree of negligence.

Fear of being fined is frequently cited by the healthcare community as a leading barrier to EHR interoperability—the ability to exchange and interpret patient health data electronically.

“HIPAA is a great example of the federal government at work where the intention is good, but the outcome in many instances is very bad,” says Michael Mirro, MD, a cardiologist in Fort Wayne, Indiana, and past chair of the American College of Cardiology’s Informatics and Health IT Task Force. “It strikes fear in the heart of every healthcare worker because they know that even an inadvertent breach can cost them their job.”

According to Mirro, HIPAA and EHR interoperability are fundamentally at odds.

But policymakers suggest HIPAA isn’t the problem.

“HIPAA rules and EHR interoperability work very well together actually,” says Lucia Savage, chief privacy officer for the Office of the National Coordinator for Health Information Technology (ONC), a division of the U.S. Department of Health and Human Services. “We know providers are out there trying to do the right thing, but there is a lot of confusion and misunderstanding about privacy laws.”

In its 2015 report to Congress, the ONC says complaints and anecdotal evidence suggests some health IT developers block or limit the availability of information intentionally for competitive gain, charging fees that are designed to deter connectivity or exchange with competing technologies or services.

Healthcare providers have also been accused of information blocking, the report found, with some hospitals or health systems allegedly seeking to control referrals and enhance their market dominance, despite their claims that they actually constrain access to comply with privacy laws.

To dispel misconceptions about HIPAA limitations and help achieve interoperability, the ONC recently released a “roadmap” to coordinate the exchange of electronic protected health information among hospitals, health plans and providers. It clarifies HIPAA rules, and sets specific goals to catalyze collaboration between the public and private sector.

The Centers for Medicare and Medicaid Services (CMS), notes, too, that HIPAA does not say “don’t share data.” “In fact, HIPAA largely deals with how to protect data in order to be able to share it in many different ways without infringing on the patient’s privacy,” the agency said in a statement, adding that HIPAA even governs that providers must comply and share data upon patient requests. “Not only do these things not contradict one another, they go hand in hand and are inherently related,” CMS says. “Using technology to share data can allow for a wide range of potential protections and security around the movement of data and the storage and encryption of ePHI in ways that paper records and transmissions may not.”

Marla Durben Hirsch, JD, a health law attorney for 30 years and editor of The Health Law Journal, says that privacy rules do not themselves create roadblocks to interoperability, noting HIPAA allows sharing of information for treatment, payment and operations without patient authorization.

But there are logistical issues that might. She cites the example of a provider who shares patient data with a health information organization, and the organization experiences a data breach. “Who is obligated to notify patients, HHS and the media about the breach and mitigate damages?,” she asks. “How much control should a patient have regarding the sharing of his or her information? And who owns the data once it’s been shared?”

Such questions complicate the debate. “The bottom line is that the technology is outpacing the law,” says Hirsh. “No one envisioned in 1996 when HIPAA was first enacted, or even in 2009, when HITECH amended HIPAA, how advanced technology would become, how much more difficult it would be to keep data secure, or the massive data breaches and security risks we’re seeing today.”
“Encryption is your ‘get out of jail free’ card. We strongly recommend that mobile technology either not contain PHI or if it must that it be encrypted.”

— ROBERT TENNANT, DIRECTOR, HEALTH INFORMATION TECHNOLOGY POLICY, MGMA, ENGLEWOOD, COLORADO

22 steps they have taken to mitigate those risks.

“The number one mistake I hear is not fulfilling the documentation requirements for security audits and failing to update it on an annual basis,” says Waldren, noting those documents can simply indicate that nothing has changed, but it must still be put in writing.

Practices must also train all workforce members, including employees, independent contractors, volunteers, and student interns and document that to cover themselves in the event of an audit, says Zeskind.

8/ Dated documents
Health plans and covered healthcare providers are required to develop and distribute to patients a notice of privacy practices, or NPP. The NPP is a document that explains in clear, user-friendly language patients’ rights to their personal health information and the privacy practices of your office—or at least it should.

Specifically, the NPP should describe the types of disclosures that HIPAA Privacy Rules permit the practice to make without authorization, including treatment, payment and healthcare operations, along with at least one example of each. And it should describe each of the other purposes for which the practice is permitted or required to use or disclose PHI without the patient’s authorization, including family members involved in the patient’s treatment or payment for care, to avoid serious threat of harm to the patient, or to a relevant business associate.

“A lot of practices simply copied something off the Internet and produced it for their patients, but they literally have not reviewed it since they created it more than 10 years ago,” says Tennant. If your practice now offers the option of receiving appointment reminders via text message, for example, the NPP should be revised to communicate the risks to patients. It should also give them the right to opt out of receiving messages from your office via email or text.

9/ Poor complaint handling
Practices that don’t have a written process in place for handling privacy complaints are setting themselves up for problems.

“Everyone needs to be trained on HIPAA, but the staff at your front desk who deal with patients specifically need to know what to do if a patient comes forward and says, ‘I think my information was disclosed inappropriately,’” says Tennant.

Such patients should be taken directly to the privacy officer so their concerns can be addressed promptly. “Don’t shoo them away, or tell them you’ll have a manager get back to them,” he says. “Those are the patients who are most likely to lodge an official complaint (with the Office of Civil Rights) and a lot of these issues can be resolved simply by good communication between the practice and the patient.”

10/ Forgetting state laws
Most states have their own privacy laws that deal with PHI, and some have sharper teeth even than HIPAA.

Practices that do business in multiple states must ensure their policies comply with all relevant rules. HIPAA does not preempt state laws that are more restrictive. Where such rules differ, the one that benefits patients the most supersedes, says Zeskind.

“The bottom line is, if you're going to do training, or have an auditor come in and check for compliance and security risks, you should address all state and federal privacy rules together,” he says.

Any state laws are more restrictive than HIPAA must be noted in the NPP document. To protect their practice in the event of an audit, employers should err on the side of complying with both federal and state rules. Regular staff training on all relevant privacy rules is a must, says Zeskind.
The MOC revolt, part 2: Alternative board fights for relevancy

Can the National Board of Physicians and Surgeons grow enough to become a true competitor to ABIM?

by ED FINKEL Contributing author

SOME PHYSICIANS opposed to maintenance of certification (MOC) have put their faith in an alternative certifying body, one that bills itself as low-cost, low-hassle and, most importantly, does not require an intensive recertification process.

The National Board of Physicians and Surgeons (NBPAS) has been growing steadily, but its membership is still modest. “We have sign-ups every day. We still have a lot of challenges, and we’re working through those,” says Paul Teirstein, MD, a cardiologist at Scripps Clinic in La Jolla, California, and president of NBPAS, which had more than 3,300 members and had gained approval at 26 hospitals as of February. It adds about 200 new members each month.

Teirstein says his challenges include hospitals that have contracts requiring American Board of Medical Specialties (ABMS) member board certification and the intentions of payers, who are mostly mum to date.

At least several hospitals accepting NBPAS certification did not experience much controversy in gaining approval for that policy, according to those involved.

At Hoag Hospital in Newport, California, the medical staff voted 97% in favor of changing its bylaws to accept NBPAS, says Rick Haskell, MD, chief of staff and a cardiologist. “Who’s the best judge of whether a doctor is qualified? His peers,” he says. “That’s a better judge than whether I can answer a multiple choice question correctly. Basically, the medical staff is saying they’re practicing their specialty in a way that we think is qualified, to work at our hospital.”

The only hesitation Haskell heard: What about insurance companies? But he’s not aware of anyone who has been impacted adversely. “We don’t know what they’re going to do, and even then, they may changed their mind in the future,” he says.

The chief of staff at Texas Heart Institute/Baylor St. Luke’s Medical Center in Houston, Texas, lent a receptive ear to Scott Greenberg, MD, an electrophysiology fellow, who raised the subject of NBPAS certification, and he gained approval from the medical executive committee. This was made easier because, unlike some hospitals, its bylaws do not specifically require certification through ABMS, Greenberg says.

“When you have a chief of staff who believes in what you’re telling him, that makes it easier,” he says. Once administrators
Policy  MOC revolt

learned more, “there was less resistance than we initially thought.”

Others still seek approval. One physician who recently signed up for NBPAS, George G. Ellis Jr., MD, says he will likely recertify with the American Board of Internal Medicine (ABIM) this year due to concerns about hospital privileges and insurance coverage.

“Guys I know who are practicing at the [local] hospital have submitted documents in hopes of getting them to accept [NBPAS]. We’re waiting to see what happens,” says Ellis, chief medical adviser to Medical Economics and an internist in Youngstown, Ohio.

When Howie Mandel, MD, did not recertify with the American Board of Obstetricians and Gynecologists (ABOG) at the end of 2015, he received notice that ABOG no longer considered him certified. Mandel has gained certification from NBPAS but isn’t sure what will happen when he’s up for reappointment at Cedars Sinai Medical Center, Los Angeles, in October.

Since he’s been in good standing as a staff member, there would be an appeals process if the lack of certification trips him up, Mandel says. If the hospital makes an issue out of MOC, “I would argue to them that they have reverse age discrimination,” he says, since doctors who were first certified only a year before him are grandfathered into MOC for life. He doesn’t take insurance, “so it’s not a problem there.”

Robert Beaumont, MD, medical director at Waukesha Family Practice Clinic in Waukesha, Wisconsin, has certified with NBPAS and let his American Board of Family Medicine certification lapse. He no longer sees patients at Waukesha Memorial Hospital but says that was his choice and that the hospital “hasn’t gotten back to me on whether they’re going to honor it.” He says payers have not asked about certification.

PAYER PENALTIES

Others have gained at least some hospital approvals. Endocrinologist Arvind Cavale, MD, says his internal medicine certification expired last year but he’s still certified in endocrinology through 2019.

Physicians fed up, feel trapped by MOC

We asked members of the Medical Economics Reader Reactor Panel, 200 physicians representing various specialties across the U.S., about their feelings on maintenance of certification and their daily lives in medicine. Here’s what they said about recertification:

“Board recertification has almost nothing to do with my daily work as a primary care physician. It is an angst-generating exercise in arcane minutiae that robs me of work and family time for little gain or benefit. In my opinion, it is academic extortion and a blatant money grab. Unless absolutely forced to because of business reasons, I hope not to recertify a third time as it is a painful experience that does not really help me or my patients.”

W. David Smith, MD
Internal medicine, Cincinnati, Ohio

“After starting the MOC process for family medicine, I realized there was no relevance to my current practice of medicine and that it was pure busy work and a waste of my time. Having recertified six times before taking the same test that residents fresh out of training were taking, I could not find any reason for the change. The certification board was assuming duties left to state licensure boards with a huge overreach grab for power. As I investigated further, the board could not supply me with a satisfactory explanation or real science to back up their claims. They were making a voluntary program mandatory with financial gain and power on their part as the real reason. I looked for alternatives and still list myself as board certified by NBPAS and am happy to recertify with continuing education requirements that match the practice of family medicine that I need to ensure my patients receive the best care.”

Rob Jones, MD
Family medicine, Phoenix, Arizona

“Board certification used to be a mark of excellence, not a form of extortion, revenue generation and busywork. Maintenance of certification, with its practice improvement, patient voice, patient safety, and secured high-stakes examination, has no bearing on what happens in the examination room; there is zero impact on the actual care of patients. I have to recertify, otherwise I...
Based in Feasterville, Pennsylvania, Cavale joined NBPAS last year and does not plan to keep his ABMS certification. St. Mary Medical Center in Langhorne, Pennsylvania, has accepted his NBPAS credentials, but Aria Health in Philadelphia, where Cavale is also on staff, has not to date.

Insurance has not been an issue for Cavale: About 70% of his patients are covered through Independence Blue Cross of Philadelphia or Highmark Blue Shield of Pittsburgh, and “when I came up for credentialing last year, I mentioned that I was certified through a new board and they accepted it and didn’t ask any questions,” he says, possibly because Cavale serves as a resource specialist for those companies. “For them to use a technical issue like this one to nail me, or get me off their panel, would probably be more damaging to them than me,” he says.

Hospital privileges have not been a problem for New York-based internist Jonathan Weiss, MD, who recertified in internal medicine in 2012 but has let his other certification lapse and recently applied to NBPAS.

“I asked the company why on December 31, 2014, I was perfectly capable of doing these things, and on January 1, 2015, I wasn’t,” Weiss says. “They said our clients want this, and we’re very sorry we can’t use you, you did good work.” The lawyers for whom he worked “bought into this notion that the only capable doctor is one who is board-certified. Many of us would dispute that, but that’s what’s been put out there very effectively by entities like ABIM.”

Tim Wingo, MD, certified through NBPAS in June 2015 and let his ABFM certification lapse at the end of the year. The attorneys for whom he handles case reviews haven’t had any issues either, says Wingo, a family medicine specialist for those companies. “For them to use a technical issue like this one to nail me, or get me off their panel, would probably be more damaging to them than me,” he says.

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physician with Atlas Healthcare in Mount Pleasant, South Carolina. One told him, “It looks better if you’re board certified,” but did not press the point. The other told him, “If you choose not to do it, then you simply tell them, ’No, I have my own way of staying current. I like to spend my day seeing patients.’”

Dermatologist H.L. Greenberg, MD, has garnered 400 signatures—more than the 320 necessary—to force a bylaws amendment that he planned to present to the American Board of Dermatology (ABD) secretary-treasurer. Greenberg, who practices at Las Vegas Dermatology, plans to recertify in 2022 but says, “There’s a monopoly in place that I didn’t choose to have put over me.”

A TRUE ALTERNATIVE?
But will the NBPAS grow into a true alternative, gaining acceptance from a sufficient number of hospitals and insurance companies to be viable in the long run?

The NBPAS requires initial certification by an ABMS board and 50 hours of continuing medical education every two years. “That’s what we substitute instead of doing computer modules and taking repeat tests,” Teirstein says. “It’s equally good, more meaningful and less onerous. Both methods are unproven. There’s no proof that any of this matters.”

Paul Mathew, MD, an NBPAS board member and neurologist at Harvard University Medical School and Brigham & Women’s Hospital in Cambridge, Massachusetts, believes ABIM and other ABMS boards will need to move in the direction of the NBPAS model—including lowering fees (which are $169 for two years at NBPAS) in addition to keeping requirements more reasonable—to stave off ongoing competition. “NBPAS is a great alternative in the event that the ABMS boards don’t buckle,” Mathew says. “If they do buckle, who knows? NBPAS may end up disbanding if it leads to the adequate reforms that a lot of us are looking to see.”

ABMS and its boards have been paying attention to NBPAS and the comments of those associated with it to improve, says Lois Nora, MD, JD, president and chief executive officer of ABMS. She also notes that NBPAS requires ABIM board certification at the outset. But beyond that, “candidly, I disagree with the criteria they have put in place,” she says. “Continuing education is important, but we believe it is only part of a larger construct. We believe that an independent assessment by a board made up of physicians in that specialty is exceedingly important.”

Richard Baron, MD, president and chief executive officer of ABIM, expects the NBPAS will continue forward but agrees with Nora that requiring only “passive” MOC through CME is inadequate. “What the community of doctors have to decide is, is that a standard that’s meaningful for them?” he says. “Do they have confidence in that? Should anybody else have confidence in that? Ours, you have to demonstrate that you didn’t just go to a course but that you have knowledge. Doctors are looking at that and making a choice.”

Westby Fisher, MD, a cardiologist and electrophysiologist at NorthShore Hospital, in Glenview, Illinois, says he’s working to change his hospital’s bylaws to accept NBPAS and encourages other physicians to do the same. He believes getting payers to go along will be critical to NBPAS’s success.

“Once Paul Teirstein gets Aetna and Blue Cross to accept his board, people won’t do this ABMS stuff anymore,” Fisher says. “Already plenty of people are quietly not doing it. Hospitals are going to say, ‘We can’t just send this guy a letter; he’s our most productive person.’ They’re going to say to insurance companies, ‘Hey, back off’.”

Some doctors who have issues with MOC don’t believe NBPAS is the answer. Ashesh Patel, MD, an internist in Washington, D.C., says he’s certified through ABIM until 2019 and does not believe NBPAS certification goes far enough in ensuring physicians are keeping current. “Something in between, I think, is a better option,” he says. “Hopefully ABIM is moving toward that.”

Still, Patel says NBPAS has applied pressure to ABMS boards. “Having competing viable boards in existence that allow physicians to choose where they are certified from will at least make ABMS/ABIM’s ‘my way or the highway’ approach to board certification untenable as a business model.”

Jay Alexander, MD, who practices at NorthShore Cardiology in Bannockburn, Illinois, isn’t convinced that enough hospitals and payers will ultimately accept NBPAS. “I personally don’t see it becoming the certifying body for cardiology,” he says.

Greenberg does not see the NBPAS as viable. “It’s a paper tiger,” he says.
GERMS. BODILY FLUIDS. STUBBORN PATIENTS.

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**TRUMP vs. HILLARY**

The showdown physicians want

*by** MEDICAL ECONOMICS STAFF*

Donald Trump versus Hillary Clinton. That’s the matchup physicians want to see in the 2016 presidential election, according to an exclusive online poll conducted by Medical Economics.

Beyond the candidates, the results suggest that physicians are deeply discontented about how little the candidates have discussed healthcare policy during the campaign.

Furthermore, only a small number—less than 5%—believe the Affordable Care Act (ACA) should continue as is, with many physicians believing it needs to be amended. Repeal is only a good move if something is being put in its place, according to 28% of physicians.

Removing federal healthcare mandates facing physicians was the top priority physicians want the candidates to address, followed by the fate of the ACA, rising healthcare costs and payer consolidation.

**If the election were held today, I would vote for:**

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<thead>
<tr>
<th>Candidate</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Hillary Clinton</td>
<td>19.5%</td>
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<tr>
<td>Donald Trump</td>
<td>17.1%</td>
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<td>Bernie Sanders</td>
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<tr>
<td>Marco Rubio</td>
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<tr>
<td>Ted Cruz</td>
<td>8.3%</td>
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<tr>
<td>John Kasich</td>
<td>7.5%</td>
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<tr>
<td>Undecided</td>
<td>9.2%</td>
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*How we got our data* We surveyed nearly 53,000 physicians to find out what they think about the election thus far, and received 1,532 responses—a response rate of 3%. Responses were gathered between February 5, 2016, and March 1, 2016. The survey was sent to readers of Medical Economics via the email newsletter.
Do you feel that healthcare issues have been adequately addressed by the candidates to date?

- Yes: 11.4%
- No: 88.6%

What do you think should happen to the Affordable Care Act under the next U.S. President?

- It should remain intact: 29.3%
- It should be repealed: 28%
- It should continue to evolve with minor amendments: 29.1%
- Other: 9.4%
- It should be repealed, but only if a replacement plan is in place: 4.2%

Readers’ questions for the candidates

As part of our election poll, we asked Medical Economics’ readers, “If you could ask the presidential candidates one question, what would you ask?” Here were some of the inquiries that summed up the majority of replies by those taking our poll.

1. Why should we not have the same healthcare insurance as you?
2. Why are health insurers allowed to make such huge billion dollar profits and pay their CEOs multiple of millions while at the same time denying the public care and not adequately paying the physicians who make life and death decisions daily?
3. What are you going to do to lure more people into primary care medicine and retain those that are in it now?
4. What would you propose to give doctors and patients more control of their health and remove all of the bureaucracy with the documentation requirements that take away from direct patient care?
5. Why should doctors accept insurance given much higher deductibles, increasingly difficult billing problems, necessary and bad faith tactics of insurers to evade payment, and the extremely low level of reimbursements now coming from the insurance companies?
6. If you repeal Obamacare, what would you say to millions of uninsured who will immediately lose health coverage?
7. Why is the government not addressing tort reform? It is obvious that the legal profession is in much need of regulation to prevent their frivolous attack on the healthcare profession and pharmaceutical drug industry that cause increased healthcare costs.
8. Why don’t you have multiple practicing physicians advising you, rather than academicians, and non-practicing docs?
9. Why is my compensation regulated and controlled by people who don’t understand the value of what we physicians bring to the table?
10. With the rising cost of healthcare and the increased responsibility for payment by patients, I am finding it more difficult to keep my practice open. How do you see that changing?

What one major healthcare issue would you like to see them address?

- Reining in government mandates on healthcare: 22.5%
- The fate of the Affordable Care Act: 20.9%
- Rising healthcare costs: 12.5%
- Possible national payer consolidation: 12.4%
- Controlling prescription drug prices: 11.8%
- Physician pay inequity: 10.9%
- Other: 9.3%
Understanding the new diabetes code for primary care

by RENE DOWLING Contributing author

Q Can you explain the intensive behavior therapy code for treating patients with diabetes? Is this a new code?

A: This new Category III CPT code, 0403T, became effective January 1, 2016, and will be used to report the services provided in a standardized diabetes prevention program (DPP) recognized by the Centers for Disease Control and Prevention (CDC).

This code should be billed when a provider conducts a face-to-face intensive behavior change therapy session in a group setting, aimed at diabetes prevention using standard program parameters. It is reported for a minimum of 60 minutes per day of intense therapy.

The standardized curricula recognized by the CDC are year-long behavior change interventions comprised of at least 24 sessions distributed across the course of a year. Typically they are provided in 16 weekly, hour-long sessions for the first six months of the year, followed by monthly hour-long sessions during the second six months.

Recent studies have shown several behavioral adjustments can be made in order to help prevent type 2 diabetes in those at high risk, specifically those patients with minimal physical activity and obesity.

However, this is not just a weight-loss program. Specific eligibility criteria include laboratory blood values or risk factors, including genetic predisposition, that indicate a high risk for type 2 diabetes. Throughout the behavior change intervention, participants have access to a trained coach who must be able to provide the program successfully. These coaches are trained in collection of weight data, physical activity, food journal review, behavior change strategies, motivational interviewing and more.

Participants are weighed at every session and work toward goals of healthier eating, 150 minutes per week of physical activity, and 5% to 7% or more weight loss. Participants also collaboratively discuss and identify solutions to health and behavior challenges for type 2 diabetes risk reduction.

Here are some coding tips for using CPT code 0403T:

- This code should be used only by CDC-recognized National DPP providers. An insurer could require verification that services were rendered by a CDC-recognized National DPP provider.
- For reimbursement, a CDC-recognized National DPP provider must negotiate a fee with a payer. If a payer receives a claim for a Category III code and a provider has not negotiated a fee, there is no assumed reimbursement. It is merely a reporting code to say that a health plan member is receiving the services of a CDC-recognized National DPP provider.

Prior to reimbursement being negotiated, it is still important for CDC-recognized National DPP providers to submit a claim when possible for all insured individuals participating in the program.

Renee Dowling is a billing and coding consultant with VEI Consulting Services in Indianapolis, Indiana. Send your billing and coding questions to: medec@advanstar.com.
IN DEPTH

Money

How physicians can determine life insurance needs

Physicians should carry levels of coverage that complement their family’s financial game plan, experts say

by JANET KIDD STEWART Contributing author

HIGHLIGHTS

Few physicians escape medical training without being lectured about carrying disability and life insurance, the eat-your-peas staples of personal finance for doctors.

Joseph Haig, MD, emergency physician in Elizabeth, New Jersey, carries both life and disability insurance policies, though his financial adviser is urging him to carry more life insurance based on some recent conversations. The married father of three already spends $12,000 a year on the policies.

“I wish I could put that money elsewhere,” Haig says, but between school loans, a mortgage and other expenses, he feels he can’t risk living without his income in case he gets sick or hurt, or saddling his family with those bills in case he dies before his other savings have had a chance to grow.

Meanwhile, 62-year-old John Verheul, MD, MPH, a family practitioner in Midlothian, Virginia, has used life insurance as an investment for nearly 40 years, both for his family and for his practice partners, though when his family was younger he had a nagging sense that the coverage amount might not adequately cover their expenses.

Now that his kids are grown, Verheul and his wife, Linda, are considering options for the insurance, including borrowing from a permanent policy or letting their beneficiaries, their adult children, take over the premiums.

How much life insurance physicians need at various stages in their careers is, of course, a moving target that depends on their other financial resources, their dependents and a host of other issues. And like Haig and Verheul, most physicians have to balance those needs with competing goals, from college savings to retirement. Little wonder, then, that financial advisers tend to bristle at generalizations about how much is needed.

“I really dislike the rules of thumb because they disregard individual circumstances,” says Peter Palion, CFP, a financial adviser with Master Plan Advisory Inc. in East Meadow, New York. “Even physicians aren’t the same. You could have one who has...
several dependents to cover and another who is married to an heiress."

Palion, who is Haig's adviser, prefers to get physician clients talking about how they would want their spouses and children cared for in the event of death. As these conversations are unfolding, Haig says he is beginning to understand more fully why the adviser is recommending more coverage, though cost remains an issue, he adds.

CONTEMPLATING COVERAGE

Palion says that while the general rule of thumb of having six to 10 times annual income is a good range, physicians who customize that amount can either save themselves some money on premiums or prevent hardship.

"I've had conversations with clients who said, 'If Frank passed away I would want to quit work and dedicate my life to the kids until the last one enters college.' And I've also heard, 'If Frank dies I'm not going to have a financial problem,'" because of other resources at the couple's disposal, he says.

Other advisers agreed.

"There's usually a set of circumstances where you could have made the case for someone having more insurance," says H. Jude Boudreaux, CFP, founder of Upperline Financial Planning in New Orleans. While more insurance would have been nice for survivors, however, physicians need to balance that against the reality that without those insurance premiums to pay over many years, they could more quickly build wealth in other ways, he says.

Determined the right amount of coverage doesn't end there, however. It has to fit with your overall financial game plan, experts say. Adviser Kevin Meehan, CFP, regional president of the Wealth Enhancement Group in Itasca, Illinois, recently counseled a new physician client with a universal life insurance policy that was eating up half the physician's total monthly savings.

"He was looking for a portion of his savings to be in a more conservative tool where he wouldn't take on the same market risk as in his 401(k) and profit sharing," Meehan says. "The idea wasn't that misdirected generally, but he had to keep paying for it to work. And there are no 30- to 40-year policies to verify it worked in the past. And to commit 50% of savings to it is just too much."

To help clients talk through their priorities, Meehan asks about their tax situation and their estate wishes (meaning a discussion of how important it is to leave large sums to heirs), what they are saving today, what kinds of life insurance they've held in the past, how much debt they carry and how much income they believe would have to be replaced if they died tomorrow.

"For someone who has only been practicing five to seven years, it's probably going to be a pretty shocking amount because they are making a good living and their biggest asset is future earnings," Meehan says. "It's also highly likely they have a ton of school and housing debt. That person is going to need a lot of life insurance. The shock factor of saying they might need $5 million is pretty substantial, and it will be ridiculously expensive."

MULTIPLE CONSIDERATIONS

There are ways to address the expense, he says. Once Meehan arrives at a recommended amount of insurance, he talks about what the client can do realistically to fit insurance into other goals such as retirement and college savings. The result is a comprehensive plan that may not be optimal for every goal, but would still leave the client significantly better off financially.

"Usually, the whole-life conversation of trying to build cash value as an investment comes off the table at this point because it's just too expensive. Large volumes of term insurance if the..."
How much life insurance to buy?

Online life insurance calculators, like the one offered by Bankrate, ask how much survivors will need to spend annually, and for how long. The Bankrate calculator also asks about children and current non-retirement savings.

For the example of a 45-year-old married physician with two children, the calculator recommended securing policies totaling $2.6 million to provide $150,000 in after-tax annual income to a family for 20 years until retirement. That figure includes a large fudge factor for unexpected costs: a one-time event costing $500,000. With only $50,000 plugged in for a one-time event such as a wedding or new car, the recommendation drops to $2.2 million.

If you use such a calculator, be sure to include all the assumptions. In the example above, for instance, the surviving spouse would need to continue funding retirement accounts out of the $150,000 income in order to have a retirement nest egg ready once the insurance money is exhausted.

Altering the scenario, consider a dual-physician household with similar-aged children, where one spouse earns $225,000 and the other makes $140,000 a year. In the event of the death of a spouse, the lower-earning spouse decides to cut back at work to focus on the children, so the household income drops from $365,000 to $90,000. And they’ll need the insurance money to cover the surviving spouse’s retirement, through age 90. The Bankrate calculator estimates the insurance need at more than $6 million.

What will all this cost in annual premiums? A 45-year-old Wisconsin male classified in the second-highest health rating would spend between $3,185 and $4,375 for term insurance with a $2.5 million death benefit, according to a range provided by www.term4sale.com. For a $6 million death benefit, the range was $7,525 to $10,405.

Recommendation:
$2.5 million

Q. How much money will you need for burial expenses (suggestion: $8,000-$10,000)?
$10,000

Q. For how many years will your income need to be replaced?
20

Q. How much annual net income (after tax) will survivors need?
$150,000

Q. Any children who will go to college?
Yes, 2

Q. How much is needed per child?
$100,000

Q. What are their current ages?
17, 14

Q. Any 1-time expenses, such as weddings, cars, etc?
$500,000

Q. How many years from now?
10

Q. How much liquid savings do you have, aside from retirement?
$200,000

Q. What will it cost?
Annual costs on $2.5 million in term life insurance:
$3,185 - $4,375, according to life insurance quoting site term4sale.com.

(Range of 50 carriers providing quotes for a non-smoking, 45-year-old male applicant with second-best health rating.)
person is in good health is not inexpensive, but it’s nothing compared with multi-million-dollar cash value policies,” Meehan says.

Before making a final decision on life insurance, he says, he discusses disability insurance as a way to protect income if the client is alive but can’t work.

“There’s no easy way to make disability insurance inexpensive because the insurance companies have such a significant risk,” he says. “You have to pair the life and disability conversation together with the reality that you can only do so much.”

For a couple in their mid-30s with $325,000 in annual income, Meehan suggests saving 20%, or $65,000, for retirement. Another $40,000 or so might be put toward shorter-term goals, like college, and for life and disability insurance, as well as an emergency fund.

Realistically, few couples are able to save a third of their income, but it’s a good goal to aim for, experts say.

For clients getting into their 50s, Meehan also begins conversations about long-term care insurance. Despite carriers leaving the market and significant cost increases in recent years, he believes it’s important at least to consider as part of overall insurance planning. Rather than trying to cover all of the costs, however, he recommends clients buy below the maximum daily benefit levels, thereby partially self-insuring for the costs.

“Long-term care is the most interesting part of the insurance discussion today,” notes Kevin Reardon, CFP, an adviser with Shakespeare Wealth Management Inc., in Pewaukee, Wisconsin. Many companies are capping the amount of coverage clients can even purchase, he says.

Another way to look at the long-term care insurance decision is to think about what happens to the daily benefit over time, says Reardon. By purchasing a relatively rich policy today without inflation protection, clients can protect themselves adequately in the short term, while they continue to build up other savings. Then, if a long-term care event happens later in life, it will be worth less due to the impact of inflation, but clients will need less because they’ve been able to save in other accounts, he says.

More popular today, he says, is the practice of buying long-term care riders on permanent life insurance policies. The coverage isn’t as rich as a stand-alone long-term care policy, but clients intuitively feel better about not “wasting” money on benefits they might not ever use. “It’s more palatable so that if they don’t use the long-term care component, they have the life insurance behind it,” Reardon says.

Yet another way to obtain long-term care protection is with so-called longevity insurance, or deferred fixed annuities, experts say. These are annuities generally purchased around age 60, typically with a lump sum of perhaps 10% of the person’s savings that begin to pay out monthly when the insured reaches his or her mid-80s. It isn’t officially long-term care insurance, so the money can be used for any expenses late in life.

Keep in mind that the 10% is a rough estimate. A person with a family history of longevity and who is uncertain about whether the nest egg will outlast a long life might put up to 30% into this type of vehicle.

The caveat: Inflation. With today’s low interest rates, these annuities won’t keep pace with even modest levels of inflation, so be sure to factor that into your plan. For people who have a serious shortfall in retirement savings, committing a large chunk of their nest egg to long-term care insurance may not be feasible.

For those concerned about legacy issues, most carriers offer additional features such as riders that guarantee heirs a certain amount back if the insured dies before collecting.

Some advisers say they like the concept of these long-dated annuities, but most believe they would be a tough sell with clients.

“My experience with clients is that they tend to have gotten away from the whole ‘pension’ concept where they give up a chunk of money in return for a payment stream for life,” Reardon says. “They are willing to take on the risk and track it rather than shift it to an insurance company. It’s the same concept as buying term life insurance and investing the difference they would have paid for whole life.”

Just bear in mind that taking on too much risk with the thought of saving enough over time to self-insure can be an enormous gamble, and a disaster for those left behind. —KEVIN MEEHAN, CFP, REGIONAL PRESIDENT, WEALTH ENHANCEMENT GROUP, ITASCA, ILLINOIS

For someone who has only been practicing five to seven years, [the life insurance they need is] probably going to be a pretty shocking amount because they are making a good living and their biggest asset is future earnings.”
Legally Speaking

Telemedicine empowers patients, but challenges physicians

by JOHN D. FANBURG, JD, and EDWARD V. HILZENRATH, JD
Contributing authors

The rapid expansion and evolution of telemedicine in the U.S. brings with it increased access at lower costs for patients and growing competition for physicians from providers with regional, national and international reputations.

WHAT USED TO be local marketplaces, in which physicians treated patients in their immediate geographic areas, has the potential to develop into a national marketplace characterized by a small number of providers dominating the healthcare landscape.

To date, 29 states and the District of Columbia have enacted legislation requiring some form of reimbursement by private insurers for telemedicine services, many times at levels equivalent to in-person services. In the past year alone, more than 200 pieces of telemedicine-related legislation have been introduced in 42 states.

Approximately 15 million people used telemedicine services in 2015, according to the American Telemedicine Association, a 50% increase from 2013. National insurers such as Cigna and Aetna continue to expand their coverage of telemedicine services. Meanwhile, telemedicine providers continue to increase the number of patient visits and are raising millions of dollars in the capital markets to fuel further growth.

The expansion of telemedicine has been slowed by state regulatory requirements and federal and state laws limiting reimbursements. For example, Medicare currently reimburses for telemedicine only for a limited number of Part B services in specific geographic areas. Medicare beneficiaries are eligible for telemedicine services only if they present from an originating site in a rural “Health Professional Shortage Area” or in a county outside of a “Metropolitan Statistical Area,” both areas typically underserved by healthcare professionals.

Change coming in DC

However, change is on the way. A bipartisan working group of the Senate Finance Committee has outlined several potential telemedicine policy options with regards to chronic care management for Medicare recipients, including:

- (i) expanding access to home dialysis and using telemedicine to satisfy the monthly clinical visit requirement;
- (ii) amending Medicare Advantage plans to allow further reimbursement by Medicare;
- (iii) allowing accountable care organizations to use telemedicine, thus waiving the geographic restrictions; and
- (iv) permitting telestroke technology, which enables stroke specialists to perform stroke-specific neurological exams via telemedicine.

In addition, a number of special interest groups, including the American Telemedicine Association, are pushing the Centers for Medicare and Medicaid Services and Congress to remove what they see as arbitrary restrictions limiting telemedicine coverage.

Most state Medicaid plans cover some telemedicine services, although the coverage varies greatly from state to state, and states continue to enact legislation requiring some form of reimbursement by private payers, many
times at levels equivalent to those provided for in-person services.

**Benefits to patients**

The expansion of telemedicine services should continue to benefit consumers.

Some office visits can be replaced with virtual visits, saving patients time and money by limiting trips to more expensive urgent care centers and emergency departments. In addition, the expansion of telemedicine services should help reduce the physician shortage that is predicted to occur in the near future, particularly in primary care.

A 2015 study commissioned by the Association of American Medical Colleges predicts that by 2025, the demand for physicians will exceed supply by up to 90,000 physicians, including a shortfall of up to 31,100 primary care physicians.

Telemedicine has the potential to be detrimental to many local independent practices, both small and large. A few specialties have already been impacted by its growth.

In dermatology, for example, companies are now providing services where patients can take pictures of their skin on their mobile devices and email the pictures to physicians for diagnoses. Psychologists are using video conferencing tools such as Skype to communicate with their patients.

More specialties are sure to be affected as the use of telemedicine expands. Healthcare providers with regional, national and international reputations have the potential to expand their brands by offering services in areas where they previously could not because of licensing restrictions and lack of reimbursement for telemedicine.

Local providers may have to compete with these providers who, because of marketing power and lower costs, could enjoy a significant advantage in attracting future patients. This may force local providers to sell their practices to regional, national and international healthcare systems or risk being forced out of business entirely.

Local providers have several options for combating the challenges posed by the expansion of telemedicine. One possibility is to join a larger practice or hospital system. This would allow a local provider to expand the geographical scope of his or her practice, but at the expense of the practitioner’s independence. Another option is for local providers to grow their practices organically. Telemedicine is still in its infancy in many specialties and first movers can still gain a significant advantage.

A third option is for local providers to partner with existing telemedicine providers and thereby take advantage of an existing infrastructure, thus reducing costs.

**Doing nothing not an option**

What physicians cannot afford to do is do nothing. Telemedicine is going to change the way medicine is practiced and provided, whether physicians are ready for it or not.

The expansion and evolution of telemedicine has the potential to benefit patients by expanding access to medical services and lowering healthcare costs. However, these benefits will come at the expense of further healthcare consolidation and regional, national and international providers continuing to acquire market share. Local providers will have to adapt their practices to this new reality by growing in scale, joining already established health care consolidators or partnering with existing telemedicine providers.

What physicians cannot afford to do is do nothing. Telemedicine is going to change the way medicine is practiced and provided, whether physicians are ready for it or not.

**Top 10 challenges facing physicians in 2016**


**The debate over healthcare interoperability**

bit.ly/interoperable-talk

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The Rise of Direct Primary Care

Opting out of the payer hamster wheel can provide greater independence but requires careful planning

by Elaine Pofeldt Contributing author

HIGHLIGHTS

One reason for the mounting interest in direct primary care among physicians is the growing complexity of managing a practice in the current environment.

Some physicians are leery of direct primary care because they fear that charging subscription fees will price out some consumers or spark a negative reaction among their patients.

INTERNIST BEN FISHER, MD, made a dramatic move recently: he opened his own direct primary care practice. Fischer treated patients for eight years as part of a 30-physician group practice in Raleigh, North Carolina. He had no disagreements with his group, but he was tired of the fee-for-service model. It forced him to spend time on cost containment for insurance companies that would be better invested in caring for patients.

“I felt a very clear sense that the work I was doing was not the work of my calling,” says Fischer, who completed his residency in 2003. “It was the work of the insurers.”

Fischer continues to work at his original practice while opening the new one, and with his wife Liz, an MBA, helping him navigate the details of setting up a practice, he feels off to a good start. “This is very much a leap of faith,” he says.

Fischer is among a growing number of physicians nationwide to transition from fee-for-service medicine, or open a new practice based on what was once considered an “alternative” practice model. In direct primary care, physicians don’t take insurance but instead charge patients a flat monthly fee—usually in the range of about $25 to $80 a month—that covers primary care services.

One reason for the mounting interest in direct primary care among physicians is the growing complexity of managing a practice. Many physicians say keeping up with the paperwork involved in value-based care, meaningful use of electronic health records, and other initiatives tied to the Affordable Care Act leaves little time to actually practice medicine.

“What is motivating physicians to convert is primarily a desire to be able to spend more time with patients,” says Mason Reiner, cofounder and CEO of B-Health, a network of more than 50 direct primary care practices in the Philadelphia area. “In the traditional hamster wheel of fee-for-service medicine, it’s all about volume and not about relationships. Almost every primary care physician I’ve ever met went into primary care because of the desire to build meaningful relationships with their patients. If you
When building direct primary care, you don’t build relationships you can’t deliver great care. That takes time.

REGULATORY CONFUSION

That said, the percentage of physicians involved in direct primary care remains very small. A major reason is lingering regulatory uncertainty.

One unresolved question is whether consumers with high deductible plans will be able to use money in medical savings accounts to cover the retainer fees. Senator Bill Cassidy, MD (R-Louisiana) introduced a bill (S.1989) in August 2015 that would make direct primary care services qualified health expenses under the federal tax code.

If the legislation passes, it would establish direct primary care as a medical service and not a health plan. People with high deductible plans would be able to pay for direct primary care services using funds from a health savings account—a potential boon to clinics trying to attract new members, according to the Direct Primary Care Coalition. In addition, the bill would enable a demonstration project that would create a pathway to direct primary care payments for people who receive Medicare.

As the Heritage Foundation pointed out in a 2014 report, the U.S. Department of Health and Human Services (HHS), which is responsible for determining which direct primary care plans qualify for the healthcare insurance exchanges, has yet to establish criteria for doing so. That creates a potential obstacle for insurance companies seeking to create wraparound high deductible plans that work well with direct primary care. But because the Affordable Care Act says direct primary care medical homes are not insurance arrangements, HHS says they do not fall under its purview.

United Healthcare’s Harken Health is offering a direct primary care-based plan in Chicago and surrounding suburbs and is opening clinics in Atlanta, notes Jay Keese, a lobbyist who runs Capitol Advocates in Washington, D.C., and executive director of the Direct Primary Care Coalition. In August, direct primary care provider MedLion Management, Inc., and Pan-American Life Insurance Group, announced they would provide a suite of insurance products that will be combined with MedLion’s Direct Primary Care programs for employers. The companies said Pan-American Life’s U.S.

As Raleigh, N.C.-based physician Ben Fischer, MD, discovered in his recent transition to direct primary care, making a move like this requires attention to many details. Here are some key factors to consider.

Your lifestyle: Many physicians continue working in other capacities while opening a direct primary care practice or converting to one. Fischer, who has three elementary school age children, planned to continue to work at his old practice through February and to moonlight as a hospitalist at a local hospital, and then start seeing patients at the new practice in March. At that point, he would no longer see patients at his original practice, under the agreement he worked out.

Fischer didn’t have to take time off to set up the new direct primary care practice, as some physicians do, because his wife Liz, an MBA, who has been an at-home mom in recent years, got it up and running for him. The couple has tended to gravitate toward keeping the family’s personal overhead low and for instance, own only one car. Liz will work in his practice as he ramps up. “With my wife and I both working there and our kids in school, they can easily come over and do their homework,” says Fischer.

Your relationship with your old practice: Fischer formed close friendships with other physicians in his original practice and took care to make sure they did not feel he was abandoning them. He made sure that practice had enough time to find a replacement before he began his formal transition. “I don’t want to leave them in the lurch with patients they can’t care for,” he says.

Your communication plan: Through his original practice, Fischer sent out a brief letter to his patients. It said he was starting his own practice that would not work with insurance and included his new phone number. To elaborate more, he put up a website where he posted a longer version of the letter and invited his patients to a town hall meeting. “We made it known we were having a meeting to talk about the practice, why I was doing it and how it would work,” he says. “That was happily well received.”

Your support network: Fischer does not know many direct primary care physicians in his immediate area. One helpful source of information, he says, was a boot camp on the subject run by the American Academy of Family Physicians. That organization has been very helpful, he says. “In most towns there is not a community of people doing this,” he says.

“wrap” insurance program exclusively for MedLion Direct Primary Care clients.

Humana and direct primary care provider Iora Health also are partnering to open seven new primary care practices in Arizona, Colorado and Washington state. The practices will exclusively treat patients who are members of Humana’s Medicare
Advantage plan. Last year, Humana and Iora partnered to open two clinics in Seattle and two in Phoenix.

According to the California Health Foundation, two other insurance carriers—Cigna and Associated Mutual—have created insurance plans tailored to users of direct primary care. Cigna’s is available only for self-insured employers who use Qliance. The first wrap-around high deductible plan paired with direct primary care went live in January 2015 in the Washington state exchange.

Meanwhile, New Jersey is piloting a plan that will give 800,000 state workers access to a direct primary care plan. The plan will be run by Aetna and Horizon and give them access to specialists in these companies’ networks.

ESCAPING THE TREADMILL
Beyond the uncertainty, some physicians are leery of direct primary care because they fear that charging subscription fees will price out some patients or spark a negative reaction among their patients.

“Physicians are a conservative bunch,” says Stephen Schimpff, MD, a retired internist who is author of Fixing the Primary Care Crisis. “They have to be pretty convinced that by making this type of change, they are not going to get themselves into a financial pickle or an emotional pickle with their patients.”

But with companies of 50 to 99 employees required to start providing healthcare this year under the Affordable Care Act, direct primary care is getting a boost, with employers increasingly interested in providing it to their employees as a way of reducing healthcare costs. Typically, most employers will match this with an insurance product, says Reiner, whose firm has been focusing primarily on partnering with employers.

Meanwhile, some physicians, frustrated by what they see as the paperwork and regulatory burdens that come with practicing medicine today, see direct primary care as their only attractive career option. Chris Larson, DO, says it’s the only way to provide “affordable care, accessible care, and care both patients and doctors are happy with.”

Larson began his practice, Austin Osteopathic Family Medicine, about two years ago and now has about 200 patients. Direct primary care appealed to him because he saw it as a way to know his patients by name and truly feel he is helping them.

“If I don’t stick with this, I am not going to be in medicine,” Larson says. “I’ll go buy and sell real estate. I refuse to be a fee-for-service provider.”

One of the biggest benefits of direct primary care, physicians say, is the ability it provides to control their schedule. When family physician Brian Forrest, MD, decided to try direct primary care 15 years ago, it was after doing his residency and some locum tenens work and realizing he didn’t want to work in a fee-for-service practice. He was distressed by how little time physicians had with patients.

In his residency, he says, “The expectation was to see a patient every 15 minutes,” he says. When he did locum tenens work in medical clinics, the pace was even quicker. At one clinic in Cary, North Carolina, he saw 63 patients in one day.

“In some cases, they double booked us every 15 minutes,” he says. “It was a pace of productivity required to pay for the increasing overhead. The overhead seemed to be greatly in part due to all of the bureaucracy associated with the insurance.”

Today Access Healthcare, his practice in
Direct pay  

What is motivating physicians to convert [to direct pay] is primarily a desire to be able to spend more time with patients. In the traditional hamster wheel of fee-for-service medicine, it’s all about volume and not about relationships.”

—MASON REINER, COFOUNDER AND CEO OF R-HEALTH, PHILADELPHIA, PENNSYLVANIA

Apex, North Carolina, a suburb of Raleigh, is thriving. His panel of 1,200 patients is full, and he employs two other physicians. As CEO and founder of AccessHealthcare-Direct, a loosely affiliated network of direct primary care physicians, Forrest frequently shares his knowledge of direct primary care with other physicians who visit his office.

“I opened with the idea I probably would make less money and probably see mostly uninsured patients,” says Forrest. “Financially, the office did fine. The uninsured people that could afford to come to our practice told their insured friends about us.”

Although his practice is full, he says he is able to allot 45 minutes for each patient visit, leaving the last 15 minutes of every hour open for patients who need to book same-day appointments.

“The busiest day is about 14 patients, but normally I’ll see 11,” Forrest says. “That gives us plenty of time with patients.” When new patients want to join the practice, he refers them to his two colleagues.

GOODBYE TO BEAN COUNTERS

Another significant benefit of direct primary care, physicians say, is its lack of bureaucracy. Without insurance paperwork to fill out, there is far less need for office staff, and therefore less overhead for payroll.

“You can run a direct primary care practice with 450 to 500 patients with one and a half or two full time equivalents as support staff—a fraction of what you need to run a full, insurance-based practice,” says Reiner.

So far Larson, for example, has needed to hire only one employee—a medical assistant—for his practice. He knows direct primary care doctors who have hired no office staff and handled all of the administrative work themselves.

When a practice doesn’t take insurance, Larson says, “You don’t have to house the people you used to pay to nag the insurance company.”

Even in larger practices, the payroll tends to be lean. In Augusta, Georgia, internist/pediatrician Robert Lamberts, MD, who has practiced for 18 years and went into direct primary care three years ago, employs two nurses and two full-time medical assistants, as well as his daughter to answer the phones at the practice. He has 670 patients.

With no need to bill insurance companies, he has no office manager. The paperwork his team does mostly is for issues, such as getting authorizations, handicapped parking, and referrals, or disability papers, he says. His staff also works to get patients free medications when possible from drug companies, if the patient is unable to afford it. One of his medical assistants does much of the accounting, keeping track of patient monthly payments and the status of accounts.

Some physicians have found they can streamline the administrative side even further with the right technology. Forrest, for instance, uses software from the company Twin Oaks to automate the billing of patients’ monthly $45 retainer fee at his practice.

“We spend zero time getting paid,” says Forrest. “We use the same software platform that Gold’s Gym and all the gyms use to get membership payments.”

Lamberts also has streamlined communications with patients by using a HIPAA-compliant app called Twistle. “Everyone can have it on a smartphone,” he says. He also monitors blood sugar levels for about 30 diabetes patients daily online, using Twine. “If their numbers are up, we can adjust them right
I felt a very clear sense that the work I was doing was not the work of my calling. It was the work of the insurers.”

—BEN FISHER, MD, INTERNIST, RALEIGH, NORTH CAROLINA

Nonetheless, for many physicians, there are tricky logistical issues to work out. One is to make sure their panel fills up, so the practice can generate enough revenue to cover overhead. It can take a while for a practice to hit the 500 to 600 patients that many say is necessary for it thrive and the physician to make a living without having to moonlight. Lamberts did not take a salary his first year. “My salary is about half the peak at my old practice,” he says, three years into his direct primary care practice. He had an estimated 3,000 to 4,000 patients at his previous practice, he says.

Patient communication also is vital. Consumers in some markets may be more open to direct primary care than others, some physicians have found, affecting how fast a physician can attract them.

Qliance, a network of clinics that provide primary care for a flat fee, is in Washington State, which Larson notes has both unions and technology companies that are very forward thinking about direct primary care. “They are in particular situations that I’ve tried to reproduce but I can’t,” he says.

Some physicians find that their current patients balk at a move to direct primary care. He knows two physicians who made the transition who sent a letter to their patients without getting outside advice first. “There were letters to the editor to the community newspaper saying doctors are greedy and not caring anymore,” he says.

Experts recommend that physicians get professional advice on handling the communications process, including notifying patients of plans to convert to a direct primary care practice, before embarking on it, because patients may react positively to the change.

**TACKLING THE FINANCES**

Beyond these issues, physicians who go into direct primary care also have some tough decisions to make. One is to figure out how much to charge patients as a retainer fee. Many are leery of charging fees so high that patients with average incomes won’t be able to afford them, but they must balance that concern with the need to create a self-sustaining practice. The majority of families who use direct primary care have household incomes of $95,000 or less, according to a survey published in *The Direct Primary Care Journal* in July 2015. The data were gathered from December 2012 through June 2015.

Forrest decided to charge a flat fee of $45 for his patients, up from $25 when he started 15 years ago. Liberty Direct, a medical sharing co-op that qualifies as insurance under the Affordable Care Act, is now paying him $60 per month per patient in a plan it recently rolled out. It is available for employers but all of his patients who have the plan bought it as individuals.

Lamberts decided it made sense to charge a range of fees—from $30 a month for the youngest patients to $60 for the oldest. About 15% to 20% of his patients are covered by Medicare, which he has opted out of so he can charge them only on a monthly basis. “I never bill insurance for anything, so I am ‘allowed’ to handle problems in any way I want,” Lamberts said in an email. “This is why patients have been loyal and have stayed with us.”

Another challenge is how to handle referrals to specialists. About 60% of patients at Forrest’s North Carolina practice have insurance, so when he needs to refer to a specialist, he does so the same way he would in any other practice.

To help patients who have to pay out of pocket, either because they have no insurance or who have high deductible plans and have not yet met their deductible, he has formed relationships with specialists, such as a radiologist, who have agreed to see such patients at discounted rates. He says these arrangements can result in savings of 80% to 90%, and that sometimes copays for insured patients are actually higher than the negotiated discount his practice can get for them.

“A colonoscopy that would normally cost $2,000, they would get for $400,” he says. Patients get a membership card that tells specialists they are entitled to the price cut.

Direct primary care practitioners often find themselves tackling tasks they might not at a fee-for-service practice, in part to save patients money. Larson, for example, helped put a patient with an injured toe in a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot, instead of sending her to the emergency department—charging her only a walking boot.

Says Lamberts, “If they don’t have insurance, I have to be very cost-aware. The big difference here is that patients really feel I am on their side.”
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Don’t expect legislative defenses against cyberattacks anytime soon

Doctors and others in healthcare who were hoping to see some immediate relief from cyber attacks thanks to the Cybersecurity Information Sharing Act of 2015 will need to wait until next year before they begin getting any help, say those familiar with the legislation.

While healthcare is the only business segment specifically mentioned in the law, the statute mandates study of the issue of healthcare cybersecurity, not immediate actions.

Leslie Krigstein, vice president of congressional affairs with the College of Healthcare Information Management Executives (CHIME) says not to expect major recommendations on healthcare data security until March 2017. But she applauds the legislation for starting the process of looking systematically at cyber threats.

The law was enacted in late 2015 as part of a larger legislative package. It calls on the U.S. Department of Health and Human Services (HHS) to establish a cybersecurity czar to study ways of protecting healthcare from cyber threats.

The task force will examine challenges and solutions for healthcare cybersecurity and has one year from its formation to deliver its report. Eventually HHS will develop a set of voluntary cybersecurity guidelines based on that report that healthcare providers can look to for enhancing their own security.

The law also protects healthcare organizations from liability when they share cyber threat information, as long as patient personal data is scrubbed from any shared files.

Critics fault the measure for not mandating actions to counter cyber threats. “I just don’t think they’re really doing enough,” says Jay Trinckes, CISSP, CISM, senior practice lead of the healthcare and life sciences practice at Coalfire, an Atlanta-based cyber risk management consulting firm. “Is it really going to do anything to enhance security in the industry?”

Supporters, such as CHIME and HIMSS, counter that the law will help healthcare because it will, for the first time, create one resource within HHS that providers can look to for cybersecurity best practices. “We’re in a state in healthcare where unfortunately, for cybersecurity, there isn’t one set of best practices,” says Lee.

Both HIMSS and CHIME endorse the law’s provision that whatever guidelines are developed will be voluntary. Responding to critics who want mandatory guidelines, Lee says it’s too early to know what guidelines would be effective, so creating mandates now would be counterproductive.

A health IT bill being considered in the Senate Health, Education, Labor and Pensions Committee doesn’t look at the broad issue of healthcare data security, says Krigstein. Instead, it says only that electronic health record manufacturers must specify that they have considered security when designing their systems. So the 2015 cybersecurity law likely is all that healthcare will get from Washington on the topic this year.

John Frank has more than 39 years of experience as a professional journalist and is a contributing author for Medical Economics.
Low LDL-C Levels
In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1988 patients treated with REPATHA had at least two LDL-C values <25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and REPATHA dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by REPATHA are unknown.

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

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

6.2 Immunogenicity
As with all therapeutic proteins, there is potential for immunogenicity. The immunogenicity of REPATHA has been evaluated using an electrochemiluminescent bridging screening immunoassay for the detection of binding anti-drug antibodies. For patients whose sera tested positive in the screening immunoassay, an in vitro biological assay was performed to detect neutralizing antibodies. In a pool of placebo- and active-controlled clinical trials, 0.1% of patients treated with at least one dose of REPATHA tested positive for binding antibody development. Patients whose sera tested positive for binding antibodies were further evaluated for neutralizing antibodies; none of the patients tested positive for neutralizing antibodies.

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

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

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

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

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

8.2 Lactation
Risk Summary
There is no information regarding the presence of evolocumab in human milk, the effects on the breastfed infant, or the effects on milk production. The development and manufacture of breastfed infants should be considered along with the mother’s clinical need for REPATHA and any potential adverse effects on the breastfed infant from REPATHA or from the underlying maternal condition. Human IgG is present in human milk, but published data suggest that breast milk antibodies do not enter the neonatal and infant circulation in substantial amounts.

8.4 Pediatric Use
The safety and effectiveness of REPATHA in combination with diet and other LDL-C-lowering therapies in adolescents with HoFH who require aggressive lowering of LDL-C were established based on data from a 12-week, placebo-controlled trial that included 10 adolescents (ages 13 to 17 years old) with HoFH [see Clinical Studies (14.3)]. In this trial, 7 adolescents received REPATHA 420 mg subcutaneously once monthly and 3 adolescents received placebo. The effect of REPATHA on LDL-C was generally similar to that observed among adult patients with HoFH. Including experience from open-label, uncontrolled studies, a total of 14 adolescents with HoFH have been treated with REPATHA, with a median exposure duration of 9 months. The safety profile of REPATHA in these adolescents was similar to that described for adult patients with HoFH.

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

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

8.6 Renal Impairment
No dose adjustment is needed in patients with mild to moderate renal impairment. No data are available in patients with severe renal impairment [see Clinical Pharmacology (12.3)].

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

13. NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
The carcinogenic potential of evolocumab was evaluated in a lifetime study conducted in the hamster at dose levels of 10, 30, and 100 mg/kg administered every 2 weeks. There were no evolocumab-related tumors at the highest dose tested corresponds to systemic exposures up to 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. The mutagenic potential of evolocumab has not been evaluated; however, monoclonal antibodies are not expected to alter DNA or chromosomes.

There were no adverse effects on fertility (including estrous cycling, spermat analysis, mating performance, and embryonic development) at the highest dose in a fertility and early embryonic developmental toxicity study in hamsters when evolocumab was subcutaneously administered at 10, 30, and 100 mg/kg every 2 weeks. The highest dose tested corresponds to systemic exposures up to 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. In addition, there were no adverse evolocumab-related effects on surrogate markers of fertility (reproductive organ histopathology, vaginal cytology, or sperm parameters) in a 6-month chronic toxicity study in sexually mature monkeys subcutaneously administered evolocumab at 3, 30, and 300 mg/kg once weekly. The highest dose tested corresponds to 744- and 300-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC.

13.2 Animal Toxicology and/or Pharmacology
During a 3-month toxicity study of 10 and 100 mg/kg once every 2 weeks for 13 weeks, no effects on body weight, food consumption, or 5 mg/kg once daily rosvastatin in adult monkeys, there were no effects of evolocumab on the humoral immune response to keyhole limpet hemocyanin (KLH) after 1 to 2 months exposure. The highest dose tested corresponds to exposures 54- and 21-fold higher than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. Similarly, there were no effects of evolocumab on the humoral immune response to KLH (after 3 to 4 months exposure) in a 6-month study in cynomolgus monkeys at dose levels up to 300 mg/kg once weekly evolocumab corresponding to exposures 744- and 300-fold greater than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC.

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

REPATHA® (evolocumab)
Manufactured by: Amgen Inc.
One Amgen Center Drive
 Thousand Oaks, California 91320-1799
U.S. License Number 1080
Patent: http://pat.amgen.com/repaha/

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REPATHA® (evolocumab)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information

1. INDICATIONS AND USAGE

1.1 Primary Hyperlipidemia

REPATHA is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).

1.2 Homozygous Familial Hypercholesterolemia

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

1.3 Limitations of Use

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

4. CONTRAINDICATIONS

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

5. WARNINGS AND PRECAUTIONS

5.1 Allergic Reactions

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

6. ADVERSE REACTIONS

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

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

6.1 Clinical Trials Experience

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

Adverse Reactions in Patients with Primary Hyperlipidemia and in Patients with Heterozygous Familial Hypercholesterolemia

REPATHA is not indicated for use in patients without familial hypercholesterolemia or atherosclerotic CVD [see Indications and Usage (1.1)].

The data described below reflect exposure to REPATHA in 8 placebo-controlled trials that included 2651 patients treated with REPATHA, including 557 exposed for 6 months and 515 exposed for 1 year (median treatment duration of 12 weeks). The mean age of the population was 57 years, 49% of the population were women, 85% White, 6% Black, 8% Asians, and 2% other races.

Adverse Reactions in a 52-Week Controlled Trial

In a 52-week, double-blind, randomized, placebo-controlled trial (Study 2), 599 patients received 420 mg of REPATHA subcutaneously once monthly [see Clinical Studies (14.1)]. The mean age was 56 years (range: 22 to 75 years), 23% were older than 65 years, 52% women, 80% White, 8% Black, 6% Asian, and 6% Hispanic. Adverse reactions reported in at least 3% of REPATHA-treated patients, and more frequently than in placebo-treated patients in Study 2, are shown in Table 1. Adverse reactions led to discontinuation of treatment in 2.2% of REPATHA-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to REPATHA treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for REPATHA and placebo, respectively).

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=1224) %</th>
<th>REPATHA1 (N=2052) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>3.9</td>
<td>4.0</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.2</td>
<td>2.3</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>2.0</td>
<td>2.1</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>1.6</td>
<td>1.8</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.2</td>
<td>1.8</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1.0</td>
<td>1.6</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>1.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>1.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Cough</td>
<td>0.7</td>
<td>1.2</td>
</tr>
<tr>
<td>Influenza</td>
<td>1.1</td>
<td>1.2</td>
</tr>
<tr>
<td>Contusion</td>
<td>0.5</td>
<td>1.0</td>
</tr>
</tbody>
</table>

140 mg every 2 weeks and 420 mg once monthly combined

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

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

Local Injection Site Reactions

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

Allergic Reactions

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

Neurocognitive Events

In placebo-controlled trials, neurocognitive events were reported in less than or equal to 0.2% in REPATHA-treated and placebo-treated patients.
A PCSK9 INHIBITOR FOR INTENSIVE, PREDICTABLE LDL-C REDUCTION
in adults with clinical ASCVD or HeFH on maximally tolerated statin therapy as an adjunct to diet

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

Important Safety Information
- Contraindication: Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha®.
- Allergic reactions: Hypersensitivity reactions (e.g., rash, urticaria) have been reported in patients treated with Repatha®, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.
- Adverse reactions: The most common adverse reactions (> 5% of Repatha®-treated patients and more common than placebo) were nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.
  - In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2% of Repatha®-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to Repatha® treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for Repatha® and placebo, respectively).
  - Adverse reactions from a pool of the 52-week trial and seven 12-week trials:
    Local injection site reactions occurred in 3.2% and 3.0% of Repatha®-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha®-treated patients and placebo-treated patients were 0.1% and 0%, respectively. Allergic reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for Repatha® and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).
- Neurocognitive events were reported in less than or equal to 0.2% in Repatha®-treated and placebo-treated patients.

In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1,988 patients treated with Repatha® had at least one LDL-C value < 25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and Repatha® dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by Repatha® are unknown.

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

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