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Questions still linger around COVID-19’s origin

Was it natural zoonotic spillover that catapulted SARS-CoV-2 from an emerging virus into a pandemic pathogen or was it something much more sinister? Is it at all possible that a lab leak in Wuhan, China, was the spark that lit the fuse?

Debate and discussion about the origin of the virus that causes COVID-19 have been at the forefront of the global consciousness since the first cases were reported in December 2019. Early on, whispers of a potentially engineered virus quickly grew to a roar and fueled speculation that China was behind the pandemic. This narrative was so pervasive that, in February 2020, a group of 27 public health scientists published a letter in The Lancet disputing the lab leak theory and announcing their support of their counterparts in China: the scientists, public health officials, and medical professionals combating the pandemic.

“The rapid, open, and transparent sharing of data on this outbreak is now being threatened by rumors and misinformation around its origins,” wrote the authors, who all declared no competing interests in their disclosures as recommended by the International Committee of Medical Journal Editors. “We stand together to strongly condemn conspiracy theories suggesting that COVID-19 does not have a natural origin.”

And although it’s true that analyses of the genomic sequence of the virus subsequently pointed to natural origins, the questions regarding China’s role persisted, led by pesky discrepancies and conflicting reports.

Fast forward to June 2021 and new evidence that has breathed new life into those origin questions. In an update to the February 2020 letter, The Lancet has published an addendum with revised disclosure statements from virologist and investigator Peter Daszak, one of the 27 authors. In the revised document, Daszak noted that his remuneration is paid solely in the form of a salary from EcoHealth Alliance, a New York-based nonprofit research foundation of which he is president. The company has reportedly worked directly with Wuhan laboratories and funded gain-of-function research at China’s Wuhan Institute of Virology.

Consider, too, other odd associations. Recent reports have uncovered financial ties between Google and EcoHealth Alliance. This comes after accusations that the tech giant was censoring COVID-19's origins continues on Page 2
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lab leak “conspiracy theory” stories in its search results. Google’s health lead, David Feinberg, has dismissed those reports, insisting that the company is simply taking steps to protect users from unverified information.

Are these coincidences or “where there’s smoke, there’s fire” situations? It’s unclear. But they add to the bank of troublesome questions standing in the way of the truth about COVID-19.

The questions extend beyond origin theory, though. With the US Food and Drug Administration’s green lighting of vaccines for adolescents and young adults comes hesitation over long-term effects: What is the effect on fertility? Do the vaccines cause heart inflammation? Dr. Robert Malone, the inventor of the mRNA technology, appeared on television recently, expressing strong concern over the risk-benefit analysis of vaccination for young adults, and the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices recently met to discuss instances of myocarditis or pericarditis in people aged 30 and younger who have received an mRNA COVID-19 vaccine.

Of course, the answer to our ultimate question is that we may never know.

We may never know where this virus came from. We may never know what triggered the global pandemic that has claimed more than 3.8 million lives. And we won’t know the long-term effects until enough time has elapsed. What we do know for certain is that the incredible strength and collaboration of the scientific community have allowed us to regain some semblance of normalcy. The development and rollout of multiple effective vaccine options have been the medical miracle of normalcy. The development and rollout of multiple effective vaccine options have been the medical miracle of normalcy. The development and rollout of multiple effective vaccine options have been the medical miracle of normalcy. The development and rollout of multiple effective vaccine options have been the medical miracle of normalcy.

That, right now, will have to be the only answer that matters.

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COVID-19 Coverage Central

Medical Economics® editors are covering what you need to know during the ongoing novel coronavirus (COVID-19) pandemic. Our ongoing coverage of COVID-19 features:

- Breaking news on the latest developments.
- Tips for physicians to extend the life of N95 respirators.
- Mental health tips for doctors and other providers.
- How physicians can protect themselves from COVID-19.
- Strategies for using telehealth.

To read all of our ongoing coverage, go to MedicalEconomics.com

Perfect your telehealth program

Tabassum Salam, M.D., the ACP’s vice president of medical education, discusses what physicians need to know to get started with telehealth right away.

Watch this video and others at: bit.ly/MedEcVideo

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Before the COVID-19 pandemic, there had been much study and focus on the effect of social issues on the cost of health care and the overall health of the population, including the marked disparities in access to care for many segments of our population. In the last year, these disparities and their effects on our patients have widened.

The question before us now is, do we have the national courage, compassion, leadership and unity to begin to address the core issues underlying this problem of equity?

An excellent Kaiser Foundation report summarizes the key categories defining social determinants of health as economic stability (jobs and poverty), neighborhood and physical environment (housing and safety), education, food, community and social context (community and family supports) and health care system (coverage, access and quality).

There are many innovative projects, including in my native North Carolina, that hold great promise. The learnings from these state initiatives will go a long way to educate us on the most successful strategies, the cost of these strategies and the answer to the questions around the impact of each element on health.

From my personal perspective, from years of practicing as a small-town family physician, the importance of social determinants, recognizing them and their impact on my patients’ health is and was a matter of daily practice. In primary care, we embrace continuity, comprehensiveness and long-term relationships with our patients. Social determinants are just part of that.

This knowledge is enhanced over the years by many patient visits, not to mention the casual interactions at high school ball games or the store. The importance of knowing your patients and their families beyond the medical facts was immediately made clear to me after I started practice and assumed the practice of a physician who spent his 43-year career caring for our community. Often I would stop by to tell him of my day or sometimes describe a difficult case or a patient I was having trouble understanding the cause of their medical issues. He would immediately tell me about the patient’s entire social and family history and the circumstances impacting the current medical condition. This was learned from years in the community but also through the trusted doctor-patient relationship.

That experience and what I learned in those early days of practice was carried throughout my years in active practice. It made me a better physician and is a key attribute defining comprehensive primary care. In our small town, it also included the knowledge of who might be of assistance in a crisis for my patients, whether it be a church, local program or a caring neighbor.

But knowing and identifying the social determinants is not enough. It must also include how we make progress in addressing the issues that have led to such disparities.

Since high-quality and available primary care improves access, lowers costs, and improves outcomes, it’s obvious that supporting primary care and addressing social determinants should be linked. My solution is simple. Invest in making sure our citizens have access to adequate and available primary care, then use the savings generated to address and solve the many obstacles and social issues facing our patients and our communities.

L. Allen Dobson Jr., M.D., FAAFP, is a family physician and Editor-in-Chief of Medical Economics®.
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Worried about inflation harming your investments? Check out these funds

By Dave S. Gilreath, CFP

Investors worried that rising inflation might hurt their stock portfolios probably should consider real estate investment trusts (REITs), because some types of this investment tend to do well in this environment.

REITs are a way to get exposure to various types of real estate without the hassle of actually owning property. Unlike actual real estate, REIT shares are highly liquid because they are traded on major exchanges. As alternative investments, REITs can add diversification to portfolios of traditional investments — stocks and bonds.

These are landlord companies that own and lease out commercial, industrial and residential properties. Nervous investors who feel that owning regular stocks is like betting the farm might think of REITs as owning the farm.

Their dividends are substantial because of a special tax status requiring them to pay out at least 90% of their income. This dividend income is almost bondlike in its reliability but much higher than bond yields — often 4% to 6% and sometimes more.

Although dividends alone are a great reason to own REITs, these investments should nonetheless be evaluated like stocks, assessing factors that could push share prices up or down. Just because you are getting regular produce from the farm does not mean you should not consider selling it for a profit someday.

The stock market is worried that rising inflation will prompt the Federal Reserve to reduce the economic stimulus that has been fueling the market since spring 2020. However, REITs are not directly correlated with the stock market and they tend to do well amid rising inflation because these companies can raise rents to avoid loss of real revenue.

In addition, they have a good record of performance during periods of rising interest rates. So if the Fed raises rates, an increased allocation to REITs can bring protection. Currently, REITs are generally undervalued, as indicated by a wide spread between REIT yields and Treasury bill rates.

Although some types of industrial REITs soared through the pandemic, others — commercial, residential, office and hospitality properties — suffered. REIT revenues are increasing as the economy reopens, but many in this category remain a good buy because they suffered when consumers were not going to retail stores, patients were postponing elective medical procedures and routine doctor visits, tenants had trouble paying apartment
rents, companies needed less office space and the hospitality industry ground to a virtual halt. These scenarios have resulted in ample room for growth now that things have reopened. Increasing demand for these spaces is likely to drive up REIT revenues and share prices.

Here are the outlooks for some categories of REITs that suffered from quarantining and are starting to recover:

**Retail:** Online shopping had hit brick-and-mortar stores hard before the COVID-19 pandemic, but malls’ death at the hand of Jeff Bezos is greatly exaggerated, especially now that they are open again and filled with shoppers. Increasing demand for this space will increase rents. Examples: Realty Income Corp., which owns a wide range of retail properties, from drugstores to movie theaters, and Simon Property Group, owner of most shopping malls you have ever visited.

**Medical:** Because leases of medical facilities, nursing homes and surgical centers tend to be long term, the pandemic did not push down these rents much. But investors’ presumption that this would happen punished share prices, nonetheless. Some of these REITs are still bargains. Now that elective surgeries are happening again and patients are no longer paranoid about their providers, already-committed space is once again undergoing brisk use and expansions are no longer unthinkable. Examples: Physicians Realty Trust, Omega Healthcare Investors and Healthpeak Properties.

**Apartments:** During the pandemic, these REITs suffered downsizing.

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**Shrinkflation explained: The sneaky way companies raise prices**

By Chris Mazzolini
Editorial Director

For decades, companies have found ways to raise prices without changing the dollar amount on the price tag. Edgar Dworsky is on to them.

Dworsky, a consumer advocate who founded ConsumerWorld.org, says this product downsizing is a perfect example of shrinkflation. Dworsky sat down with Physicians Financial News® (PFN) to explain the concept, why it matters, and what consumers and businesses can do about it.

PFN: What is shrinkflation?
What do we mean by that term?

Dworsky: Shrinkflation is manufacturers deciding to make a product smaller, instead of raising the price directly. It really is a sneaky way to pass on a price increase, because consumers are not so conscious of changes in the size of the product, but they are price conscious. So if the manufacturer is kind of sneaky, and takes a little bit out of a product, they think consumers won’t notice. And unfortunately, the manufacturers are right.

PFN: Why does shrinkflation happen? And in particular, why is it happening now?

Dworsky: Shrinkflation tends to happen in waves. When we have periods of higher inflation, manufacturers tell me that the price of raw materials has gone up, or the price of shipping the goods to the store because gas prices have gone up. So they need to try to find a way to pad their bottom line and have those costs compensated for.

So two basic ways to do it: you can raise the price directly, but they know consumers will spot the increase. So if orange juice, for example, is normally $2.99, if the manufacturer raises it to $3.19, they know consumers are going to see it and notice it and not be happy. But if it takes a few ounces out of the carton, they are still going to be saving money. And consumers won’t notice and won’t gripe as much.

PFN: What’s the connection between shrinkflation and financial inflation?

Dworsky: That’s one of the primary reasons I hear from manufacturers. I mean, they tell me it’s all about the price of raw goods. So for example, several months ago, the paper companies — paper towels, toilet paper, napkins, tissues — they announced that by the end of June they were going to be raising prices. But my sense is that paper towels, for example, have gotten smaller. I’ll be presenting some examples of Bounty and Sparkle paper towels losing 10 or 20 sheets on a roll. But my sense is the price has also gone up, because they’ll say the paper pulp prices have gone up, or the cost of getting it to the store with gas prices have gone up. So I think those are legitimate reasons. And certainly in times of high inflation, we see more downsizing.

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Check out the entire interview at: https://www.medicaleconomics.com/topics/physicians-financial-news

Using your smartphone camera, hover over the QR code.
Opportunity zone investment: What physicians need to know about this option

BY JOHN BLATCHFORD
CONTRIBUTING AUTHOR

In 2017, Congress passed the Tax Cuts and Jobs Act, which included legislation establishing Opportunity Zones (OZs) that offered a win-win for distressed neighborhoods, real estate developers and many investors. The underlying concept of OZs is to promote long-term economic development in distressed areas through incentives for investors and real estate developers to revitalize these areas by constructing new residential or commercial buildings that attract residents and businesses.

Communities and neighborhoods are the first to benefit from being designated as OZs. To be in one, the area must be designated by its state and approved so by the IRS. To date, there are nearly 9,000 qualified OZs in the United States, which makes investment and development opportunities available throughout the country.

Real estate developers also win because they have a clear incentive to undertake OZ construction and renovation projects. They can create OZ funds to attract investors and to finance their projects. They are then able to earn revenue from the rental or sales of these properties as well as from management fees paid by investors. In some areas, additional state or community funding for those specific projects is also available to the developer.

Individuals who have realized taxable capital gains from the sale of other assets also win with OZs. The 2017 legislation permits individuals who meet the accredited investor criteria to invest their capital gains in OZ funds within 180 days of realizing them. In turn, they can defer the income taxes on those capital gains until 2026. For example, assume an individual makes a $100,000 investment of some type and sells it later for $500,000, resulting in a capital gain of $400,000 and creating a capital gain tax liability of $80,000 (assuming a 20% capital gains tax rate). By investing that same $400,000 in a qualified OZ fund, the $80,000 tax burden is deferred until 2026. If the investor remains in the fund for 10 years, there will be no tax on the additional income earned.

Most fund sponsors do charge investors a management fee of approximately 1% to 3% of the fund’s assets, so investors need to make sure they understand the associated fees.

David S. Gilbreath, a certified financial planner, is a 40-year veteran of the financial service industry. He is the chief investment officer of Sheaff Brock Investment Advisors LLC, which handles portfolios for individual investor clients, and Innovative Portfolios, an institutional money management firm. Based in Indianapolis, the firms manage over $1 billion in assets from clients nationwide.
fee. They may also guarantee investors a specific rate of return and may charge a fee if the total return exceeds the guaranteed amount. The specific length of time each individual’s money must remain in the fund and the tax impact when it is withdrawn should be discussed with a financial adviser or fund sponsor.

There are more than 230 OZ funds available to potential investors. They differ in terms of the OZs being served, the types of construction or renovation projects being undertaken, the past experience of the fund sponsors and the minimum investment levels required. Typical investment minimums can range from $25,000 to $100,000. Some funds require a minimum investment of $250,000 or even $1 million.

The accredited investor term mentioned above bears explanation. As defined by the Securities and Exchange Commission, an accredited investor is one who can accept investment risk. To qualify, a single individual must have a net worth of $1 million, excluding a primary residence, or show two consecutive years of an annual income of $200,000. For a married couple, that threshold is $300,000.

Some funds are developing large multifamily residential or commercial office buildings, whereas others are building schools, storage units, student housing and medical facilities, to name a few. Not all focus on new construction. Some choose to renovate existing buildings in an OZ. Those choices are often based on the size of the fund and the economic and cultural needs of the OZ and surrounding areas. It is common to find large funds undertaking projects in multiple cities or even across states, whereas smaller funds may focus all their activity in a single OZ. Clearly the size and scope of these projects determine the amount of money the fund must raise, and the time required for it to begin generating revenue for its investors.

The tax advantages of OZ funds for investors are much the same for all funds. What differs are the returns promised to investors, the economics and demographics of the OZs they have targeted, size and scope of the projects they undertake, their experience and successes, additional funding that might be available, the time required to generate a return on the properties, and their communications with investors.

It makes sense for investors facing a substantial capital gain, with their financial advisers’ help, to conduct their own due diligence to identify appealing OZ funds. Most have websites that will provide answers to key questions such as:

1. In what locations will the fund be active?
2. Why did these locations warrant an OZ designation?
3. What is the relevant social, economic and business history of those locations?
4. How will the fund’s real estate interests affect these locations?
5. What specific type of real estate does the firm have or will it create on those sites?
6. If some new, renovated property has been completed, what is the sponsor’s track record on occupancy or sale?
7. If these are renovation properties, what is the firm’s experience in this type of development?
8. What is the minimum investment?
9. What is the sponsor’s communication program to keep investors up to date?
10. What investment return does the sponsor project?

John Blatchford is the founder of Kunst Real Estate, an opportunity zone sponsor headquartered in Cincinnati, Ohio.

Hospital consolidations in crosshairs of Biden administration

By Todd Shryock
Managing Editor

As part of a sweeping executive order, President Biden addressed hospital mergers and their sometimes negative effects on patients and the health care system. The order specifies that the Justice Department and Federal Trade Commission review and revise their merger guidelines to ensure patients are not harmed by the mergers.

The administration points out that hospital consolidation has hit rural areas especially hard, leaving many patients without good options for convenient and affordable health care services. Since 2010, 139 rural hospitals have shuttered, including a high of 19 last year during the pandemic.

When rural hospitals closed, people living in areas that received health care from them had to travel on average about 20 miles farther for common services like inpatient care. For less common services, such as alcohol and drug abuse treatment, the average was 40 miles. Areas where a hospital closed also saw a decrease in the number of doctors available.

The Biden administration also pointed out that when hospitals consolidate, patients pay more, referencing a study that showed hospitals in consolidated markets charge far higher prices than hospitals in markets with several competitors. Mergers have resulted in the 10 largest health care systems controlling a quarter of the market. More closings and mergers are expected in the coming years.

According to the Kaiser Family Foundation, consolidation’s promise of greater efficiencies and better care coordination are often unmet. Evidence of the benefits of improved quality after a merger are mixed at best, and some studies suggest that market consolidation can actually lead to lower quality care. Kaiser reports that while it is difficult and time consuming to achieve true integration of care among newly merged health systems, price increases occur immediately after consolidation.

The executive order also directs HHS to support existing hospital price transparency rules and to finish implementing bipartisan federal legislation to address surprise hospital billing to protect patients.
Physician wellness post-pandemic: steps to getting back to normalcy

by Rebekah Bernard, M.D.

The COVID-19 pandemic has taken a toll on our mental health, with 42% of all Americans reporting depression or anxiety symptoms in December 2020 compared with just 11% the previous year, according to Nature. Physicians and other health care workers may be at higher risk for psychological distress because we must not only cope with our own feelings but also the emotional needs of our patients. A survey of health care workers found that 93% reported stress, 86% had anxiety, 76% reported exhaustion and burnout, and 75% felt overwhelmed. Caregivers also reported significant problems with insomnia, appetite changes, and physical symptoms like headaches and stomach pains.

Although we may not be experiencing the same stressors that we faced at the beginning of the pandemic— anxiety over personal safety and the health of our family members due to a lack of personal protective equipment, financial insecurity, and “lockdown” isolation — there are constantly new challenges to overcome. In the last year, we have been forced to develop new lifestyles, learning to work virtually, have kids at home, and avoid in-person social activities with friends and family.

Throughout this phase, physicians have been exposed to another challenge: public skepticism over COVID-19. Whether it is a debate about masking, vaccines, or whether COVID-19 is real, doctors must navigate a world in which acceptance of scientific authority is no longer a given. This is particularly difficult for physicians who are working on the front line, exposed to the harsh realities of the disease.

Now that the COVID-19 vaccine is ramped up, we find ourselves in a third stage — a tentative pivot toward pseudo-normality. We are back in the office and starting to engage in activities with others, all while wondering whether it is really over and we are safe.

Fortunately, there are steps that we can take to improve our mental well-being as we continue to navigate the (hopefully) post-pandemic world.

Accept that having negative feelings and emotions is normal.

According to psychologist Steven Cohen, PsyD, co-author of a book on physician wellness, physicians must learn to acknowledge their feelings nonjudgmentally. “Emotional reactions occur automatically. They are neither good nor bad — they just are,” says Cohen. He notes that although we cannot control these feelings, we can control how we choose to think about them.

Pay attention to your emotions.

“The worst thing that we can do is to try to suppress or ignore our negative feelings and emotions,” says Cohen. This doesn’t mean we must dwell on distressing feelings, but we do need to learn to identify these emotions and give them a label. For example: “I feel angry that my patient refused to believe that COVID-19 is real,” or “I feel overwhelmed and exhausted with seeing so many sick patients.”

“While it may feel uncomfortable to acknowledge these feelings, push through the discomfort,” says Cohen, who notes that this is where emotional growth takes place. He also advises physicians to take it a step further by asking themselves whether
there is anything more triggering their feelings. For example, “When patients don’t believe in COVID-19, it means they don’t believe in science, which means they don’t believe in me as a doctor.” Or, “There are so many sick people. It feels like there will never be an end to this disease.”

**Challenge your beliefs.**
Consider whether there is any truth or evidence to support your negative thoughts. For example, if you find yourself thinking “this disease will never end,” evaluate the thought logically. Do you know for a fact that the disease will never end? Consider the fact that all pandemics eventually end and life gets back to normal. Critically analyze any negative thoughts that you have in this way.

**Ask yourself how you want to feel, and practice cognitive reframing.**
No one wants to feel angry, worried, or stressed. We want to feel calm, in control, and at peace. Visualize how you want to feel and ask yourself how you can achieve that goal. One step is to practice deliberate cognitive reframing, in which you consider alternate explanations for your beliefs and then choose to think more positively.

For example, if you become angry at a patient who calls COVID-19 a “hoax” and find yourself thinking that your patient doesn’t trust you as a doctor, choose an alternate belief. Perhaps, “Right now, this patient is in denial because it is too emotionally painful for them to accept that COVID-19 is real, but it doesn’t mean that they don’t trust me as a doctor. After all, they came to the office to see me. It is very likely that with patience, I will be able to help them see things differently.” If you would like to learn more about how to practice cognitive reframing, there are many online resources or you can make an appointment with a mental health professional for one-on-one practice.

**Practice mindfulness daily.**
Cohen is a strong advocate of mindful meditation practice. “Studies show that even brief sessions of mindfulness activities — five minutes daily for six to eight weeks — improves mental health.”

“THE WORST THING THAT WE CAN DO IS TO TRY TO SUPPRESS OR IGNORE OUR NEGATIVE FEELINGS AND EMOTIONS.”

**Know that you are not alone, and that distress can get better.**
When we have negative emotions, we sometimes feel isolated and alone, and that we are the only people feeling this way. Sometimes we believe these feelings will never get better. Talk to a trusted friend or family member. Reach out for support from your colleagues. Even better, schedule an appointment with a primary care physician, psychiatrist or psychologist. You don’t have to wait for a crisis or emergency to call. It’s far better to talk about your feelings before they reach a critical state. Another option for help is the Physician Support Line, a free and confidential service offered by volunteer psychiatrists to practicing physicians across the country. You are not alone and you do not have to continue to feel this way. It can — and will — get better.

Rebekah Bernard, M.D., is a family physician in Estero, Florida, and the author of “Patients at Risk: The Rise of the Nurse Practitioner and Physician Assistant in Healthcare.”

**Engage in some degree of in-person communication.**
It’s time. We have been isolated for over a year, and most of us in the health care field have been vaccinated for COVID-19. At this point, we have developed new patterns and habits that can make interacting with others difficult. We need to get out of the virtual world and start to ease back into in-person socialization and relationship building with our friends, family and colleagues. Even if it’s as simple as talking outside in your yard with a neighbor or having coffee with a friend, start making plans to interact with others.
Prepared medical staff key to stopping ransomware

by Art Gross Contributing Author

What if your smartest, most trusted employee turned out to be the person who unintentionally sabotages and destroys your practice? This unfortunate turn of events can occur when physicians and medical employees are not trained to prevent stealth attacks by cybercriminals who use fake emails and other tactics to access a company’s data and hold it hostage until ransomware demands are met.

Health care is particularly vulnerable to this type of cybercriminal activity, which shows no signs of slowing down. In recent years, ransomware attacks have frozen patient data in medical facilities from Hollywood to London and around the world.

Because ransomware attacks and data breaches can severely damage the reputation and bottom line of a medical practice, it is critical to develop a cybersavvy staff. To achieve that goal, health care employees must learn to recognize the security risks that can lurk in ordinary activities such as accessing email, viewing social media images or setting passwords. Here are a few approaches to arming employees with the tools they need to defend themselves from hackers.

Simulate scams
Cybercriminals rely heavily on phishing scams using fake email to lure unsuspecting employees to open messages or click on links that serve as pathways for malware to infect computer systems. Once this happens, hackers can lock up a computer network and make ransomware demands or steal sensitive personal health information.

One way to deflect this type of attack is for medical practices to conduct their own simulated email phishing scams to expose employees to common cybercriminal ruses. Arthritis and Rheumatism Associates in Maryland conducted one such exercise and found that approximately 15% of the company’s employees fell for the scam.

Significantly, neither the number of years on staff nor the job title of the employee made a difference in those results; both physicians and non-clinical staff failed the test. In response, administrators required employees to complete a training module to learn how to avoid the problem. To keep pace with constantly evolving cyberthreats, managers can repeat this type of simulation and provide staff members with updates on the latest digital dangers.

Safeguard social media
In addition to spreading ransomware through spearphishing, cybercriminals are also transmitting it through images and graphic files shared on Facebook or LinkedIn. Preventing this type of infiltration requires employees to be vigilant about avoiding infected downloads. First, everyone on staff needs to know that social media websites should be able to display photos or images without the user having to download anything.

If a user clicks on a social media image and the browser starts downloading a file, the file should not be opened. Other images that should not be downloaded or opened have unusual file extension letters such as SVG, JS or HTA and not the common extensions like JPG or TIF. In short, whenever engaging in digital communication,
whether through social media or email, no one should download attachments from unknown individuals or sources.

**Protect passwords**

Passwords are meant to protect sensitive data from those who should not see it. These online gatekeepers are not always effective, however, because they may be too old or too easy for hackers to decipher.

By following a few best practices for creating passwords, employees can strengthen this line of defense and possibly avoid a costly ransomware incident. One effective tactic is to set a password to expire in a certain amount of time, such as 90 days, at which point that password is reset. In addition, a company can create locking accounts that cannot be accessed after five failed password attempts.

Once those attempts have failed, the account cannot be opened and must be reset by IT personnel. Employees can also be trained to create passwords that are complex enough to foil hackers yet easy for staffers to remember. For instance, the first letter from each word in a memorable phrase can be combined with numbers or punctuation marks to create a secure password.

**Valuable training**

Training health care staffers to avoid hackers’ scams pays enormous dividends by preventing costly ransomware attacks and the potential loss of patients after a data breach. Along with technological firewalls and meaningful security risk assessments, employee training offers a key layer of protection against the ever-growing threats of cybercrime.

Art Gross is president and CEO of HIPAA Secure Now!, which provides risk assessment, training and other security services to medical practices. He can be contacted at artg@hipaasecurenow.com.

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**The ransomware threat grows: How to prepare**

by Rachel V. Rose, J.D. Contributing author

A May 12 presidential executive order from the White House stated, “The United States faces persistent and increasingly sophisticated malicious cyber campaigns that threaten the public sector, the private sector, and ultimately the American people’s security and privacy.” This executive order came days after the Colonial Pipeline ransomware attack that underscored the vulnerabilities of the government and energy industry participants.

The health care industry is likewise plagued by myriad cybersecurity-related attacks, including use of ransomware. For example, the hackers in a recent ransomware attack went so far as to voice their displeasure with the hospital for denying it had been hacked, stating, “Does (the hospital) have control of this system? The answer is no. The last time we checked, we own their Ascom system and their data,” according to the indictment. This arrogance is similar to that of many cybercriminals, including those who prompted the Cybersecurity and Infrastructure Security Agency, Department of Justice, FBI, and Department of Health and Human Services to publish Joint Cybersecurity Advisory — Ransomware Activity Targeting the Healthcare and Public Health Sector (updated Oct. 29, 2020), in light of six ransomware attacks against hospitals across the United States. The primary tactics utilized to infect systems with ransomware for financial gain were Ryuk and Conti. The primary activities “include credential harvesting, mail exfiltration, cryptomining, point-of-sale data exfiltration, and the deployment of ransomware,” according to the federal advisory.

In light of the heightened awareness and the increased proclivity of attacks, the National Institute for Standards and Technology published Tips & Tactics: Ransomware, an infographic that includes quick steps individuals can immediately take to reduce the threat of a ransomware attack:

- Use antivirus software consistently.
- Keep computer patches up-to-date.
- Block access to ransomware sites by installing the appropriate software and services.
- Allow only authorized apps on computers, tablets and smartphones.
- Restrict personally owned devices.
- Use standard user accounts versus accounts with administrative privileges whenever possible.
- Avoid the use of personal apps and websites on company or work computers.
- Train the workforce to be aware of unknown sources and social engineering.
- Be sure to run antivirus software and/or look at links carefully.

Rachel V. Rose, J.D., MBA, advises clients on compliance and transactions in health care, cybersecurity, and corporate and securities law, while representing plaintiffs in False Claims Act and Dodd-Frank whistleblower cases. She also teaches bioethics at Baylor College of Medicine in Houston. Rose can be reached through her website, www.rvrose.com.
Beyond urgent care: Why virtual second opinions are telehealth’s next value differentiator

For years, health care stakeholders viewed telehealth as the stuff of one-time visits for patient urgent care needs without the expense or the inconvenience of a facility visit.

Now, the shift to virtual care during the pandemic has prompted the industry to consider: Where is telehealth headed — and how can we optimize its value?

For health plans, who have often been siloed as separate decision makers in the care continuum, data demonstrates the need to embrace virtual second opinions for complex health diagnoses. Adopting this approach not only offers strong potential to improve quality of care and the member experience, but also to reduce health care costs for plans and members. This is especially critical as payers become more interoperable with the rest of the industry.

The business case for virtual second opinions

The depth of misdiagnoses in health care is staggering — and it comes with a substantial cost, both human and financial.

Most Americans will be misdiagnosed at least once, research shows, including 21% of patients with serious illnesses. At The Clinic by Cleveland Clinic, our experience shows:

- When patients receive a second opinion for life-altering diagnoses, such as cancer, 28% of patients receive a change in diagnosis.
- When reviewed by expert physicians, 72% of treatment plans are modified after analysis.

These are just some of the reasons why the market for second opinions in health care is soaring, projected to reach $7 billion by 2024, up from $2.7 billion in 2019. Yet for health plans, second opinions remain a largely untapped opportunity. Most health plans do not have a ready off-ramp for members who wish to get expert confirmation of their diagnosis and treatment plan. Meanwhile, many members are uncomfortable initiating this discussion with their physicians—even when facing a life-altering condition.

Virtual second opinions change the game. With the proliferation of telehealth during the pandemic, health plans now have more options for pairing members with coordinated support for medical review. Relaxed telehealth licensing rules also make it easier to close gaps in medical expertise by empowering health plans to connect members with high-demand specialists from anywhere in the world. It’s a model that strengthens value while creating a better experience for members with complex care needs.
Designing a value-added approach
Members who receive a life-altering diagnosis such as cancer want assurances that they are making the right decisions for their health. Digital transformation gives health plans new avenues for connecting members with experts in their specific medical condition. For members who live in rural areas or communities where access to specific specialties is limited or unavailable, virtual consultations help close gaps in care, providing peace of mind while eliminating the risk of unnecessary treatment.

But the availability of a tele-health platform alone won’t provide the value that health plans and members seek. The right mechanism for virtual second opinions should incorporate these elements:

1. Deep access to medical expertise. Medicine has become so specialized that physicians must continually stay on top of the current treatment strategies in their discipline. The right virtual second opinion offering will match members with medical experts who are highly experienced in their condition—for example, an electrophysiologist for a member with a cardiac arrhythmia rather than a cardiologist. In some instances, the expertise members need might not be available anywhere nearby, making virtual second opinions a convenient and cost-effective solution.

The business case for specialized virtual support is strong. Three-in-four employers say they will ramp up the move toward value-based care models over the next three years. In this environment, digital centers of excellence will emerge, marked in part by their ability to match members with the expert best suited to review their case—and not just locally.

2. Speed to insight. If the expertise is great but the experience is subpar, the experience is what members will remember over the long run. That’s why speed to insight is critical: When members are struggling with a medical challenge or are about to make a major decision in their health journey, they need fast access to experts who can answer their questions and provide appropriate guidance.

When investing in a virtual second opinion offering, make sure that member access is simple, efficient, and effortless. Wait times for intake appointments should be short — ideally, available on demand. Further, workflows should enable members and their local providers to receive a detailed analysis within two weeks.

3. Results members can trust. Care is only as good as it is reliable. In spite of the advancements made in medicine, one out of 10 patients with cancer, an infection, or a major vascular event, such as a heart attack or stroke, are misdiagnosed each year. These conditions, commonly called the “Big Three,” account for 75% of serious harm resulting from diagnostic error. In 85% of these instances, failures in clinical judgment are to blame.

To avoid scenarios such as these, well-designed virtual second opinion programs incorporate multidisciplinary case analysis. They also give members the opportunity to speak by video conference directly with the expert physician on their case.

By bringing the right expertise to bear — virtually — health plans can better ensure that members with complex conditions receive the right diagnosis and a treatment plan based on the best evidence and experience available.

Frank McGillin is CEO at The Clinic by Cleveland Clinic.
Focus on coding compliance to safeguard practice revenue

by Lisa A. Eramo, MA Contributing Author

The reimbursement side of medicine is filled with the potential for denials on every claim you submit. Each payer has its own policy, and rules change frequently. Then, of course, there are post-payment audits. Just when you think you are in the clear, a payer decides to recoup that money. It all depends on the codes you assign and whether your documentation supports them.
E/M coding

Office visit evaluation and management (E/M) coding saw some big changes this year, namely new E/M guidelines that took effect Jan. 1, 2021. Experts say it is important for physicians to review this information because they may be over- or undercoding without realizing it. Experts provide these tips to ensure accurate revenue capture.

**Tip #1: Familiarize yourself with new time thresholds.**
One of the most common mistakes physicians make is that they try to bill 99214 when they spend 25 minutes with an established patient, says Toni Elhoms, CCS, CPC, chief executive officer of Alpha Coding Experts, LLC, in Orlando, Florida. However, beginning in 2021, they should bill 99213 instead. Elhoms urges physicians to review the new thresholds below and update their billing practices accordingly.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>TIME THRESHOLD IN 2020</th>
<th>TIME THRESHOLD IN 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>99202</td>
<td>20 minutes</td>
<td>15-29 minutes</td>
</tr>
<tr>
<td>99203</td>
<td>30 minutes</td>
<td>30-44 minutes</td>
</tr>
<tr>
<td>99204</td>
<td>45 minutes</td>
<td>45-59 minutes</td>
</tr>
<tr>
<td>99205</td>
<td>60 minutes</td>
<td>60-74 minutes</td>
</tr>
<tr>
<td>99212</td>
<td>10 minutes</td>
<td>10-19 minutes</td>
</tr>
<tr>
<td>99213</td>
<td>15 minutes</td>
<td>20-29 minutes</td>
</tr>
<tr>
<td>99214</td>
<td>25 minutes</td>
<td>30-39 minutes</td>
</tr>
<tr>
<td>99215</td>
<td>40 minutes</td>
<td>40-54 minutes</td>
</tr>
</tbody>
</table>

Equally important is knowing when to bill based on time, says Deborah Grider, CDIP, CPC, senior consultant at KarenZupko & Associates, Inc., in Chicago. “You don’t want to bill everything by time because, in some cases, you might be getting less revenue than if you had billed based on the complexity of the problems addressed, amount of complexity of data reviewed or analyzed, and risk of morbidity and mortality (i.e., medical decision-making [MDM]).”

**Tip #2: Document all assessments you perform.**
Physicians can easily under- or overcode because they do not accurately document their MDM — specifically the number and complexity of problems addressed, says Joe Rivet, Esq., CCS-P, CPC, CHPHC, CHC, CAC, founder and health care attorney and arbitrator at Rivet Health Law, PLC, in Norton Shores, Michigan. For example, they might briefly assess a chronic problem or think about the impact of that condition on the current presenting problem but do not document that thought process in the medical record.

“If you do any type of assessment or evaluation around those diagnoses — no matter how slight they may be — then that can factor into the overall (MDM),” says Rivet. “Physicians should document this so they can get appropriate credit in the E/M. It adds to the complexity, and they’re doing work they should be compensated for.” However, simply documenting that another professional is managing the problem does not count toward the E/M, he adds.

Be sure to document the complexity of the problem addressed, says Grider. This includes using terms such as acute, systemic, chronic worsening, exacerbating, severely worsening, and threat to life or body function, she adds.
**Tip #3: Know what labs and tests count toward the MDM.**

Ordering and/or reviewing unique labs or tests is another area rife with compliance vulnerabilities for over- and undercoding, says Rivet. A unique test is defined as one with its own CPT code, and physicians must understand whether and how the ordering and reviewing of these labs or tests can be used as a data element toward the overall MDM.

Here are three examples to consider:

- A physician orders a complete blood cell count (CBC) with differential. This test includes hemoglobin, CBC without differential, and platelet count. According to the AMA, single tests with overlapping elements are not unique even when those individual elements each have their own distinct CPT codes. This means ordering a CBC with differential only counts once toward the MDM.

- A physician orders a chest X-ray and reports CPT code 71046. They cannot count the ordering of this diagnostic test as a data element in the MDM if the provider performed and billed an interpretation of the X-ray, says Rivet. The same is true for an electrocardiogram when the physician reports CPT code 93000.

- A physician orders a dipstick urinalysis and reports CPT code 81001. This is a results-only test, and the AMA has clarified that physicians can count reviewing the results of this test as a data element in the MDM, he adds. The same is true for a quick strep test, CPT code 87880.

**Tip #4: Document review of prior external notes.**

When physicians review prior notes, they can count this toward the MDM, and notes from each unique source can be counted separately, says Rivet. A unique source is defined as a physician or qualified health care professional in a distinct group or different specialty or subspecialty, or a unique entity.

**Tip #5: Document a clinically relevant history and examination.**

Although the new E/M guidelines say history and examination do not count toward the E/M level, they are still important from a clinical perspective and to justify medical necessity, says Grider. “Payers will read the entire note,” she adds. “They’re going to look at what brought the patient into your office, past medical history, the exam you performed and what you found — and then, based on these variables, the assessment and plan of care.”

**Tip #6: Get credit for social determinants of health (SDOH).**

Physicians can count SDOH toward their MDM when those determinants have an impact on the patient’s health, but only when they clearly document that impact, says Rivet. For example, a patient with uncontrolled, worsening diabetes lacks access to safe and reliable transportation, making it difficult for them to refill prescriptions and thus manage their insulin levels. When properly documented, this equates to a level 4 E/M code, he adds.

**Tip #7: Use caution with cases related to COVID-19.**

Assigning an E/M level for COVID-19 cases can be tricky, says Grider. For example, an asymptomatic patient says they were exposed to COVID-19 and wants to be tested. This is a minimal problem with one unique test ordered, which is a level 2 E/M code. However, if that same patient presents with signs and symptoms — and the physician prescribes an antibiotic — it’s an undiagnosed new problem with prescription drug management, which is a level 4 E/M code.

**Tip #8: Update your E/M template, audit your documentation.**

“Templates were designed largely around the old E/M guidelines and elements, which means they may no longer be accurate,” says Rivet. “Still, the provider — not the vendor — is ultimately liable on an audit.”

Once you’ve asked your vendor to update the E/M template, select at least 10 records per provider, including a combination of E/M levels 3, 4 and 5, says Grider. Then hire an external consultant to audit those records, she adds.

“This can be done fairly inexpensively,” agrees Rivet. “The cost associated with this is minuscule compared to the upward benefit.”
Telehealth

With post-payment audits of telehealth services on the rise, physicians should pay close attention to telehealth billing, says Elhoms. “There’s a false sense of security during the public health emergency,” she adds. “Providers think they can do whatever they want, and this isn’t the case.”

Elhoms provides several tips to ensure compliance.

**Tip #1: Pay attention to audio-only versus audiovisual requirements.**

During the current public health emergency that was renewed on April 21, 2021, Medicare requires the use of audiovisual technology for certain telehealth services and permits audio-only for others, says Elhoms. For example, physicians can render a telehealth visit for an annual wellness visit using audio only, but they must use audiovisual technology for all E/M levels of new and established patient office visits. Note that commercial payers may have specific telehealth requirements.

Best practice is to document the technology used and whether the encounter included audiovisual communication with the patient, says Elhoms. “In the absence of this documentation, the payer will say you can’t prove you did this through a compliant technology, and thus you can’t support the service,” she adds.

**Tip #2: Know your place of service (POS) codes, modifiers.**

Use POS code 11 and modifier-95 when billing Medicare, says Elhoms. Note that commercial payers may require a different POS code (e.g., POS 2 or POS “other”) and modifier.

**Tip #3: Document patient consent.**

“It seems really simple, but it’s important,” says Elhoms, adding that payers look at utilization patterns and are quick to audit providers whose utilization spikes suddenly or steadily increase over time. Having consent is key to proving that these visits took place. Some providers, for example, may not realize that their practice management system automatically bills appointments even if the encounters do not ultimately occur (e.g., because the patient is a no-show).

**Tip #4: Beware of incident-to billing for telehealth.**

Does documentation clearly indicate that a supervising physician is immediately available? For example, does the physician’s schedule show that they are supervising during the hours in which incident-to visits are billed? Payers may request this information to validate services rendered, says Elhoms.

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REMOTE PATIENT MONITORING: BUILDING A VIRTUAL PRACTICE

Jon Regis, M.D. is a trailblazer when it comes to remote patient monitoring. He used the COVID-19 pandemic to create a virtual practice as an offshoot of his traditional practice, with its own staff, workflows and more.

*Medical Economics*® sat down with Regis last year to discuss his virtual practice model and provide advice for physicians who want to start one themselves.

*Medical Economics*®: How should physicians get started on their own journeys in terms of using virtual care and remote patient monitoring technologies to help them treat their patients? What advice would you give them on where to start?

**Regis:** I would start small. I think that you, first of all, find a technology partner that can work with you. Sometimes, you have to make the investment, if you’re large enough to do that. Or cut out some time from your existing staff to make this happen. They can start with 100 patients. 100 patients may generate $16,000 to $17,000 a month from remote monitoring. This is new revenue. And it’s not revenue that depends upon Congress to pass a stimulus package. It’s revenue that’s already there. I’m tapping into codes that already exist.

Look, health care is a business. I’m trying to use the tools that are there to make sure I can pay my staff and providers commensurate with what they’re doing. And for primary care, we’ve always been on the low end, our margins have always been very small. So I’m saying, ‘Look, we’ve got to revolutionize this thing.’ The pandemic is going to hasten this and help all of us look at other ways that we can engage our patients, generate additional revenue and reduce costs.

Check out the full interview, visit: [bit.ly/MedEcVideo](http://bit.ly/MedEcVideo)
Remote patient monitoring

Remote patient monitoring (RPM) helps physicians keep patients healthy; however, it is not without its own unique reimbursement challenges, especially in light of more specific RPM guidance published in January. “The OIG (Office of Inspector General) is just now starting to audit practices that are using RPM for compliance with this rule,” says Kaitlyn O’Connor, J.D., senior counsel at Nixon Gwilt Law in Richmond, Virginia, who works with more than 80 RPM providers and vendors.

However, these audits should not necessarily scare providers away from offering RPM, says O’Connor. The startup costs associated with RPM (i.e., purchasing devices) should not either. “Most vendors will wrap the cost of devices into a flat monthly fee rather than requiring practices to purchase devices outright,” she says. “Now that we’ve been through COVID-19, I think a lot of practices are starting to integrate RPM. If you’re not doing it, you may start to lose patients to practices that are.”

Consider the following relevant RPM codes.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
<th>2021 NATIONAL AVERAGE MEDICARE PAYMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>99453</td>
<td>Initial device setup and patient education for RPM that includes at least 16 days’ worth of data (billable only once per episode of care*)</td>
<td>$19.19</td>
</tr>
<tr>
<td>99454</td>
<td>Rental fee for devices that supply daily recordings or programmed alert transmissions for at least 16 days’ worth of data (billable once every 30 days)</td>
<td>$63.16</td>
</tr>
<tr>
<td>99457</td>
<td>RPM treatment management service by clinical staff, physicians, or other qualified health care professionals requiring 20 minutes of live, interactive communication with the patient or caregiver during a 30-day period</td>
<td>$50.94</td>
</tr>
<tr>
<td>99458</td>
<td>[Each additional 20 minutes]</td>
<td>$41.17</td>
</tr>
<tr>
<td>99091</td>
<td>Collection and interpretation of physiologic data digitally stored and transferred, requiring a minimum of 30 minutes of analysis by a physician or other qualified health care professional during a 30-day period**</td>
<td>$56.88</td>
</tr>
<tr>
<td>99473</td>
<td>Self-measured blood pressure using a device validated for clinical accuracy (including patient education/training and device calibration)</td>
<td>$11.52</td>
</tr>
<tr>
<td>99474</td>
<td>Collect and review separate self-measurements of two readings: one minute apart, twice daily over a 30-day period (minimum of 12 readings), and communicate a treatment plan as well as average systolic and diastolic pressures to the patient</td>
<td>$15.00</td>
</tr>
<tr>
<td>95250</td>
<td>Continuous glucose monitoring requiring a minimum of 72 hours, billable once every 30 days</td>
<td>$157.37</td>
</tr>
</tbody>
</table>

*An episode of care is defined as beginning when the RPM service is initiated and ends with attainment of targeted goals.

**Note that providers cannot use 99091 when the RPM is performed by clinical staff. They also cannot report 99091 on the same day as a separate E/M service.
Common denial: The RPM device doesn’t meet federal requirements.
How to avoid it: Use a medical device, as defined by the United States Food and Drug Administration, that provides automatic data upload and transmission, says Charles C. Dunham IV, J.D., business and health care attorney at Greenberg Traurig in Houston. Dunham says he encounters physicians who bill RPM when patients manually input their weight and other physiologic data into an app and then manually upload that data to the practice. “If at any point your patient needs to enter information, that’s not the type of device the government is willing to cover,” he says.

If physicians are working with a vendor to supply RPM devices and manage the RPM program, Dunham says, they should include a provision in the vendor agreement that the vendor is supplying the practice with a device that meets functionality requirements for RPM under the Medicare Part B program and that it will indemnify the practice for any damages or overpayment recoupment.

Common denial: There’s no medical necessity for RPM.
How to avoid it: Only use RPM for patients with an acute or chronic condition that must be monitored, says Dunham, adding that documentation should clearly reflect how remotely monitoring the patient supports the care plan and period of use. Also, if the RPM is for an acute condition, Medicare’s expectation is that the RPM will cease at some point in the short-term when it no longer becomes medically necessary, he adds.

Common denial: The RPM doesn’t include 16 days’ worth of RPM data.
How to avoid it: Physicians may use multiple devices or a single device that captures more than one type of physiological data, says Dunham. “You can pull data from multiple devices to meet the 16-day requirement,” he adds. One important caveat: Physicians can only bill 99453 once per episode of care and 99454 once every 30 days regardless of how many devices the patient uses.

That does not preclude physicians from billing more specific codes when possible, adds Dunham. Examples include 95250 for continuous glucose monitoring as well as 99473 and 99474 for self-measured blood pressure monitoring.

It can also be helpful to work with a vendor that helps manage your RPM program because the vendor typically reminds patients when to take their readings, which can help with adherence, says O’Connor. Some vendors may also use devices that incorporate software that automatically reminds patients to take their readings, she adds.

Common denial: Provider submits a date range for RPM services.
How to avoid it: Only submit one date of service for CPT codes 99453 and 99454 even though the codes require at least 16 days of data, says O’Connor. Practices usually use the first or last day of the month, for example.

Common denial: Medicare Administrative Contractor (MAC) doesn’t apply RPM rules correctly.
How to avoid it: Although these denials can be frustrating, the good news is that practices can often simply point out the error and ask the MAC to adjust the denial, says O’Connor. For example, some MACs have denied RPM claims in the past, stating the service can only be used for cardiology. “Because RPM originated in the cardiology space, there’s a misconception that it can only be used for cardiology patients, which is not accurate,” she adds.

Managing denials and appeals
It is the part of running a medical practice that no physician wants to spend time addressing: Denials...and then appealing them. However, experts agree that a few simple steps can go a long way in terms of improving cashflow. Consider the following tips.

Tip #1: Run daily reports.
What is the denial rate by payer and reason code? “A lot of practices will just sit on denials,” says Rozmin Bapat, CCS-P, CPC, CPCO, CPMA, founder and CEO of CodeRite Healthcare Consulting in Allen, Texas. “If
there’s a denial, they need to work on it right away.”

Tammy Tipton, owner of Appeal Solutions Inc. in Oklahoma City, agrees. “So few practices have a good handle on their denial rate and appeal success rate,” she says. “It’s very important to know this information and to look at it on a payer-by-payer basis.”

**Tip #2: Use technology to your advantage.**
For example, coordination of benefit (COB) denials can be easily addressed by requiring staff to use payer portals to check insurance eligibility. Staff might also be able to check eligibility from within the practice’s billing software. Another strategy is to put edits in place to catch front-end errors. For example, practices could create an edit that would, for example, prohibit staff from entering a Blue Cross Blue Shield ID that isn’t typed in an alphanumeric format.

**Tip #3: Provide ongoing education for staff.**
For example, certified medical coders require ongoing education and training to maintain their certification and to help ensure revenue integrity. A reasonable budget for this type of education is approximately $350 per coder annually, says Bapat.

**Tip #4: Use the right forms.**
Each payer has its own appeal guidelines and forms, and appeals may be rejected if providers don’t follow the rules, says Bapat.

**Tip #5: Involve patients in clinical appeals related to the application of policy benefits.**
That is because patients can often provide helpful policy language, says Tipton. “A broad appeal letter that’s not specific to the claim ends up sacrificing some effectiveness,” she adds.

In some cases, patients may be able to handle the appeal themselves, says Tipton. “If you’ve got a motivated, well-educated patient, it’s probably better to let them handle it. To the payer, it can be more persuasive coming from the patient,” she adds.

**Tip #6: Negotiate payer contracts that include additional appeal protections.**
For example, practices can negotiate longer time frames for appealing denials or require payers to disclose the clinical information and guidelines it used to determine the denial, says Tipton.

**Tip #7: Correlate denials with patient satisfaction.**
“With high deductible plans and greater out-of-pocket patient responsibility, patients are being very vigilant,” says Bapat. “They’re going online looking at their explanation of benefits and questioning things.”

Tipton says everyone within the practice should understand how their role fits into the bigger picture of helping patients avoid inaccurate bills and unnecessary frustration. For example, patient access staff can file pretreatment benefit clarification requests and pretreatment appeals when authorizations are denied. Patient financial staff can review claims that fail on front-end edits. Clinical staff can file clinical denials, work with payers to understand reasons for denials, and review managed care contracts annually for problematic terms that impact quality of care. “Everybody can really play a part in reducing denials,” she adds.
Ways to prevent delinquencies
Before physicians worry about collecting delinquent payments, there are several strategies to ensure collections take place up front. “Patients are consumers and they need to be treated like consumers,” according to Noel Felipe, senior vice president and revenue cycle practice leader at Firstsource, a company based in Columbus, Ohio, that offers digital solutions in the health care space. “Consumers make decisions about where they shop and what they pay. They make value judgments based on their perceived value of a product or ease of consuming that product. The health care industry has to migrate to that type of mentality.”

This means making payment as simple and efficient as purchasing a product on Amazon, utilizing technology so patients can pay by phone or iPad, steering clear of too much technical jargon and having a comprehensive patient portal. “Your patient portal should allow them to make payments, to establish payment plans,” he adds.

Additionally, he urges physicians to take some payment up front. “You should collect 100% of your copays at the time of service. Your chances of collecting money go down post-service by 54%.”

The only exception to taking payment up front may be in a practice that includes services such as labs or X-rays, according to Lillian Phelps, senior director for product management at Availity, a health information network in Jacksonville, Florida. “Maybe collecting payment is better on the back end in that case, because you don’t know if they have to get a lab drawn or an X-ray,” she says.

Payment plans
Payment plans and options are an effective way of getting patients to pay, Phelps says. “You should come up with a financial clearance policy that sets dollar thresholds and time frames. You might even look at the relationship you have with the patient — if this has been your patient for 10 or 15 years, and he’s never had a financial collection, there should be some sort of consideration for their history.”

Any form of collections is improved by including digital means of paying, says Phelps. “Are you sending your statements digitally? Do the statements have a link to pay the bill? Folks don’t go to the post office (much) anymore,” she says. “Being able to offer digital or mobile payment options is a great place to ensure the bill is paid.”

Having a digital means of paying also increases the likelihood of patients making some payment rather than none, Felipe points out. “If I owe my physician 500 bucks and I go onto the portal and I have no choice but to pay 500 bucks or leave, and I can’t afford it, I’m going to exit out. But if I have payment terms, I’m going to pay what I can pay.”

Propensity-to-pay analytics
Beyond simply making easy payment options available, Felipe encourages physicians to utilize propensity-to-pay analytics to drill down and figure out the demographic of a practice. “It’s easy to collect from people with high ability and high desire — those are automatic,” he says. “The people with low desire and high ability, you’re going to have to work at a bit. Propensity-to-pay modeling to help you understand where to place your expectations is critical in a successful physician practice.”

This sort of analysis can circumvent delinquencies by allowing the physician to preemptively offer financial resources and support to those patients most likely to have trouble paying, according to Srulik Dvorsky, cofounder and CEO of TailorMed, a health care IT company for health care providers and pharmacies in New York City. “Instead of waiting for patients to experience financial distress or have a bill be written off, if you have the technology that can screen for patients based on their out-of-pocket responsibility, you can come to those patients as early as their diagnosis or registration...
and offer assistance programs,” Dvorsky says.

Additionally, remember that not every patient will engage in the same way, so pick the right strategy for the right demographic, Felipe says. “Baby boomers will not respond to text messages, but millennials will. Millennials will not talk to you on the phone and they don’t really care to look at email. So, if you want to collect more money, you have to pick the right engagement strategies for your patients.” He recommends having software that uses algorithms to predict engagement behaviors. Physicians who utilize software and technology of this sort have an advantage in collections. “I think physician practices are in a very unique and enviable position where they can predict pretty closely what the patient should owe, and I think that conversation should happen either at the time of service or before service,” Felipe says.

**Having the conversation**

When a balance is outstanding, Felipe advises that physicians should not be the ones to raise this issue directly with patients. “This is a relationship that doesn’t need to be strained over financial dialogue,” he says. He gives the example of how most dental practices work. After your oral examination, the dentist comes in to tell you what services you will need, and the billing staff member talks to you about the money.

He recommends having a financial counselor of some form on staff — this could be your billing person, a care coordinator, or another front office employee. This person can direct the patient to philanthropic organizations and resource documents such as those already prepared by the Centers for Medicare and Medicaid Services.

“You don’t have to recreate the wheel with resources,” says Gloriann Sordo, J.D., a principal at AdviCare, a company in Lakeland, Florida, that handles clinical denials for hospitals. She also encourages physicians, or their billing staff, to ask insurers what resources they have for patients. “I believe the payers should be doing more in trying to help patients understand what their responsibility is.” Additionally, this person can help patients review and understand their insurer’s explanation of benefits, says Sordo. “Patients assume it’s their physician’s office that is responsible for their balance, rather than the insurer,” she says.

Other strategies

Sometimes the simplest steps can ensure the most efficient collections. Phelps urges physicians to make sure their front desk and billing staffs are collecting basic but crucial information. “Make sure you have a copy of their card. Get the ABCs down and run patient eligibility,” Phelps says. “Ask for the money up front.”

Phelps also recommends preparing ahead for each day by running all patients’ eligibility and benefits the night before. “Doing that work the night before makes your check-in process go more smoothly and gives you the opportunity to accurately calculate what their cost share would be once they’ve done their visit.”

Phelps says, “At the end of the day I tend to believe that people want to pay their part and they want to have the opportunity to do so. But sometimes they need education.”

**”You should collect**

100% of your copays at the time of service.

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Noel Felipe, senior vice president and revenue cycle practice leader at Firstsource, a company based in Columbus, Ohio

Your chances of collecting money go down post-service by

54%
Coding office visits: The 99211 checklist

Q: 99211 doesn’t have any specific guidelines like the rest of the office visit codes. Can you give us some insight about what to document for these visits?

A: When considering whether to assign 99211 for a service, remember these important points for proper reporting.

- Do make sure there is a separate E/M service. Check for a documented evaluation of the patient along with management of the patient’s care. For example, if a nurse only refills the patient’s medications and no other E/M service takes place, you should not report 99211.

- Do ensure the patient is an established patient. Based on the CPT code description, you should report 99211 for an established patient, meaning one that has been seen by the rendering provider (or provider of same group and specialty/subspecialty) within the past 3 years, in any setting. You cannot report 99211 for a new patient.

- The established-patient rule also is important because Medicare applies the concept of incident-to services for 99211, meaning a provider previously furnished a direct, personal, professional service to initiate a course of treatment, and the 99211 service being performed is an incidental part of that care plan.

- Do be certain that the supervising provider is in the office suite. Reporting 99211 to certain payers (including Medicare) requires that the supervising provider be in the office suite at the time of the appointment. The billing provider is not required, however, to be in the room or to provide face-to-face services for the patient. The supervising provider doesn’t have to be the one who created the care plan. Medicare Benefit Policy Manual, Chapter 15, Section 60, provides more information about incident-to services.

- Do prove that the visit is medically necessary. Look for a documented clinical reason that supports the visit and proves it was above the scope of the other services provided that day. In other words, if you’re reporting the E/M code along with another code, make sure the E/M documentation is significant and separately identifiable from the procedure documentation. For example, a nurse may document the reason for the visit, a brief history of the patient’s illness, any exam processes such as weight or temperature, a list of the patient’s medications, and a brief assessment to support the E/M in addition to the other service performed.

- Do bill the service under the supervising provider. All incident-to services must be billed under the provider present in the office when services were performed.

99211: An office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician.

Renee Dowling is a billing and coding consultant with VEI Consulting in Indianapolis, Indianapolis. Send your diagnosis coding questions to medec@mjlifesciences.com
Win financial freedom: Pay debt, grow wealth
How physicians should handle their biggest financial dilemma

by Todd Shryock Managing Editor

Physicians often finish their education burdened with a debt load that can reach six figures. But they also start their professional careers years behind their colleagues in nonmedical fields when it comes to saving for retirement.

Once they start earning a good salary, the biggest challenge they face is deciding whether to pay down their debt or invest for retirement. Medical Economics® spoke with Jamie Malone, principal and financial strategist with Agili, about how doctors should approach this dilemma. The transcript has been edited for brevity and clarity.

Medical Economics® (ME): Many doctors enter practice with substantial amounts of debt and focus their efforts on paying it down, often at the expense of investing in retirement. Is this a mistake?

Jamie Malone: The advice many individuals get is to pay off all your student debts and then start thinking about retirement. We don’t necessarily view this as an either/or; we take the approach of pay down your student debt and start saving for retirement. You’ve been in medical school for a long time, you’ve gone to a residency and fellowship, and we want to make sure that you’re using compound interest while time is on your side. To delay retirement investing…can definitely have a negative impact if you wait too long.

ME: Is there a certain ratio that young physicians should use when determining how much to invest in retirement versus paying down debt, and will this ratio change over time?

Malone: We don’t look at it so much as a ratio. I would use more of an analogy of a balancing scale. There are going to be certain factors that would say we need to pay debt down more quickly (and) others that say, actually, put a little bit more money toward retirement. So, for example, if you have high interest rate loans, or there could be also cases where excess cash flow is just really not there…then you should probably be focusing more on paying down your debt and you might not get to save as much for retirement. On the other hand, let’s say you’ve got low interest rates and you have excess cash flow. Then I think that you would really want to consider saving more money for retirement as well as working on paying down that debt.

ME: If doctors have variable rate loans, and...
the interest rate goes up, will this change how they approach retirement investing versus paying back their loans?

Malone: Yes. Using the scale analogy, if one side of the equation changes, then you definitely want to look at the overall picture. If interest rates shot up and rates became a lot higher, then that would definitely be a factor to say let’s pay down that debt a little more quickly, let’s be smart about this decision between retirement savings and debt. And once again, if you need to shuffle a little bit, that’s fine.

ME: When starting out, are there particular types of investments doctors should focus on building up first?

Malone: Before someone starts to save for retirement, I would suggest making sure that you have an emergency fund. I think that is important, to have at least three to six months’ worth of expenses. And then once you have that in place, then I think there (are) some great vehicles to use to invest. One of the ones that I really like is an employer-sponsored retirement plan like a 403(b) and a 401(k), you can have tax deferral but the benefit is you could save those funds in that health savings account. Then down the road, if you need it for medical expenses, you can take it out tax free. If not, you could just use it for your retirement needs.

Another strategy is what some people call a backdoor Roth. This works really well when you don’t have any other IRA accounts, and what you do is simply make a nondeductible IRA contribution. You put money into an IRA, but there’s no tax benefit, there’s no tax deduction, and then you can convert that amount. So let’s say you put in $6,000 this year — you don’t get a tax deduction, then you convert that money into a Roth. Since you never got a tax deduction in the first place, it doesn’t cost you anything — there’s no tax to convert it. So I think this can be a great strategy for doctors who want to have some Roth money but may not qualify due to the income limitations that are currently in place.

And the last thing I would suggest is just a taxable brokerage account. If you’ve exhausted some of the other areas to defer income, a taxable brokerage account is the way to invest. And it’s also a lot easier to get that money out if you need to, down the road, than it would be from a retirement account that may have some type of penalties to take money out of that account.

ME: Is there a certain point where a doctor should just pay off any existing loans if they have the means to do so? For example, maybe they have $5,000 in loans remaining and they’ve got plenty of money in their bank account — should they just get rid of those loans and be done with them?

Malone: There are cases where… taking that burden off the plate would make a lot of sense. In your example, if there’s a small remaining balance, and especially if the monthly payment was kind of high, then you could pay that off, free up some additional monthly cash flow and use that to help fund your retirement or other long-term goals. I think another example is if interest rates were really high on those loans it would
make a lot of sense to go ahead and pay that off, especially if you can’t make more money in the market than you would with what you’re paying on that loan. We just think it’s important to balance the ability to pay down that student loan as well as make sure that you’re not missing out on saving for retirement.

ME: After scrimping through medical school and residency, some physicians rapidly increase their lifestyle expenses when they enter practice. How can this hurt them long term and what are some guidelines they can follow to keep their spending in check?

Malone: Banks are willing to lend to physicians, and because of that it’s easy to get their hands on money. Having deprived themselves for many years going through medical school, residency, fellowships...a lot of doctors are ready to kind of have a more normal life. My suggestion is to think about the goals that you want to accomplish and try to balance that with your spending. It’s so easy to start spending and maybe not reconcile or realize the goals that you have. So when I was growing up, saving 10% for retirement, that was kind of what a lot of people suggested. More recent studies suggest 15%. But think about it for doctors: It’s going to typically be higher than 15%. Why? Because they’re starting later in the game to save. So I think this can sometimes surprise a lot of physicians, going, ‘Wow, I need to save 15(%) or 20(%),’ or whatever that number might be for retirement. The other piece I would suggest is having a mindset of working toward your goals. A lot of people appreciate being able to take the rest and use that for their expenditures. So in other words, if I have a retirement goal, and maybe I’m trying to save for my child’s college, pay down my debt, and I’m reaching those goals, then OK, go ahead and use the rest to live the lifestyle you want to but don’t forget to take into account saving for those important life goals.

ME: How can physicians protect their income and their families long term with insurance or other products?

Malone: If we think about the future earning potential of a young physician, it’s going to be at the very highest just as they begin practice. On the other end, their financial assets are typically the lowest. So a couple of really key insurance measures would be disability insurance that would protect if a doctor had an injury or is unable to perform their work, and the other one is life insurance, premature death, especially when you have a family to take care of. I think those two are really important. One tip on the disability side: Some employers offer disability insurance. The one thing that sometimes people forget is if you are making payments with pretax dollars, then those benefits would be taxable. So you want to make sure that with employer disability insurance, that if you can pay it with after-tax dollars for the premium, then any benefits you’d receive would be tax free.

ME: Markets change over time, as does the physician’s financial situation. How often should a doctor take a look at his or her investment strategy?

Malone: From the outset, I think it’s important to have what’s called an investment policy statement in place. This would outline the objectives, any type of constraints on the portfolio, and I would suggest at least reviewing that once a year, because life happens, things change. Make sure that your portfolio is lined up with those overarching objectives. Secondly, we recommend that clients have a strategic or long-term investment allocation. That’s something that’s simply not going to change from day to day or maybe even from year to year. That’s for down the road. And so although that may not change very often, there still might be tactical adjustments, short- or midterm adjustments that need to be made in the portfolio. If we think more recently, the stock market growth stocks have been on a tear. A lot of people think that it might be a time that value stocks may start outperforming growth stocks. Well, in that case, you’d want to make some adjustments, similarly with your own portfolio. It needs to be reviewed periodically and make sure that it lines up with those long-term objectives, and you make any short-term changes that you need to reach your goals.
Personalized medicine has become something of a buzzword, with many different meanings. However, the overriding goal is the same whether referring to targeted medicines or caring for a patient’s general health: avoid one-size-fits-all solutions by tailoring patients’ care to address their individual traits, needs and health goals.

For many physicians, the systems we work within can make that aspiration extremely challenging to put into practice. The limited time primary care physicians have with patients during a typical office visit is rarely enough to obtain a clear picture of the many factors impacting a patient’s health and provides a very narrow window into the life that person actually leads. The opportunity to understand the reality of a patient’s circumstances is even more restricted in the emergency department and in-hospital settings. In the ED, we’re focused on getting the patients in and out as quickly as possible, while admitted patients are often so depersonalized, they’re known primarily by their room number or diagnosis.

These structural barriers prevent health practitioners from learning about important aspects of our patients’ lives, leaving many of us frustrated and feeling we’re doing little to fix the underlying issues causing their health problems—which means we’re also doing little to stem their recurring visits to the ED. At the same time, patients feel unseen and lack the necessary information to care for themselves once home, often leading to costly overuse of the healthcare system. I can’t count how many times I have seen a patient present to the ER because they were confused about their medication list or unable to refill their prescription.

BACK TO OUR MEDICAL ROOTS WITH IN-HOME HEALTHCARE

There is a more personalized and equally effective way to care for patients: It’s in their home.

In-home healthcare is not only preferred by patients, it also allows clinicians a much fuller understanding of a patient’s life and health circumstances, enabling us to provide more individualized, continuous care.

As health practitioners, we know well the limitations of medical treatment. Clinical care accounts for just 20% of health outcomes, while 80% are attributable to social determinants of health (SDOH). There’s no better way to identify the environmental and lifestyle factors impacting health, as well as the support systems available to a patient, than seeing someone in their home environment. The intimacy of a home setting is also more conducive for building a strong relationship with a patient, promoting conversations that help us know more about the person, understanding their health challenges, and better educating patients and caregivers about their condition and treatment.

The pandemic helped accelerate interest and acceptance of in-home care. At Humana, we are working to make it a first-line option for patients for the long term, expanding access to a wide range of at-home services including primary, emergency and hospital care.

In partnership with DispatchHealth, we doubled the number of ER home visits treating low and moderate acuity cases from 2019-2020, lowering the cost of emergency care by up to 80% compared to a facility setting. Based on our successes with ER home visits, we will be expanding into Hospital at Home care this year. We have also seen a 25% reduction in ER visits among patients who engaged Humana at Home behavioral specialists compared with a matched population. And through our home services, Humana has made over 86,000 referrals to address SDOH and clinical gaps in care so far this year.

There was a good reason why doctors once made house calls. Care at home is truly personalized medicine.

Amal Agarwal, D.O., MBA, is Vice President, Home Solutions Business Development and Strategy at Humana, and a board-certified emergency room physician. He serves as clinical faculty-gratis at the University of Louisville and continues to practice emergency medicine at the Louisville Veterans Affairs Medical Center. He also advises several healthcare start-ups.
Keeping your estate out of taxable terrain

If you're an experienced physician with a substantial net worth, you might want to look down the road and ask yourself: "How much will I be worth in 10 or 20 years? And what will be the ultimate value of my estate?"

For many physicians, the acuity of this vision is becoming more critical these days, as Congress is expected to reduce limits on how much can be passed on to heirs free of federal estate tax.

Another cause for concern: Congress may soon increase federal income and capital gains tax rates on the wealthy.

The good news is that there's a tool to lessen this tax exposure and also assure a quick infusion of cash for your heirs to pay any tax on inheritance, due a short nine months after your death. This cash can help them avoid a fire sale on illiquid assets, such as real estate or equity in your medical practice, by giving them time to get a good price.

This tool is whole life insurance. The use of these policies can go way beyond simply providing insurance proceeds for your heirs: They can help you build a larger legacy, protect assets during your lifetime.

Currently, estates totaling $11.7 million for individuals and twice that amount for married couples have no federal estate tax liability. But every dollar above that limit is taxable. These limits, known as the unified gift and estate tax exclusion, are the total amount you can give away during your lifetime and leave to your heirs without incurring tax.

Not owning it
Unbeknownst to many wealthy individuals, the cash value and death benefit of their life insurance policies are ultimately factored into the value of their estates. But if someone else owns the policy on which you're the insured, that's a different story.

You can arrange ownership of a whole life policy on yourself by a beneficiary, such as one of your adult children. This way, the policy's growing cash value and death benefit proceeds don't increase the value of your estate one wit.

Of course, the adult child holding the policy must pay the premiums, and you can give them money every year to do so — up to $15,000 from you or $30,000 from you and your spouse together, in what's known as a present-interest gift. This means there's no gift tax due on this money, nor does it count toward your lifetime gift/estate tax exclusion.

Just say no
The policy premium can be paid with money that you've initially offered as a beneficiary — typically, an adult child — as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notifies the child that the money is available as a gift in what's known as a Crummey letter. This letter notify...
in a return letter. Then arrange for the ILIT’s trustee use this money to pay the policy premium. The offer and rejection of the gift makes the gift tax-free and takes the money out of your estate. This arrangement requires responsibility on the adult child’s part, but not as much as if he or she were the policy’s owner.

There’s no tax on the growth of the policy’s cash value because you don’t own it. Rather, the trust does. When properly structured, ILITs can enable grantors to borrow against this cash through loans arranged by the trustee.

Such loans are typically made at market interest rates, far below the capital gains rates (which Congress may soon increase) that you’d pay on investment gains and the ordinary income rates (which also may soon rise) on dividends. Thus, the tax advantages of borrowing against an ILIT-held policy as an alternative to selling assets likely will soon become even greater.

This access to low-interest loans is a key advantage of using an ILIT rather than having an adult child own the policy. In the latter scenario, only the adult child can borrow against the policy.

These trusts are expensive to set up and maintain, primarily because of legal fees. Yet the larger your estate and the larger the policy, the more this may be worth this expense.

So it’s a good idea to plan now, with the help of a qualified estate planner and, preferably, a skilled wealth manager. Otherwise, you and your heirs could end up paying a lot more in taxes.}

David Robinson, a certified financial planner, is founder/CEO of RTS Private Wealth Management, an SEC-registered firm in Phoenix that provides fiduciary services to help clients achieve their financial goals. His practice focuses on helping wealthy individuals with custom financial plans, using a holistic approach to grow/protect wealth, manage taxes, identify insurance solutions, prepare for retirement and manage estate plans. Send your financial questions to medec@mjhlifesciences.com.

**Rule changes**

Using life insurance to reduce tax exposure is a time-honored estate planning technique, but recent changes in the tax code by Congress make it an even better tool. One result of these changes, says Scott Witt of Witt Actuarial Services, is that for a given amount of premium, life insurance policies don’t have to include as much death benefit, proportionately, as they did previously. “They’re now more efficient for accumulation-oriented designs,” Witt says. And to the extent that this value isn’t tapped through loans, this accumulation could mean a greater legacy for your heirs, particularly if you live to a ripe old age.

Though your net worth may currently be nowhere near the new exclusion limit that Congress approves this time around, or new limits set in years to come, asset growth over the next decade or two could push your estate over the threshold.

**“Using life insurance to reduce tax exposure is a time-honored estate planning technique, but recent changes by Congress make it an even better tool.”**

David Robinson, a certified financial planner, is founder/CEO of RTS Private Wealth Management, an SEC-registered firm in Phoenix that provides fiduciary services to help clients achieve their financial goals. His practice focuses on helping wealthy individuals with custom financial plans, using a holistic approach to grow/protect wealth, manage taxes, identify insurance solutions, prepare for retirement and manage estate plans. Send your financial questions to medec@mjhlifesciences.com.
The work billers and coders do for a medical practice plays a large role in its survival. Coders and billers are tasked with translating care delivered by medical professionals into billable services, using a complex system of CPT, ICD-10 and HCPCS codes — all while maintaining compliance with evolving insurance industry regulations.

Because of the tediousness of the job, coding and billing mistakes in medical practices are common. However, when a miscoded procedure is the result of substantial negligence or fraud, it can be detrimental to a medical practice or physician. That is why it is vital for medical practices to establish robust oversight, audit and remediation procedures that work to ensure accurate coding and billing.

The reality of mitigating risk as a solo practitioner or when running a small practice often means spending less time with patients and more time completing management tasks like coding and billing. In many private practices, the doctor is solely responsible for selecting codes at the time the note is complete, based on documentation of the visit in a paper chart or through an electronic health record (EHR). In some health care systems and hospital groups, all the coding is performed by a certified medical coder. Other times, the provider codes the service and the coder then verifies or recodes it.

Although it is clear that various methods of coding and billing can involve multiple individuals who prepare and submit claims, doctors should know that liability ultimately falls to the provider whose National Provider Identifier number the service was billed under, and a physician’s signature on a claim attests that the medical services provided were necessary and reasonable. Because physicians are responsible for ensuring that submitted claims accurately reflect the services they provided, they need to take an active role in their practice’s coding and billing processes.

Many medical coding and billing errors are not malicious but are attributable to incorrect patient information, duplicate billing, unclear claim numbers, wrong codes and poor documentation. Although it is not common for simple errors to escalate to the level of fraud, physicians can establish processes and policies that help them manage that risk.

I have a gastroenterologist client who codes 95% of the services she performs herself but will flag an encounter through EHR to be inspected by her coder when the procedure is an infrequent one. The coder and my client use their combined expertise to move forward together with complete transparency to decide which codes should be billed.

Another of my clients, an old-school cardiologist, relies mainly on dictation for his medical charting and coding. To ensure he is providing enough detail to his coders, he dictates the amount of face-to-face time spent with the patient; the details of any chief complaints; review of systems, history of present illness, past medical, family and social history, and physical examinations; clearly stated treatment plans; and accurate details. Using this system, he feels confident he can accurately back up any details for claims that are called into question.

In contrast to medical coding and billing errors, medical fraud occurs when a false claim misrepresenting the facts is intentionally submitted to insurance to receive payment. Although most physicians oppose outright fraud, some still unknowingly participate in behaviors or systems that inflate health care costs.
The case of Michael Stevens, M.D., is an example of worst-case scenario when fraud affects medical billing and code. An anesthesiologist and owner of a pain management clinic, Stevens was forced to surrender his medical license when it was found that his medical biller was committing fraud. The biller, Edward Bailey — a family member with no experience or expertise in medical billing — had met with a Medicare contract provider to seek guidance on which CPT codes to use for a new treatment the practice had started to provide. Soon, claims that had previously been denied by payers started to come back approved.

However, when the state licensure board began investigating Stevens, they noticed that the practice routinely billed the same five CPT codes for the treatment, one of which was for a neuromuscular junction test that was likely never performed. It turned out that Bailey had taken it upon himself to find the combination of CPT codes that would ensure payment for the new treatment, whether those services were performed or not.

When questioned, Stevens admitted that he did not review the claims that his biller submitted and that he was not aware of the specific CPT codes that were being billed on the claims. Stevens said he believed that Bailey was using the correct CPT codes as directed by the Medicare contract provider. Although Bailey pleaded guilty to health care fraud and conspiring to defraud health care benefit programs in connection with the false or fraudulent claims submitted for the CPT code in question, the Kentucky Board of Medical Licensure eventually concluded that Stevens engaged in “dishonorable, unethical or unprofessional conduct” and he relinquished his medical license, effectively ending his medical career.

Several government entities are involved in detecting and overseeing cases of medical abuse and fraud, including the Department of Health and Human Services, the Office of Inspector General, the Centers for Medicare & Medicaid Services, and the Department of Justice, which negotiated $2.3 billion in judgments relating to health care fraud and abuse in 2018, including 1,139 criminal fraud investigations.

The False Claims Act imposes liability on anyone who knowingly presents or causes to be presented a false or fraudulent claim for payment, or who conspires to submit a false claim for payment. Statute 31 U.S.C. § 3729 (b) defines “knowingly” as:

■ Having actual knowledge of the information.
■ Acting in deliberate ignorance of the truth or falsity of the information.
■ Acting in reckless disregard of the truth or falsity of the information with no proof of specific intent to defraud required.

To reduce risk, doctors need to provide oversight of the billing and coding processes of their practices, whether they hire a credentialed in-house coder or choose to outsource the process. At a minimum, in-house coders, billers and providers should be trained annually on updates to CPT codes and other regulatory changes. Coders should also feel empowered to ask providers about anything they identify as questionable before billing to payers and meet with providers regularly to provide feedback and identify risks.

When outsourcing your practice’s coding and billing services, it is critical that the service carry errors/omissions insurance and liability coverage, which will pay for breach disclosure communications and lawsuits in the event of a security breach involving patient records. Whether coding and billing are kept in house or outsourced, physicians can always submit reports to their certified public accountants to check for transparency and accuracy and hire additional qualified professionals to perform independent audits.

Max Schloemann is a 12-year medical insurance industry veteran and the founder of MEDPLI, a national medical malpractice insurance brokerage. The company’s clients include over 200 doctors and surgeons, as well as physician assistants, nurse practitioners and health care entrepreneurs.

## The 5 Kinds of Fraudulent Medical Billing to Avoid

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<tr>
<th>Kind of Fraudulent Billing</th>
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<td><strong>Total Neglect or No Services Provided:</strong></td>
<td>Billing for services that were not provided to the patient</td>
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<tr>
<td><strong>Worthless Services:</strong></td>
<td>Ordering a service that had no medical value</td>
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<tr>
<td><strong>Inadequate Services:</strong></td>
<td>Submitting a claim for a procedure without completing one of the necessary components</td>
</tr>
<tr>
<td><strong>Unnecessary Services:</strong></td>
<td>Ordering unnecessary tests or medical services to increase a practice’s profit margin through reimbursement</td>
</tr>
<tr>
<td><strong>Improper Coding:</strong></td>
<td>Including upcoding (reporting a higher level of service than what is supported) and unbundling (reporting more CPT codes than necessary to increase payment)</td>
</tr>
</tbody>
</table>

## Improper Coding

### Categories of Improper Coding

- **Upcoding:** Reporting a higher level of service than what is supported.
- **Unbundling:** Reporting more CPT codes than necessary to increase payment.

### Common Examples of Upcoding and Unbundling

- **Examples of Upcoding:**
  - Billing for a procedure that was actually a simpler one.
  - Billing for a more expensive procedure without medical justification.
- **Examples of Unbundling:**
  - Billing for a single service as multiple services.
  - Billing for individual components of a bundled service as separate services.

### Legal Implications

- **Penalties:**
  - Fines or imprisonment.
  - Repeal of Medicare billing privileges.
  - Loss of medical license.

### Compliance Measures

- **Medical Reimbursement:**
  - Implementing system for claims review and payment through the use of algorithms.
  - Monitoring medical records for suspicious billing patterns.
- **Negotiation:**
  - Reviewing and negotiating settlements with payers for improper billing practices.
- **Cost Savings:**
  - Reducing overall costs through compliance with coding and billing regulations.

### Conclusion

Proper medical billing and coding compliance is essential to protect both patients and healthcare providers from fraudulent practices and the legal consequences that come with them. By adhering to best practices and staying informed about evolving regulations, healthcare providers can ensure their practices remain compliant and financially secure.
A proud partner of Medical Economics®, Practical Cardiology™ is an online resource for cardiologists, nurse practitioners, primary care providers, and other health care professionals to rely on as they navigate the complex, evolving landscape of cardiovascular care. Our editorial content highlights clinical data and medical policy issues as well as guideline updates, case studies, advances in diagnostics, and best practices.
Mandating COVID-19 vaccines for employees? Not as safe as it sounds

COVID-19 vaccines are now widely available but while that may relieve some health care workers, there are others who still have their reservations. Their employers, on the other hand, often feel it’s in their best interest that as many of their employees as possible get vaccinated.

The question for these employers has become: “Should I make vaccines mandatory?”

The trouble with mandating or incentivizing the vaccine

The U.S. government is making a big push for as many people as possible to get vaccinated as possible. Cases are on the rise again, a result of the COVID-19 Delta Variant spreading in the United States. If cases continue to rise, it could put further strain on medical clinics and hospitals. But while the threat to essential health care workers is still very real, making COVID-19 vaccines mandatory may come with risks to the employer.

There are a number of reasons why employees may be hesitant or refuse to get vaccinated. They may be immunocompromised, pregnant, or have other pre-existing health conditions that cause their doctors to recommend they avoid the vaccine. Some may be wary of getting a vaccine that isn’t fully FDA-approved. Others may have strong religious reasons for not getting vaccinated.

There are multiple laws that could be violated if employers aren’t cautious, such as the Americans with Disabilities Act (ADA), Title VII of the Civil Rights Act, the Age Discrimination in Employment Act (ADEA), and certain privacy laws.

Employers could also invite further risks to their organizations if, instead of mandating the vaccine, they attempt to incentivize employees to get vaccinated. It’s important to consider whether such incentives can be provided in a consistent and fair manner. For example, the Americans with Disability Act and the Civil Rights Act require that reasonable accommodations be provided — including the eligibility for any incentives without receiving the vaccine — and that protected employees have an opportunity to engage in the interactive process. The potential for legal liability should be carefully considered by employers when creating policies and programs.

What the law says

The U.S. Equal Employment Opportunity Commission provides extensive advice on how to maintain compliance with the various laws governing employees’ rights. It reports that under the ADA, Title VII, and other federal employment nondiscrimination laws, employers can require all employees who enter their work premises to be vaccinated for COVID-19. However, this mandate is subject to the reasonable accommodation provisions of various laws and other equal employment opportunity (EEO) considerations.

“In some circumstances, Title VII and the ADA require an employer to provide reasonable accommodations for employees who — because of a disability or a sincerely held religious belief, practice, or observance — do not get vaccinated for COVID-19, unless providing an accommodation would pose an undue hardship on the operation of the employer’s business,” the EEOC report states.

“Employers should keep in mind that because some individuals or demographic groups may face greater barriers to receiving a COVID-19 vaccination than others, some employees may be more likely to be negatively impacted by a vaccination requirement.”

It’s important to note, too, that some states have passed laws in recent months that restrict employers from requesting or requiring employees to share proof they received a vaccine. Other states are considering similar legislation. Further, court cases are now in process and additional ones will likely follow that will provide greater clarity around the parameters and guidelines in this area. All employers would be wise to follow these developments and consult their legal counsel regarding the latest legislation and court rulings.

48% of adult patients in the United States are fully vaccinated against COVID-19.

Latest data as of July 13, 2021.

Medical Economics.com
Important considerations
If an employer is considering mandating or strongly recommending the vaccine because it employs high-risk frontline workers, it is critical that regardless of vaccine status, safe workplace requirements and/or reasonable accommodations be in place and consistently administered. These accommodations can include:

- Requiring and providing masks, face shields, and any necessary personal protective equipment (PPE).
- Symptom and/or temperature checks.
- Social distancing from coworkers, patients, and other non-employees.
- Disinfecting shared workspaces and equipment.
- Modifying shifts whenever possible to reduce the employee’s exposure to others.
- Periodic COVID-19 testing.
- Reassignment of duties if necessary.
- Flexibility to telework if possible.

Here is a real-world example of how one employer, a palliative care hospice provider, accommodated a pregnant registered nurse (RN), who refused to be vaccinated and who claimed she could not safely perform her duties due to potential exposure to COVID-19 when administering care to patients:

1. The RN refused to obtain a vaccine and provide direct care to patients that were displaying COVID-19 symptoms.
2. The employer, in partnership with its HR representative, engaged in the interactive process to determine what reasonable accommodations would be needed to assist the employee.
3. The RN provided appropriate documentation from her physician related to her high-risk pregnancy requiring she avoid the vaccine in addition to direct patient care.
4. The employer and HR representative created a reasonable accommodation that would allow the RN to work from her home by performing triage calls; scheduling shifts for licensed practical nurses (LPNs); and performing other telework duties for a determined period of time, which was mutually beneficial to the employee, staff, and employer.

Accommodations need not be expensive or overly burdensome for the employer. Leveraging the skills of an HR expert can help employers determine creative and agreeable alternative solutions that also promote positive morale and safety while preventing legal complications. Each potential accommodation situation is unique and should be reviewed independently. Employers who consult with their HR team and, when needed, legal counsel, will help ensure a proper assessment and better outcome.

Communication is critical
To avoid the risks that come with mandating vaccines, employers should focus on increasing their communications with employees. Implement a COVID safe workplace policy that stays on top of best-practice safety and health guidance from the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA). Clearly articulate expectations for employees, highlighting the steps the organization is taking to ensure that employee safety and protection is a priority.

Employers can work with their human resources and internal communications teams to share key messages with updated information about:

- The different vaccines available.
- Potential benefits and risks associated with each of the available vaccines.
- How getting vaccinated can protect employees, their families, their vulnerable patients, and their entire communities.

Leave the door open for employees to voice their concerns about getting vaccinated or using personal protective equipment (PPE), and then provide answers to their frequent questions and publish them somewhere accessible to employees.

The CDC offers a number of resources to help organizations communicate with essential workers about the COVID-19 vaccine, including a customizable email template, a newsletter article template, a COVID-19 Vaccine Basics PowerPoint slide deck, a myth vs. fact vaccine FAQ, and more.

Constantly evolving laws in a high-risk industry make it imperative that every organization remain up to speed with the latest CDC and OSHA recommendations. Seek assistance from HR advisers and legal counsel to navigate the law and determine whether a vaccine mandate or incentive is the right course ahead.

Jacqueline Trujillo is a client success manager for G&A Partners, a leading professional employer organization that has been helping entrepreneurs grow their businesses for more than 25 years. She currently serves several clients in the health care industry from her office in Arizona. Send your legal questions to medec@mjhlifesciences.com.
Preventing your practice for an efficient flu season

How medical practices can create effective vaccination programs for the months ahead

by Keith Loria Contributing Author

The combined effectiveness of vaccinations, masking, social distancing, handwashing, and surface cleaning nearly eliminated flu as a significant health threat this year. Will that mean people will be less concerned about flu this coming season?

There has been considerable speculation that after what the country has gone through with the COVID-19 pandemic, the population could be vulnerable to a flu epidemic this winter because people haven’t been as concerned about getting their flu shots.

However, following the vaccine rollout for COVID-19, much of what was done could be extended to a flu vaccination program, helping a greater percentage of the population.

Family medicine practitioner Benjamin Caplan, M.D., founder and chief medical officer of CED Clinic in Boston, notes that this year, perhaps more than in seasons past, patients have come to expect ease of access, speedy intake, quick delivery, and efficient visit wrap-ups.

“Patients have experienced the efficiency of grand-scale vaccinations that were done well,” he says. “Medical practices that lag behind in making the system accessible and simple for patients will no longer be well tolerated. Also, the world culture is much more comfortable wearing masks in public, and people understand the great benefits. I think this added comfort with masks will likely lead to reduced prevalence of airborne infections, including influenza.”

Last year, the prevalence of influenza plummeted with the presence, and associated protections, of COVID-19 preventive measures. Caplan believes that could keep people from seeking flu shots this year.

“Many people have become accustomed to the benefits of quarantined living, including the reduced likelihood of infections,” Caplan says. “I suspect that people will not be interested in becoming vaccinated because they feel like they have less contact with others. Overall, people have the impression that they are safer from common infections, although as the culture comes back into closer quarters this impression will become a false sense of safety.”
That’s why medical practices need to continue to emphasize the benefits of vaccination, especially for those in higher-risk categories.

For example, patients with comorbid concerns — such as advancing age, obesity, diabetes, heart disease, respiratory illnesses, or those for whom a serious illness could pose life-threatening risk — need to know about the severity of getting the flu.

“They should understand the very real risk of morbidity and mortality,” Caplan says. “On the other hand, after the trials of COVID-19, people also need accurate information about the risks of (side) effects, potential long-term implications of vaccination, and all of the similar facts that have become part of the public dialogue, perhaps even to the point of understanding who manufactures the vaccines and how the vaccine functions.”

Saint Anthony Amofah, M.D., chief medical officer of the Community Health of South Florida and Health Choice Network in Miami, notes several things have to happen to achieve an efficient flu vaccination program, whether at the private or community health facility level.

“First, you have to make sure that the entire staff at the practice that is implementing the flu vaccine are vaccinated and invested in the positive benefits of flu vaccinations,” he says. “The people who are promoting the flu vaccine should really believe in it in order to effectively generate enthusiasm to tap into others who may be less invested. This is one way to maximize the impact and really make a difference.”

Secondly, he notes, a truly efficient and successful flu vaccination program will use more than one path for reaching the people who will benefit from the vaccinations.

“People get their information in different ways and through different platforms and mediums,” Amofah says. “E-blasts are great for getting your message out to your patients; reaching out to media through press releases and publicizing your program is important; mass texting is another way to reach patients; and mailouts detailing the availability and importance of the vaccine can help reach the elderly (patients) who may be less inclined to addressing information from tech platforms.”

William Lang, MD, a family physician for more than 30 years and chief medical director of WorldClinic, notes all practices should make the flu vaccination a part of routine care. “For anyone not doing an acute illness visit, once this season’s flu vaccine is available, part of the exit process from the clinic should be to receive a flu vaccine,” he says.

Lang notes physicians should make flu vaccination status part of the vital signs checklist, with the question “Have you had your flu vaccine yet?” as integral to the intake process as taking blood pressure.

“The key is to create a sense that the flu vaccine is just simply something that is needed,”
he says. “Train staff in simple answers to flu vaccine concerns. Leave the big issues to providers but have approved FAQs that address the most common concerns — such as when someone says they are worried about getting the flu from the flu shot.”

**Key to profits**

Vaccination programs that are efficient and easy to use are inherently likely to gain traction and publicity. Caplan notes that if an efficient program can be linked to other services, from medical products and/or services sales or affiliate revenue streams such as advertising sales or data collection, it would be logical to expect increased profitability.

Amofah notes achieving profitability for a flu vaccination program really comes down to having many patients who have insurance coverage for the flu vaccine.

“At a community health center like ours, we really depend on insured patients who can thereby pay for the flu vaccine, in order to be able to also reach uninsured patients who are also critical to minimizing the spread of the flu,” he says. “To make a program profitable that also really positively impacts overall public health, you have to make it so efficient that it can reach the uninsured, as well. To get your margin, you want a mass effort for a mass turnout.”

Lang agrees that flu vaccines are typically not profit centers and because of that, many providers just choose to leave this to pharmacies. However, to make these visits profitable, he suggests seeing flu shots as a mechanism to reconnect with patients and identify other (perhaps more remunerative) services that are needed.

**Tips of the trade**

One way to increase the numbers of those being vaccinated for the flu is to make it as easy as possible for people. Amofah recommends setting up walk-in facilities so that patients are in and out in 15 minutes.

“It’s going to be crucial for practices to stress the importance of getting the flu shot because there is nothing more confusing for a health professional than having a patient coming in with flu symptoms and we have to wonder if this is COVID-19 or the flu,” Amofah says. “Getting the flu shot really helps medical professionals and patients avoid periods of confusion about the cause of their illness.”

Primary care practices should also consider making flu vaccine expectation a central theme in any late summer/early fall communications to patients. “Many patients go to pharmacies for flu shots because the pharmacies have made it a strategic priority to make it easy for patients,” Lang says. “Going to a typical primary care clinic is not easy. Differentiate yourself from the pharmacies. A flu vaccine visit can give the opportunity to identify other preventive issues that can be identified without initial provider involvement.”

By the time the U.S. gets to flu season, most of the COVID-19 vaccinations will be behind it, so public health and other medical agencies will be able to effectively market flu vaccinations. “Educating patients on the dangers of the flu is key to maintaining a successful flu vaccine program,” Lang says, “Vaccine and respiratory protection makes a difference.”

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Learning Objectives
Upon successful completion of this activity, you should be better prepared to:
- Recognize key risk factors and diagnostic tests that could improve early symptom recognition and prognosis of the disease.
- Evaluate key data on new and emerging treatment options for SSc-ILD to properly educate patients.

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To learn more about this topic, including new insights for diagnosing SSc-ILD, emerging treatment options, and team-based strategies to improve individual care plans, go to gotoper.com/online-cme-activities/cpc/cpc-epc21

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Falls Church, VA

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CONTINUING MEDICAL EDUCATION

Follow-Up VISIT from PER®
Scleroderma, or systemic sclerosis (SSc), is a multiorgan disorder characterized by autoimmunity, systemic inflammation, vascular injury, and tissue fibrosis. Interstitial lung disease (ILD) is a common early complication of SSc and a leading cause of death in patients with SSc. The pathogenesis of SSc-ILD involves the interplay between immunologic and biologic pathways that start with tissue injury. Early and regular screening of patients at risk for the development of ILD can lead to prompt treatment, with the goal of slowing disease progression. Here are 3 things you should know about SSc-ILD.

**1. SSC-ILD diagnosis is generally based on HRCT features.**

SSc-ILD is suspected when a patient with known SSc develops dyspnea, cough, auscultatory crackles, or abnormalities on pulmonary function testing (PFT) or chest radiographs, although not all patients will have respiratory symptoms. The PFT may reveal a restrictive pattern with reduced forced vital capacity (FVC) and diffusing capacity of the lung for carbon monoxide (DLCO). However, normal lung volumes do not rule out ILD. The diagnosis of SSc-ILD is generally based on the presence of characteristic high-resolution computed tomography (HRCT) features in a patient with known SSc, when other etiologies of pulmonary parenchymal disease (eg, heart failure, drug-induced lung toxicity, or recurrent aspiration) have been excluded.

Disease features on HRCT may include a pattern consistent with nonspecific interstitial pneumonia with varying degrees of ground-glass opacities, along with coarse reticulation. A usual interstitial pneumonia pattern may also be seen. As management is not dependent on the underlying radiographic or pathologic patterns, a lung biopsy is usually not needed to confirm the diagnosis of SSc-ILD. A patulous esophagus on chest HRCT is frequently observed in patients with SSc, and microaspiration is purported to play a role in the development and progression of SSc-ILD. Increasing esophageal diameter on HRCT in patients with SSc is associated with more severe radiographic ILD, lower lung volumes, and lower DLCO percent predicted.

**2. The clinical course of SSc-ILD is heterogeneous.**

The clinical course of SSc-ILD can display varying rates of progression, which underscores the need for early systematic screening. Although there is a lack of consensus regarding which tests to use for screening and monitoring, the progression of ILD is associated with several clinical and biological factors. A recent study demonstrated that most patients experience both progressive and stable periods; 30% of patients with SSc-ILD experienced ILD progression during any 12-month period, and 67% of all patients with SSc-ILD experienced progression at any time over the mean 5-year follow-up.

**3. Approved treatments for SSc-ILD are now available.**

Of all patients with progressive SSc-ILD, only a minority showed a pattern of rapid, continuously declining FVC, with consecutive episodes of FVC decline and no periods of FVC stability or improvement. Skin fibrosis (higher modified Rodnan skin score), male sex, and the presence of reflux/dysphagia symptoms were the strongest predictors of FVC decline over time. Other predictive parameters included the presence of inflammation (higher erythrocyte sedimentation rate) and a shorter disease duration. Diffuse cutaneous SSc puts patients at risk for developing ILD early in the course of their disease. Patients with limited cutaneous SSc, in which skin sclerosis is generally restricted to the hands and feet, and to a lesser extent, the face and neck, are less likely to develop ILD early in the course of disease but may develop ILD as a late manifestation. Other risk factors for early ILD include African American ethnicity, older age at disease onset, higher skin score, and serum creatine phosphokinase levels, hypothyroidism, and cardiac involvement. Anticentromere antibodies appear to be protective against ILD, whereas the presence of anti-topoisomerase I (anti–Scl-70) antibodies increases the likelihood of ILD.

Mycophenolate mofetil and cyclophosphamide, used off-label, have been shown to stabilize
and/or improve SSc-ILD in randomized controlled trials, and they are the most used first-line immunosuppressive agents for SSc-ILD. However, the evidence in favor of these agents is not overwhelmingly positive.\textsuperscript{2} Several agents have recently received expanded indications to include SSc-ILD. Nintedanib was the first agent to receive approval to slow the rate of decline in pulmonary function in adults with SSc-ILD, based on results from the SENSCIS trial.\textsuperscript{8,14} The phase 3 randomized controlled trial included 576 patients with SSc-ILD, aged 20 to 79 years. Patients received treatment for 52 weeks, with some treated for up to 100 weeks. The annual rate of decline in FVC was lower with nintedanib than with placebo; no clinical benefit of nintedanib was observed for other manifestations of SSc.

### Recently Approved Treatments for SSc-ILD

- Nintedanib
- Tocilizumab
- Treprostinil*  

*T For treating pulmonary hypertension associated with ILD

Tocilizumab, an anti–interleukin-6 receptor antibody, is the first biologic therapy approved for slowing the rate of decline in pulmonary function in adult patients with SSc-ILD.\textsuperscript{15} The focuSSced trial evaluated tocilizumab in patients with SSc and progressive skin disease.\textsuperscript{16} Participants underwent baseline and serial spirometry along with HRCT scans at baseline and at week 48. Quantitative interstitial lung disease (QILD) and fibrosis scores were assessed by computer software. QILD was classified into the following categories of lung involvement: mild (>5% to 10%); moderate (>10% to 20%); and severe (>20%). Of 210 participants, 136 (65%) had ILD. Most of these patients (77%) had moderate-to-severe involvement (defined as >10% lung involvement). Results demonstrated that tocilizumab stabilized FVC percentage over 48 weeks in patients with early SSc-ILD and progressive skin disease. This was independent of the extent of radiographically evident QILD.

One of the major causes of morbidity and mortality in patients with SSc is pulmonary arterial hypertension (PAH).\textsuperscript{17} Treprostinil is a prostacyclin vasodilator indicated for the treatment of PAH (WHO Group 1), to improve exercise ability. Results of the INCREASE study recently led to additional approval of inhaled treprostinil for patients with New York Heart Association Functional Class III symptoms of PAH associated with connective tissue diseases.\textsuperscript{18} The INCREASE study was a 16-week randomized, double-blind, placebo-controlled trial evaluating the use of inhaled treprostinil in patients with various forms of ILD (including SSc-ILD) and associated pulmonary hypertension (documented by right heart catheterization).\textsuperscript{19} Patients were assigned to receive inhaled treprostinil 4 times daily or placebo. Inhaled treprostinil resulted in improved exercise capacity compared with placebo over the 16 weeks of the study, as assessed by the 6-minute walk test.

Currently, there is no consensus regarding treatment initiation or escalation for SSc-ILD.\textsuperscript{20} Most SSc experts draw on their clinical experience and consider the risk factors for SSc-ILD progression to inform their decision on when to initiate therapy on a case-by-case basis.\textsuperscript{21}

“Typically, first line we use mycophenolate mofetil, sometimes in conjunction with low-dose prednisone, depending on how much alveolar infiltrates there are, to address any active inflammation. Based on the results of the INBUILD study, if patients develop evidence of progression, then they would be candidates for nintedanib. In fact, the SENSCIS study provides justiﬁcation for the implementation of nintedanib in patients [with scleroderma] in the absence of progression, provided there is evidence of at least 10% ﬁbrosis on their chest CTs.”

Steven Nathan, MD

### KEY REFERENCES


For a full list of references go to gotoper.com/go/3SSc-ILD
1. A 53-year-old woman with SSc presents for follow-up pulmonary function tests. She reports extreme fatigue at times, a nonproductive cough, and shortness of breath, even during mild activity. What will be the most likely findings on high-resolution CT scans for this patient?
   A. Pattern of usual interstitial pneumonia with honeycombing
   B. Pattern consistent with nonspecific interstitial pneumonia
   C. Middle lung, peripheral distribution
   D. Upper lung, heterogeneous distribution

2. The SENSCIS trial demonstrated which of the following in patients with SSc-ILD in the nintedanib treatment group versus those in the placebo group?
   A. Nintedanib reduced the rate of decline in forced vital capacity
   B. Patients receiving nintedanib had significantly lower modified Rodnan skin scores
   C. Patients treated with nintedanib had significantly higher 6-minute walk test scores
   D. Patients treated with nintedanib reported higher quality of life scores

3. The focuSSced trial demonstrated which of the following, when comparing patients receiving tocilizumab with those receiving placebo?
   A. Gastrointestinal adverse events were more common in patients treated with tocilizumab than in those who received the placebo
   B. Infections were more common in patients who received the placebo than in those treated with tocilizumab
   C. Tocilizumab stabilized FVC% over 48 weeks in patients with early SSc-ILD with progressive skin disease
   D. Patients receiving tocilizumab had higher Health Assessment Questionnaire–Disability Index scores than those receiving the placebo

To learn more about this topic, including new insights for diagnosing SSc-ILD, emerging treatment options, and team-based strategies to improve individual care plans, go to gotoper.com/online-cme-activities/cpc/cpc-epc21
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<td>23.5</td>
<td>25</td>
<td>Glass</td>
<td>2,541.00</td>
</tr>
</tbody>
</table>

### PHARMA-LAB

Refrigerators & Freezers
From 23 to 49 Cu.ft.

<table>
<thead>
<tr>
<th>Model</th>
<th>Capacity</th>
<th>Height (in)</th>
<th>Width (in)</th>
<th>Depth (in)</th>
<th>Door Type</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARG23ML</td>
<td>23 cu.ft.</td>
<td>83.75</td>
<td>27.5</td>
<td>31</td>
<td>(1) Stainless</td>
<td>2,476.00</td>
</tr>
<tr>
<td>ARG25ML</td>
<td>25 cu.ft.</td>
<td>83.75</td>
<td>27.5</td>
<td>31</td>
<td>(1) Glass</td>
<td>2,812.00</td>
</tr>
<tr>
<td>ARG30ML</td>
<td>30 cu.ft.</td>
<td>83.75</td>
<td>27.5</td>
<td>31</td>
<td>(2) Glass</td>
<td>3,634.00</td>
</tr>
<tr>
<td>ARG40ML</td>
<td>40 cu.ft.</td>
<td>83.75</td>
<td>27.5</td>
<td>31</td>
<td>(2) Glass</td>
<td>4,299.00</td>
</tr>
</tbody>
</table>

### Choosing the Right Sized Unit

Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

1. Multiply (max inventory) with the minimum cubic feet needed to safely store your vaccine.

### Maximum Doses

<table>
<thead>
<tr>
<th>Refrigerator</th>
<th>Max. Doses Minimum Cubic Ft.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**For product application suggestions or recommendations please feel free to contact our product specialists to discuss your options at:**

**Medical Device Depot**

www.medicaldevicedepot.com
MEDICAL EQUIPMENT

Bionet CardioCare 2000: $1,255.00
Schiller AT-2 Plus: $2,626.00
*Bundled Spirometry: $499.00
Durick JL 230C: $4,988.60
Wohn A215 M/SD: $3,415.00

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jshippoli@mjhlifesciences.com

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— Mark J. Nelson, MD FACC, MPH

Joanna Shippoli
Advertising
(440) 895-2615
jshippoli@mjhlifesciences.com

August 2021
MEDICAL EQUIPMENT

3 WAYS TO START IMMEDIATELY INCREASING REVENUE

1 Neuro-Cognitive Testing
- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
- Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
- Reimburses using 6 CPT codes:
  - National Average = $750 - $1000 per test
  - Each test is processed into a fully-finished, clinically actionable report
  - Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

2 ANS Testing
(can be combined with SUDOMOTOR into 1 full system)
- Takes less than 10 minutes to perform, software provides verbal cues
- Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
- Reimburses $170/test using 3 CPT codes
- Provides a 1 page summary up to a full 24 page comprehensive report

3 SudoMotor Testing
(can be combined with ANS into 1 full system)
- Takes 3 minutes to analyze a patients’ hands and feet
- Provides a 1 page summary report
- Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
- Reimburses $130/test (national average)

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ejshippoli@mjlifesciences.com

Medical Economics
AN MH Life Sciences Brand
SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

Limitations of Use:
• SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE AND ADMINISTRATION

2.1 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store reconstituted between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule: A first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX [see Description (11) of full prescribing information].

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

5.2 Guillain-Barré Syndrome (GBS)

In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with SHINGRIX [see Adverse Reactions (6.2)].

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Overall, 17,041 adults aged 50 years and older received at least 1 dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (24.9%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects were aged 60 to 69 years, and 17,531 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.2%), and gastrointestinal symptoms (17.3%), respectively.

The reported frequencies of specific solicited local adverse reactions and general adverse events (overall per subject), by age group, from the 2 studies are presented in Table 1.

Table 1. Percentage of Subjects with Solicited Local Adverse Reactions and General Adverse Events within 7 Days* of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Older (Total Vaccinated Cohort with 7-Day Diary Card)

<table>
<thead>
<tr>
<th>Local Adverse Reactions</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHINGRIX %</td>
<td>Placebo%</td>
<td>SHINGRIX %</td>
<td>Placebo%</td>
</tr>
<tr>
<td>Pain</td>
<td>88.4</td>
<td>14.4</td>
<td>82.8</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10.3</td>
<td>0.5</td>
<td>6.9</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7</td>
<td>1.2</td>
<td>38.4</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>2.8</td>
<td>0.0</td>
<td>2.6</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5</td>
<td>0.8</td>
<td>26.5</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1</td>
<td>0.0</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).

* 7 days included day of vaccination and the subsequent 6 days.

b Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.

c Placebo was a saline solution.

d Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.

Grade 3 myalgia, fatigue, headache, shivering, GI: Defined as preventing normal activity.

f Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as >39.0°C/102.2°F.

g GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

The incidence of solicited local and general symptoms was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The majority of solicited local adverse reactions and general adverse events seen with SHINGRIX had a median duration of 2 to 3 days.

There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 13.8%, respectively). Grade 3 solicited general adverse events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and (continued on next page)
Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX and placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.1%) from the first administered dose up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (<0.01%) reported lymphadenitis and 1 subject (<0.01%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo; available information is insufficient to determine a causal relationship with SHINGRIX.

Deaths

From the first administered dose up to 30 days post last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. From the first administered dose up to 1 year post last vaccination, deaths were reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

Potential Immune-Mediated Diseases

In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

Dosing Schedule

In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

General Disorders and Administration Site Conditions

Decreased mobility of the injected arm which may persist for 1 or more weeks.

Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

Nervous System Disorders

Guillain-Barré syndrome.

Postmarketing Observational Study of the Risk of Guillain-Barré Syndrome following Vaccination with SHINGRIX

The association between vaccination with SHINGRIX and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare claims data, from October 2017 through February 2020, vaccinations with SHINGRIX among beneficiaries were identified through National Drug Codes, and potential cases of hospitalized GBS among recipients of SHINGRIX were identified through International Classification of Diseases codes.

The risk of GBS following vaccination with SHINGRIX was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with SHINGRIX, with an estimated 3 excess cases of GBS per million doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of SHINGRIX, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of SHINGRIX. These analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review. While the results of this observational study suggest a causal association of GBS with SHINGRIX, available evidence is insufficient to establish a causal relationship.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

For concomitant administration of SHINGRIX with inactivated influenza vaccine [see Clinical Studies (14.5) of full prescribing information].

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no available human data to establish whether there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion [see Use in Specific Populations (8.2) of full prescribing information].

8.5 Geriatric Use

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (46.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse events in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years) [see Adverse Reactions (6.1)].

17 PATIENT COUNSELING INFORMATION

- Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.
- Inform patients about the potential for adverse reactions that have been temporally associated with administration of SHINGRIX.
- Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Storage:

Store vials of Lyophilized eG Antigen and Adjuvant Suspension Components refrigerated between 2° and 8°C (36° and 46°F). Protect vials from light. Do not freeze. Discard if the vials have been frozen.

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March 2021 SHX:5BRS

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SGXJRNA210012 April 2021

Produced in USA.
NOT VACCINATING IS RISKY BUSINESS.
SO MAKE IT YOUR BUSINESS.

99.5% of people 50 years and older are infected with the varicella zoster virus¹
In 1 out of 3 people, the virus reactivates and causes shingles²³

SHINGRIX
(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

There are certain medical conditions that are normally associated with aging, but your patients might not even be aware of a potentially serious one—shingles. So make sure you talk about the risk with patients 50 years and older.

Are you making shingles prevention a priority in your practice?

See a range of potential patient types at ProfilesSHINGRIX.com

Indication
SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

Important Safety Information
• SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
• Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX
• In a postmarketing observational study, an increased risk of Guillain–Barré syndrome was observed during the 42 days following vaccination with SHINGRIX
• Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%)
• Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%)
• SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion
• Vaccination with SHINGRIX may not result in protection of all vaccine recipients


Please see Brief Summary of Prescribing Information for SHINGRIX on the previous pages.
As part of an elite group of hospitals with the highest ranking from the Society of Thoracic Surgeons (STS), the Riley Heart Center is one of the nation’s more highly respected programs for diagnosis and treatment of congenital and acquired heart conditions in children.

With consistently high volumes and a unique integrated care model, Riley at IU Health achieves exceptional patient outcomes year after year.

Explore our Specialty Programs

- **Pulmonary Hypertension Program**: Offering inpatient and outpatient consultation from a cardiologist, pulmonologist and dedicated nursing team who are actively engaged in collaborative research with other centers to improve care quality, shape practice and elevate the standard of care.

- **The Fetal Cardiology Program**: Offers in-depth diagnostic imaging and counseling during pregnancy to enable thorough evaluation and development of a care plan.

- **The Home Monitoring Program**: Designed for babies with complex physiology discharged after initial intervention to digitally assist parents in tracking wellness and enable cardiologists to evaluate data in real time.

- **The Cardiovascular Genetics Program**: Includes 5 multidisciplinary clinics with cardiology spanning the spectrum of genetic and inherited conditions, providing family-based care leading to earlier diagnosis of at-risk individuals and earlier medical intervention to improve outcomes.

- **The Adult Congenital Heart Disease (ACHD) Program**: Through our partnership with the Adult Cardiovascular team at IU Health, we provide the only formalized comprehensive program in Indiana for patients as they enter adulthood and plan for their lifelong cardiovascular care journey.

To refer a patient to the Riley Heart Center or for more information about the program, visit [rileychildrens.org/heart](http://rileychildrens.org/heart)

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Indiana University Health
Partner with a **national leader** for your most complex pediatric heart patients.

**Delivering Nationally Ranked Pediatric Cardiovascular Care**

From fetal diagnoses to complex surgical interventions, our cardiac-dedicated specialists deliver care for the most complex, but also the most common, conditions patients experience. The care team within the Riley Heart Center includes pediatric cardiologists, cardiac intensivists, cardiac anesthesiologists and neonatologists.

**Committed to a Unique Continuum of Care**

As an internationally recognized program for complex heart care, Riley Children’s Health provides a depth and a breadth of pediatric cardiovascular care with expertise and options not available everywhere. Our integrated continuum care model focuses on promoting excellent sub-specialty care coordination with a re-imagined approach to cardiac intensive care, including inpatient navigation and home monitoring.

With world-class facilities and the latest technology, Riley Heart Center experts provide the full continuum of care from fetuses and premature babies to adults with congenital heart disease, including:

- A cardiovascular intensive care unit with a team of intensive care doctors and nurses who monitor patients 24/7, reacting quickly to changes during critical care and healing.
- A specialty-trained team of advanced providers, nursing staff and navigators dedicated to our cardiac patients and families, keeping the care team and patient’s local physicians connected.
- A consulting team of more than 40 pediatric-trained specialties working alongside the Heart Center team.

To refer a patient to the Riley Heart Center or for more information about the program, visit **rileychildrens.org/heart**