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- The future of telehealth payment
- What’s next for value-based contracts?

Plus

- Careers
  Cures for the jaded doctor

- Practice Management
  Coding audits 101: What physicians need to know

- Tech
  The road to a better EHR

- Legal
  Will your employee handbook get you in trouble?
MAKE THEIR SHINGLES RISK YOUR RESPONSIBILITY

99.5% OF PEOPLE 50 YEARS AND OLDER ARE INFECTED WITH THE VARICELLA ZOSTER VIRUS
IN 1 OUT OF 3 PEOPLE, THE VIRUS REACTIVATES AND CAUSES SHINGLES

SHINGRIX (ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

99.5%

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
- Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
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. And if they’re over 50 years of age, the risk is real. Take a closer look to learn more about the risk of shingles:

50+ YEARS

99.5% of people ≥50 years of age are infected with the varicella zoster virus

In 1 out of 3 people, the virus reactivates and causes shingles

Shingles—a blistering rash that can be excruciatingly painful

It’s time to prioritize shingles in your practice—are you considering your patients 50 years and older for vaccination with SHINGRIX?

Important Safety Information (cont’d)

• Solicited local adverse reactions reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%)
• Solicited general adverse reactions reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%)
• The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women
• It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfeeding infant or on 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 following pages.


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Produced in USA.
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 (HZ) (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

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated 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 2 to 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)].

5.3 Syncope

Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

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.

Adults Aged 50 Years and Older

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 (25%) subjects were aged 50 to 59 years, 4,488 (15%) subjects were aged 60 to 69 years, and 17,531 (60%) 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%), followed by Asian (16%), Black (1.4%), and other racial/ethnic groups (8%); 58% were female.

Solicited Adverse Reactions: In Studies 1 and 2, data on solicited local and general adverse reactions were collected using standardized diaries 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 and general adverse reaction following administration of SHINGRIX (both doses combined) were pain (78%), redness (38%), and swelling (26%); and myalgia (49%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

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

Table 1. Percentage of Subjects with Solicited Local and General Adverse Reactions 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>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></td>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
</tr>
<tr>
<td></td>
<td>n=1,311 %</td>
<td>n=1,312 %</td>
<td>n=1,311 %</td>
</tr>
<tr>
<td>Local Adverse Reactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>88</td>
<td>14</td>
<td>83</td>
</tr>
<tr>
<td>Grade 3</td>
<td>10</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Redness</td>
<td>39</td>
<td>1</td>
<td>38</td>
</tr>
<tr>
<td>Grade 3</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Swelling</td>
<td>31</td>
<td>1</td>
<td>27</td>
</tr>
<tr>
<td>Grade 3</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>General Adverse Reactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td>57</td>
<td>15</td>
<td>49</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>9</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57</td>
<td>20</td>
<td>46</td>
</tr>
<tr>
<td>Fatigue, Grade 3</td>
<td>9</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Headache</td>
<td>51</td>
<td>22</td>
<td>40</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>6</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Shivering</td>
<td>36</td>
<td>7</td>
<td>30</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>7</td>
<td>0.2</td>
<td>5</td>
</tr>
<tr>
<td>Fever</td>
<td>28</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
<td>1</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

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

* 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.

a Placebo was a saline solution.

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

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

® 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.

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

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

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

(continued on next page)
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% and 21%, respectively) compared with Dose 1 (24% and 14%, respectively). Grade 3 solicited general adverse reactions (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3%, 4%, and 4%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

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 51% and 39% of subjects who received SHINGRIX (n = 14,645) or 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 (4% 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 0.6%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX or 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%) or placebo (2.2%) from the first administered dose up to 30 days post-last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and 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 exacerbations 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.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation
Risk Summary
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
Adults Aged 60 Years and Older
Of the total number of subjects who received at least 1 dose of SHINGRIX in Studies 1 and 2 (n = 14,645), 2,243 (15%) were aged 60 to 69 years, 8,837 (47%) were aged 70 to 79 years, and 1,921 (13%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse reactions 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).

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July 2021 SHX:6BRS

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Produced in USA.
Focusing on your money in 2022

Physicians are pulled in every direction these days, and the challenges of patient care and running a practice seem to multiply with each passing year. 2022 will be no different. Reimbursement, revenue, income — these are all important aspects of being a physician, even if patient care is the reason most physicians answer the call. And this issue of Medical Economics® focuses on how physicians can grow revenue and personal wealth. Here’s a sample of our coverage this month:

- Our cover story analyzes and anticipates the payment challenges physicians could experience this year and takes a big-picture look at recent policy moves, and reimbursement trends when it comes to both Medicare and private payers.

- We won’t neglect personal finance coverage. Medical Economics® is pleased to announce a partnership with Seeking Alpha, the largest crowd-sourced investment community in the world, in which we will share some of their great investing and financial content in the pages of this magazine. In return, Seeking Alpha has agreed to a nice subscription discount for exclusive for Medical Economics® readers. Learn more on page 12.

- This month’s installment of Physicians Financial News looks at equity trends in 2022. Our columnist, Dave S. Gilreath, CFP, examines what kind of investment environment physicians can expect.

In addition to this financial coverage and more, we’re also examining ways physicians can take stock in the joys of practicing medicine. Burnout is rampant, and as author Rebekah Bernard, M.D., terms it, many are feeling “jaded” with the practice of medicine. Her column this month takes a long look at what physicians can do about these feelings.

As always, we love feedback on how we’re doing. If you have story ideas, or thoughts on our coverage, please reach out to our content team at medec@mjhlifesciences.com. =

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It’s time to bring competition back to health care

Cost increases are not the result of overutilization, but rather, legalized kickback schemes.

Drug costs in the United States are regulated in an unusual way among industrialized countries: hardly at all.

The United States is exceptional in that it does not regulate or negotiate the prices of new prescription drugs when they come onto market. Some commentators argue that in a free market, it is not the role of government to do this. But we don’t have a free market. If one considers the essential elements of a free market, we’re not even close when it comes to health care. We need Medicare to use its group purchasing power to restrain drug prices, but we can’t seem to get that done, which is ironic because our antitrust laws seem to favor group (consolidated) purchasing.

Others argue that if we did lower drug prices, we would be making a trade-off. Lowering drug profits, they say, would make pharmaceuticals a less desirable industry for investors. And less investment in drugs would mean less research toward new and innovative cures. But many, if not most, new drugs developed have had the benefit of government grant funding (at taxpayer expense). Plenty of money could still be made in the pharmaceutical industry if it were subject to reasonable regulation. If our government approached cancer, heart disease and dementia with the same truncated timelines and sense of urgency as COVID-19, there would be great innovation and profits.

Vertical integration

Vertical integration now dominates our health system. Physician practices are acquired by hospitals, hospitals are acquired by health systems, health systems “align” themselves with one of an ever-decreasing number of insurance companies and now the insurers are being acquired by national drugstore chains.

When vertical integration is achieved through internal expansion, it is generally allowed by antitrust laws. However, it may not be allowed when vertical integration is achieved through mergers, or perhaps “partnering,” and unduly harms competition in the marketplace.

The courts make these decisions by weighing the competitive and anti-competitive factors associated with the vertical integration on a case-by-case basis — but only if such cases are brought forth, say, by Department of Justice (DOJ). If I were a sitting U.S. senator of the party in power, I wouldn’t be making phone calls to drug company executives. I would be talking to the DOJ.

Drug costs

We have allowed our health care system to fall victim to a highly consolidated group of pharmacy benefit managers. These organizations control drug pricing using formulary inclusion fees and other bizarre techniques that we permit to the detriment of those who need life-enhancing or lifesaving medications. We also permit the acquisition of patent rights to orphan drugs (important drugs that don’t have a large market) by venture capitalists who corner the market and raise prices to very high levels — because that’s the point of cornering the market. Such conduct may or may not be illegal, but it certainly is immoral.

As a resident of Minnesota, I recently saw our own U.S. Senator Amy Klobuchar on television discussing her new book “Antitrust.” Because the senator has long been an outspoken critic of price gouging and other anomalies in our health care system and because I have spent the past 40 years as a health care attorney and lobbyist, I decided to read her book, share my perspective on some of the health care issues it raises and suggest some possible solutions.

David Feinwachs, J.D., Ph.D., M.H.A., M.A.

February 2022
Monopsony
In a monopsony, a market has few sellers; in a monopsony, a market has few buyers.

Our health care system has antitrust problems, but monopoly is not at the top of the list. Rather, the problem is monopsony.

Senator Klobuchar herself introduced the Consolidation Prevention and Competition Promotion Act, which would insert “or a monopsony” after every instance of the term “monopoly” in section seven of the Clayton Antitrust Act. The Federal Trade Commission has held public hearings to discuss the topic.

Despite recent interest in monopsony, the lack of case law on the topic means that antitrust agencies may well have a more difficult time advancing cases based on buyer power than seller power. Perhaps that’s why the business strategies in health care embrace the monopsony concept.

There are those who argue that monopsony is only an issue if it ultimately causes consumers to pay higher prices. Others argue the activities that create a monopsony (whether by merger or agreement) are, or should be, unlawful.

Either way, we need to do something. For example, at the state level, we could repeal certificate of need (CON) laws. These little anti-competitive gems prevent doctors or anyone else from building new hospitals. The original justification was to control health care costs, increase health care quality and improve access to care for people with low incomes, along with the desire to protect our current hospitals from competitive forces to ensure their survival; and if we had more hospitals, sick people would just use them and drive up the cost of health care. The CON strategy was first adopted in 1974.

In my opinion, the use of CON has been a complete failure in every aspect of its original intentions. Someone once said, “The road to hell is paved with good intentions.” Never in medicine has this been more true than now. With hospitals full and turning away patients (not just COVID-19 patients) and insurance companies being acquired by national drugstore chains, people are beginning to realize that health care cost increases are not the result of overutilization, but rather, legalized kickback schemes. Without fair and effective government oversight, this death spiral can be expected to continue. Large corporate systems acquire small, outdated facilities, not to improve them, but to close them and drive patients to regional centers for system financial gain.

Currently, 35 states have CON laws; 24 states have repealed these laws. CON has increased health care costs in the states that have retained this failed relic of the past.

It’s time to bring competition back to health care while regulating anti-competitive practices and price gouging. The repeal of this outdated, failed and ill-conceived hospital construction moratorium law would be a good start.

Nonprofit hospitals don’t need this kind of protection. They pay no property or income tax, and they provide little or no real charity (unless you count their write-off of bad debt after they have forced patients into bankruptcy or their nonsensical claims of “community benefit,” which is a fabricated term that has no real meaning).

For-profit organizations use this state-sponsored franchise mechanism to enrich themselves but, more importantly, to assure that an industrial-engineering approach to medical care will replace M.D. physicians with mid-level practitioners, technicians and other non-M.D. “providers.” All this is occurring without patient knowledge or consent, partly because of deception (the increased prevalence and allowed use of the title doctor by non-M.D.s) and partly because of the system consolidation factors discussed previously. Everyone talks about patient choice and involvement in their own care, but what could be more basic than choosing who will treat you?

The time has come for patient rights legislation to require the disclosure of the “doctor’s” credentials. The time has long passed for many to get off their high horse and acknowledge the need and desirability for things like “any willing provider legislation” to give patients choice and access to doctors of their choosing.

Where do we go from here?
So now let’s try something different. Let’s give these vertically integrated monopsonies a little competition. It’s time to stop protecting those who price gouge and those who claim to be charitable but are the leading cause of bankruptcy.

Doctors and technology are not the cost drivers in our convoluted system. The problem is the system itself, coupled with the lack of any meaningful oversight. If you’re waiting for what remains of medical association advocacy and state licensure boards to take action, you’re in for a long wait.

It’s time to do something else. Dumping CON would be a good start.

David Feinwachs, J.D., Ph.D., M.H.A., M.A., is a health care attorney and lobbyist in St. Paul, Minnesota. He was general counsel for the Minnesota Hospital Association and Aging Services of Minnesota from 1998 until 2010. He was a senior lecturer at the University of Minnesota’s Carlson School of Management and School of Public Health.
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4 trends informing equity purchases in 2022

BY DAVE S. GILREATH, CFP

Individual investors often approach stock purchases with trepidation. But you can ease these fears by assessing trends likely to affect sectors, companies and funds.

January is a good time to sell shares to raise cash for purchases because of the timing of tax liability from capital gains. Taking gains in January means the tax on them won’t be due for 15 months. This is the flip side of selling shares of losers late in the year to get the deduction on losses the following April, known as loss harvesting. If you didn’t harvest losses in 2021, don’t kick yourself; just resolve to do it next December. (All this assumes that the shares are in a taxable account, rather than a tax-deferred account such as a 401[k] or an IRA.)

The next step in the portfolio rebalancing process is deciding what to buy, a discipline that involves factors such as sector and industry predictions, your view of the market’s direction, a stock’s fundamentals, your ultimate goals and your time horizon for starting withdrawals (for most people, the amount of time until retirement). Unless your risk tolerance is fairly high, the current, highly appreciated market may mean it’s a good time to focus on lower-risk value stocks — those that have good fundamentals but are widely unloved. If recent indications prove prescient, value stocks — especially small-cap value — may be getting more love this year.

To avoid looking for love in all the wrong places, it helps to identify trends that will likely affect a stock. This is only one tool among many, and all we know for certain, of course, is what’s happening now. Yet this consideration can significantly inform buying decisions. Here are a few trends to consider:

**Interest rate increases.**

The financial media obsesses over Federal Reserve rate increases as though a resulting stock market decline is a foregone conclusion. And now that the Fed is projecting three rate increases this year, market coverage based on this obsession is constantly in our faces. Yet, if history is any guide, the talking heads have it all wrong. Following the first increase in the eight Fed rate-hike cycles since 1983, and in the three-month periods before the first increase, the index was up an average of 5.1%. The second increase has often been followed by market gains in ensuing months, so it usually hasn’t been a bad idea to buy on dips after the first two rate hikes. Dips following the third hike in a series have been another matter; buying on them generally isn’t advisable.

**Infrastructure growth, both private and public.**

Some industrial stocks in the infrastructure subsector have done quite well from private projects during the past 18 months or so, and the category benefits from the legislation already be priced in? Not necessarily. Although the market is usually forward looking, it sometimes has the patience of an adolescent. And, preferring big-tech growth stocks, many investors aren’t turned on by unsexy industrials. Ironically, some of these companies are surprisingly techy. An example is Caterpillar (CAT), which manufactures autonomous earth-moving vehicles. As of late December, CAT shares had risen about 50% since mid-August of 2020. Which companies will ultimately benefit substantially from the coming surge in federal infrastructure spending isn’t clear, but investors can reduce risk by buying targeted exchange-traded funds (ETFs).
For example, holdings of Global X U.S. Infrastructure Development ETF (PAVE), which grew more than 50% in 2021 from mid-January to late December, include manufacturers of construction equipment and materials used in road, bridge and rail construction. Why invest in prospectors when you can invest in the picks and shovels they need?

Continuing inflation. The Fed seems confident that the high inflation they underestimated during most of 2021, which reached a 30-year high in November of 6.8% (annualized), will simmer down this year. However, some large financial firms’ projections are well above the Fed’s, and some of them expect inflation to get worse this winter before it gets better. Inflation is widely deemed a bogeyman for stocks, but there’s evidence to the contrary. Clearly, though, this is a good opportunity to buy real estate investment trusts (REITs), which can do well amid high inflation because these landlord companies can just raise rents, often through automatic escalator clauses. This renown for inflation resiliency has been attracting substantial new investment in recent months, pushing up REIT prices. However, there’s probably still room for some to rise. And well-chosen REITs can make good long-term holdings, producing income in the form of dividends. If they grow substantially in share price, so much the better.

Stock market volatility. Factors causing the market to yo-yo include the omicron variant and projected interest rate increases. Volatility holds inherent opportunities for gain because it’s actually an asset class. Various ETFs, such as WisdomTree CBOE S&P 500 Put-Write Strategy Fund (PUTW), harness volatility through options trading. Such funds can serve as a good alternative to bonds, especially now that bonds are paying negative yields after inflation.

This is an unusual market period, in part because of heavy, yet now-waning, government economic stimulus. For this and other reasons, the market is now in largely uncharted terrain, creating uncertainty that will fuel continued high volatility. As a result, there will be buying opportunities, so it’s a good idea to maintain some dry powder — cash.

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What are the best growth stocks for 2022?

by Bradley Guichard, M.S., CPA, CFE

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Picking growth stocks successfully is no easy task. 2021 was a mixed year. Many growth stocks took the roller coaster ride up and then troughed lower than they opened the year when the macroeconomic winds changed. The growth stocks that return to their previous highs and beyond will be those with scalability to be successful long term, so it is going to be essential to choose wisely in 2022. There are several helpful metrics that investors can examine to make their picks.

In this article, I highlight three top growth stock picks for 2022, and each offers something different to its customers and investors.

DigitalOcean

DigitalOcean Holdings Inc. (DOCN) provides cloud services to small and medium-sized businesses and individual developers. Year to date (YTD), DigitalOcean stock has returned more than 90%.

It has also pulled back sharply from its recent highs, which is an opportunity for investors to accumulate shares. DigitalOcean occupies a niche in the cloud services market, which is dominated by Amazon (AMZN) Web Services, Microsoft Corporation (MSFT) Azure and Google (GOOG) Cloud. The big tech giants focus on large corporations with complex and expensive needs, whereas DigitalOcean focuses on businesses with 500 or fewer employees. DigitalOcean expects to have a total addressable market (TAM) of $116 billion by 2024 just from this pool of companies. Excellent customer support, straightforward pricing and simple cloud solutions are the advantages that DigitalOcean offers to customers.

DigitalOcean accelerated its revenue growth in 2021 to 34%, and this growth should continue into 2022 and 2023. The company trades at a forward price-to-sales (P/S) ratio of just over 20.

The company is also adjusted EBITDA positive and expected to generate $130 million in 2021 alone based on $427 million in total revenue. Because of this, DigitalOcean is currently long-term debt-free and had $590 million cash and equivalents on hand as of Q3 2021. This should allow the company to fund general operations without raising capital through further debt or equity financing for a significant period.

Finally, DigitalOcean has a net retention rate (NRR) well above 100%. This high NRR means the company generates growing revenue from existing customers above any customer churn — a terrific sign. The company reports that the average revenue per user was up from $51.25 in Q4 2020 to $61.97 in Q3 2021.

These combined metrics and opportunities make DigitalOcean one of the top growth picks for 2022.

PagerDuty

PagerDuty Inc. (PD) may be the least well known of the three companies, although it is held in the ARK Innovation portfolio (ARKK). As of December 23, 2021, PagerDuty made up more than 13% of the portfolio’s total holdings. PagerDuty provides customers with a digital operations management platform. The stock is down more than 13% YTD because growth stocks have recently fallen out of favor due to mac-
roeconomic conditions and sector valuation concerns.

Former Amazon software engineers started PagerDuty in 2009. PagerDuty boasts more than 14,400 paying customers, with 543 generating more than $100,000 annually as of October 31, 2021. Customers include more than 65% of the Fortune 100 across all sectors. While DigitalOcean is focused on the little guy, much of PagerDuty’s success will hinge on the growth of large customers.

Revenue is expected to reach $286 million in the current fiscal year on 34% growth. PagerDuty also has a tremendous net retention rate of 144% at the last report and estimates its total TAM at $36 billion.

The company is not EBITDA positive at this time and is spending very heavily on sales and marketing to achieve growth. The increase in large customers will be a crucial metric to watch for in subsequent quarters. The company’s balance sheet is solid, although it does have $281 million in long-term debt to service.

PagerDuty may be the highest risk of the three picks. The current market cap is $3.11 billion, putting the forward P/S at just under 11.

**CrowdStrike**

CrowdStrike Holdings Inc. (CRWD) investors had a challenging year. The company is doing terrific, but the stock has struggled due to its valuation and unfavorable macroeconomic factors. The stock is just about even YTD, with investors seeing significant gains evaporate rather quickly.

CrowdStrike is a cloud-based cybersecurity platform whose stated mission is, “We stop breaches.” Cybersecurity is an enormous challenge for enterprises of all sizes. The federal government is also looking to shore up systems across departments. The Cybersecurity and Infrastructure Security Agency (CISA) recently selected CrowdStrike as a powerful platform for end point protections across government agencies.

“CISA is on the front lines when it comes to defending our country’s most critical assets against the persistent and evolving threats that nation-state and e-crime adversaries present,” said George Kurtz, co-founder and chief executive officer of CrowdStrike. “Improving our nation’s defenses and cyber resiliency requires strong collaboration between the government and the private sector. This partnership will arm CISA and government agencies with CrowdStrike’s powerful technology and elite human expertise to stop sophisticated attacks and protect our nation’s critical infrastructure.”

CrowdStrike has some of the best software-as-a-service (SaaS) metrics around. When it comes to growth, few can match CrowdStrike’s 75% compound annual growth rate during the past five years, inclusive of this fiscal year’s guidance.

Annual recurring revenue (ARR) also reached the $1.5 billion mark in Q3 fiscal 2021, an impressive milestone for the company. To achieve this growth, CrowdStrike is spending efficiently on marketing. One measure of sales and marketing spending efficiency is the SaaS magic number. The magic number is calculated by taking the increase in quarterly ARR and dividing it by the quarter’s sales and marketing expenses. A magic number over 0.75 is seen as efficient, and CrowdStrike reported a 1.3 as of October 31, 2021.

Gross margins are expanding, and subscription gross margin is approaching 80%, pointing to scalability. There is plenty of room for scaling with an estimated TAM of $116 billion by 2025.

The recent pullback makes the valuation metrics much more attractive. The company now has a forward P/S ratio of less than 34. Analysts are also turning bullish on the stock once again.

**HONORABLE MENTION**

**The Trade Desk**

I would be remiss not to mention The Trade Desk Inc. (TTD) in this article. The stock is up approximately 22% YTD. Digital advertising spending is exploding, and the company has a tremendous TAM as a demand-side platform. The platform is not reliant upon third-party cookies. Revenue growth took a step back in 2020 as advertisers cut back on spending; however, it came roaring back in 2021.

The company has generated $383 million in cash from operations over the TTM, has a gross margin near 80%, is long-term debt free and has nearly $800 million in cash and short-term investments on hand. This will allow the company to fund general operations and put it in a great position to make acquisitions if need be.

The Trade Desk’s potential is no secret because it currently trades at nearly 40 times sales. Still, if Q4 2021 is the record-setting quarter many of us expect, the stock could take off, and the company could reward investors appreciably over the next five years.

All three growth plays I mentioned have unique positives and challenges, but all three have significant potential for market-beating gains in 2022. »

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For adults on maximally tolerated statins with TG ≥150 mg/dL and established CVD or diabetes and ≥2 CVD risk factors

Add VASCEPA® (icosapent ethyl) to a statin for an additional 25% CV risk reduction

Capsule is not actual size.

INDICATIONS AND LIMITATIONS OF USE
- VASCEPA® (icosapent ethyl) is indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and ≥2 or more additional risk factors for cardiovascular disease.
- VASCEPA is indicated as an adjunct to diet to reduce TG levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

IMPORTANT SAFETY INFORMATION
- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.
- It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.

The wholesale price of VASCEPA is $344.22 for 120 1g capsules and $402.73 for 240 0.5g capsules. Commercially insured patients can save with the VASCEPA Savings Card.

With the rise of COVID-19 cases nationwide, the Office for Civil Rights (OCR) has temporarily lifted penalties associated with private telehealth communications between health care providers and their patients. For additional information, please visit the temporarily updated guidelines at hhs.gov/hipaa.

INDICATIONS AND LIMITATIONS OF USE

• VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.

• VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

• VASCEPA is indicated as an adjunct to diet to reduce TG levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia and established CVD or diabetes and ≥2 CVD risk factors.

For adults on maximally tolerated statins with TG ≥150 mg/dL and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease or established CVD or diabetes and ≥2 CVD risk factors, Add VASCEPA to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

IRREVERSIBLE OF TG LEVELS
VASCEPA showed robust CV risk reduction irrespective of achieved TG levels.

AVAILABLE COST SAVINGS
With the VASCEPA Savings Card, commercially insured patients can pay as little as $9 for a 90-day supply. Subject to eligibility. Restrictions apply*.

Indicate “Dispense as written (DAW)” or “Brand medically necessary” to help ensure your patients are getting the benefits of VASCEPA.

Please see adjacent Brief Summary of full Prescribing Information for VASCEPA or go to www.vascepahcp.com.

*Offer Restrictions: May not be used to obtain prescription drugs paid in part by Federal or State Programs including Medicare, Medicaid, Medicare Advantage, Medicare Part D, Tricare, VA. Most eligible, insured patients will pay as little as $9 of their copay for either each month or a 90 day fill, with a maximum savings of up to $150 per month or $450 on a 90 day fill. Not for use by residents of VT, nor medical professionals licensed in VT. This offer is not valid for those patients under 18 years of age or patients whose plans do not permit use of a copay card. Void where prohibited by law, taxed, or restricted. Eligible patients include those who participate in commercial insurance, through a healthcare exchange, or pay cash. Offer good through December 31, 2021.

1Cardiovascular events including myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization.

VASCEPA® (icosapent ethyl) capsules, for oral use

Brief Summary of Prescribing Information

Please see Full Prescribing information for additional information about VASCEPA.

1 INDICATIONS AND USAGE

VASCEPA® (icosapent ethyl) is indicated:

• as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
• as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Limitations of Use:
The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been established.

2 DOSAGE AND ADMINISTRATION

2.1 Prior to Initiation of VASCEPA

• Assess lipid levels before initiating therapy. Identify other causes (e.g., diabetes mellitus, hypothyroidism, or medications) of high triglyceride levels and manage as appropriate.

• Patients should engage in appropriate nutritional intake and physical activity before receiving VASCEPA, which should continue during treatment with VASCEPA.

2.2 Dosage and Administration

• The daily dose of VASCEPA is 4 grams per day taken as either:
  o Four 0.5 gram capsules twice daily with food, or
  o One 2 gram capsule twice daily with food.

• Advise patients to swallow VASCEPA capsules whole. Do not break open, crush, dissolve, or chew VASCEPA.

3 DOSAGE FORMS AND STRENGTHS

VASCEPA capsules are supplied as:

• 0.5 gram amber-colored, oval, soft-gelatin capsules imprinted with VSG0
• 1 gram amber-colored, oblong, soft-gelatin capsules imprinted with VASCEPA

4 CONTRAINDICATIONS

VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.

5 WARNINGS AND PRECAUTIONS

5.1 Atrial Fibrillation/Flutter

VASCEPA is associated with an increased risk of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial of 8,179 statin-treated subjects with established cardiovascular disease (CVD) or diabetes plus an additional risk factor for CVD, adjudicated atrial fibrillation or atrial flutter requiring hospitalization for 24 or more hours occurred in 127 (2%) patients treated with VASCEPA compared to 84 (2%) patients receiving placebo. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.

5.2 Potential for Allergic Reactions in Patients with Fish Allergy

VASCEPA contains ethyl esters of the omega-3 fatty acid, eicosapentaenoic acid (EPA), obtained from the oil of fish. It is not known whether patients with allergies to fish and/or shellfish are at increased risk of an allergic reaction to VASCEPA. Inform patients with known hypersensitivity to fish and/or shellfish about the potential for allergic reactions to VASCEPA and advise them to discontinue VASCEPA and seek medical attention if any reactions occur.

5.3 Bleeding

VASCEPA is associated with an increased risk of bleeding. In a double-blind, placebo-controlled cardiovascular outcomes trial of 8,179 patients, 462 (12%) patients receiving VASCEPA experienced a bleeding event compared to 421 (10%) patients receiving placebo. Serious bleeding events occurred in 111 (3%) patients on VASCEPA vs 85 (2%) of patients receiving placebo. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel, or warfarin.

6 ADVERSE REACTIONS

The following important adverse reactions are described below and elsewhere in the labeling:

• Atrial Fibrillation or Atrial Flutter [see Warnings and Precautions (5.1)]
• Potential for Allergic Reactions in Patients with Fish Allergy [see Warnings and Precautions (5.2)]
• Bleeding [see Warnings and Precautions (5.3)]

6.1 Clinical Trials Experience

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

Cardiovascular Outcomes Trial

In a double-blind, randomized, placebo-controlled cardiovascular outcomes trial, 8,179 statin-stabilized patients were randomized to receive VASCEPA or placebo and followed for a median of 4.9 years (see Clinical Studies (14.1)). The median age at baseline was 64 years, 29% were women, 90% White, 5% Asian, 2% Black, and 4% identified as Hispanic ethnicity.

Common adverse reactions (incidence ≥ 3% on VASCEPA and ≥ 1% more frequent than placebo) included musculoskeletal pain, peripheral edema, constipation, cough, and atrial fibrillation.

Hepatic/pancreatic Toxicity

In two randomized, double-blind, placebo-controlled trials in patients with triglyceride levels between 200 and 2000 mg/dL, treated for 12 weeks, adverse reactions reported with VASCEPA at an incidence ≥1% more frequent than placebo included increased amylase and lipase.

6.2 Postmarketing Experience

Additional adverse reactions have been identified during post-approval use of VASCEPA. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

• Diarrhea
• Blood triglycerides increased
• Abdominal discomfort
• Pain in the extremities

7 DRUG INTERACTIONS

7.1 Increased Bleeding Risk with Anticoagulants and Antiplatelet Agents

Some published studies with omega-3 fatty acids have demonstrated prolongation of bleeding time. The prolongation of bleeding time reported in those studies has not reached normal limits and did not produce clinically significant bleeding episodes. Monitor patients receiving VASCEPA and concomitant anticoagulants and/or antiplatelet agents for bleeding.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

In pregnant rats given oral gavage doses of 0.3, 1 and 2 g/kg/day icosapent ethyl from gestation through organogenesis, all drug treated groups had non-dose-related imbalances in visceral and skeletal findings, including 13% reduced ribs, additional liver lobes, testes medially displaced and/or not descended, at human systemic exposures following a maximum oral dose of 4 g/day based on body surface area comparisons. In a preclinical rabbit orally administered icosapent ethyl during organogenesis, there were no clinically relevant adverse developmental effects at exposures that were 5 times the clinical exposure, based on body surface area comparisons (see Data).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

In pregnant rats given oral gavage doses of 0.3, 1 and 2 g/kg/day icosapent ethyl, by oral gavage from gestation day 7-17, icosapent ethyl did not affect viability in fetuses (F0, F1, F2).

Non-dose-related imbalances in findings of absent optic nerves and unilateral testes atrophy at human exposures based on the maximum dose of 4 g/day and on body surface area comparisons. Additional variations consisting of early incisor eruption and increased percent cervical ribs were observed at same exposures. Pups from high dose treated dams exhibited decreased copulation rates, delayed estrus, decreased implantations and decreased surviving fetuses. F0 suggesting potential multigenerational effects of icosapent ethyl at 7 times human systemic exposure following 4 g/day dose based on body surface area comparisons across species.

In pregnant rats given oral gavage doses of 0.1, 0.3, 1 and 2 g/kg/day icosapent ethyl from gestation through organogenesis, a decrease in body weight and food consumption was observed at the high dose of 1 g/kg/day (5 times the human exposure at the maximum dose of 4 g/kg/day, based on body surface area comparisons). Slight increases in recorded and dead fetuses were noted in the 1 g/kg/day group, but these were not statistically different from the control group. There were no differences between the icosapent ethyl groups and control group as to the number of corpora lutea, number of implantations, number of surviving fetuses, sex ratio, body weight of female fetuses or placental weight. There were no treatment related malformations or skeletal anomalies.

In pregnant rats given icosapent ethyl from gestation day 17 through lactation day 20 at 0.3, 1, 3 g/kg/day no adverse maternal or developmental effects were observed. However, complete litter loss (not dose-related) was noted in 2/23 litters at the low dose and 1/23 mid-dose dams by post-natal day 4 at human systemic exposures at a maximum dose of 4 g/kg/day, based on body surface area comparisons.

8.2 Lactation

Risk Summary

Published studies have detected omega-3 fatty acids, including EPA, in human milk. Lactating women receiving oral omega-3 fatty acids for supplementation have reported higher levels of omega-3 fatty acids in human milk. There are no data on the effects of omega-3 fatty acid ethyl esters on the breastfeeding infant or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VASCEPA and any potential adverse effects on the breastfed child from VASCEPA or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Of the total number of patients in well-controlled clinical studies of VASCEPA, 46% were 65 years of age and over. No overall differences in safety or effectiveness were observed between elderly and younger patients.

8.6 Hepatic Impairment

In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be monitored periodically during therapy with VASCEPA.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling before starting VASCEPA (Patient Information). Inform patients that VASCEPA may increase their risk for atrial fibrillation or atrial flutter [see Warnings and Precautions (5.1)].

Inform patients with known hypersensitivity to fish and/or shellfish about the potential for allergic reactions to VASCEPA and advise them to discontinue VASCEPA and seek medical attention if any reactions occur [see Warnings and Precautions (5.2)].

Advise patients to swallow VASCEPA capsules whole. Do not break open, crush, dissolve, or chew VASCEPA [see Dosage and Administration (2.2)].

Instruct patients to take VASCEPA as prescribed. If a dose is missed, patients should take it as soon as they remember. However, if they miss one day of VASCEPA, they should not double the dose when they take it.

For more information about VASCEPA, go to www.VASCEPA.com or call 1-855-VASCEPA (1-855-827-2372).

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Keeping physicians informed for almost a century
The end of the 2021 session of Congress saw what has become an annual last-minute scramble to stem massive cuts to Medicare reimbursement. Although the reprieve was welcomed by physician organizations, at some point, cuts will have to be made to achieve the required budget neutrality. In addition, telehealth changes are likely coming whenever the public health emergency is lifted, and physicians can also expect more prior authorizations and other cost-saving moves from payers.

“People are wondering, ‘How much will I get paid for this or that?’ The answer is: It’s never enough,” says Mark Bethke, FSA, managing director of Deloitte Consulting LLP. “They are never going to cover your underlying costs that you need to get.”

Bethke adds that the congressional scramble around Medicare will probably continue each year and that fee schedules are not likely to increase by significant amounts. “At some point, people need to think about getting off the hamster wheel of fee for service and think of alternative ways to collect revenue.”

by Todd Shryock Managing Editor
What follows are the reimbursement challenges that physicians face for 2022.

The Medicare cliff
In mid-December, Congress averted what would have been a devastating cut to physician payments in Medicare, which were scheduled to be reduced by 9.7% across several areas. Physician payments were scheduled to see a 3.75% reduction to meet budget neutrality requirements, but because of COVID-19, Congress opted to delay all but 0.75%.

Physicians can also look forward to a slow reinstatement of the Medicare sequester. “The sequester is not completely going away,” says Anders Gilberg, senior vice president of government affairs for the Medical Group Management Association (MGMA). “It will be phased back in 1%, in March, and the 2% will be phased back in July.”

Gilberg says that 4% of the original 9.75% of Medicare cuts originates with Congress not offsetting money that was appropriated as part of the American Rescue Plan Act from early 2021.

“So what happens when Congress spends money and doesn’t offset it?” asks Gilberg. “It triggered statutory pay-as-you-go requirements, which would have resulted in 4% cuts.”

All told, physicians saw a 0.75% reduction to the Medicare conversion factor Jan. 1, which is a carryover from 2021. The other cuts — other than the phased-in 2% sequester — will be prevented through the end of 2022.

The challenge with Medicare reimbursement is when the program makes changes to its relative values that result in spending increases, it triggers budget neutrality requirements that reduce the Medicare conversion factor to offset increases in the relative values. Congress stepped in with a short-term solution of providing about $3 billion to fund the 3% of the scheduled 3.75% in cuts.

“But that was only for one year,” says Gilberg. “At some point, there will be a day of reckoning when the budget neutrality requirements will be implemented. That’s a requirement by law. The medical community has been successful in delaying this, but ultimately Congress is not going to repeal budget neutrality requirements, so we may have 3% of this to deal with in 2023.”

To permanently eliminate it would cost $30 billion or more, and Gilberg says he doesn’t see Congress being willing to do that. At some point, Medicare is going to have to square its books to meet the budget neutrality requirements. They were delayed in 2021 and this year because of the pandemic, but as 2023 approaches, will Congress be willing to do it again?

“Medicare doesn’t pay a lot, and oftentimes practices use their commercial contracts, which tend to be higher than Medicare, to offset what they lose on the Medicare side of their book of business,” says Gilberg. “But at some point, if rates go below a certain point and they can’t offset the losses that they incur by seeing Medicare patients, then they have to make tough decisions about whether they could still see Medicare patients.”

Bethke says that leaving Medicare probably isn’t a long-term solution to a practice’s problems, noting that commercial payers are dealing with the same challenges as the government and can’t keep raising rates at an increasing pace.

“You don’t want to move away from Medicare because that is still where a lot of the money is; that’s still where a lot of services are; that’s where a growing percentage of the population is,” Bethke says. “And there is a lot of opportunity to still improve care, improve chronic conditions and focus on wellness and improving the quality of life and outcomes.”

If payment cuts are so severe that physicians start a mass exodus out of Medicare, it might force Congress to come up with a better solution. Gilberg points to the since-repealed sustainable growth rate. “It would have cuts looming over physicians every year in Medicare, and it destabilized practices; it caused them not to invest in new technology. It’s obviously hard to plan and project out in the year if every December Congress is deciding whether or not your reimbursement could be cut significantly.”

Because Congress got rid of the vast majority of cuts this year, it does show they are aware of the potential damage to the Medicare program. “Hopefully, this is more short term and not the long-term problems we had for at least a decade going up to 2015 with the SGR (sustainable growth rate formula),” says Gilberg. “But these cuts were largely a result of Congress overspending and not offsetting legislation that was completely unrelated to Medicare. We don’t know, for example, what may or may not happen with various infra-structure legislation, so it could happen again — that these cuts are kind of hanging over the head of physicians and Medicare.”

Does telehealth reimbursement have a future?
When the pandemic hit and many patients were in lockdown or simply afraid to go to a doctor’s office, telehealth filled the gap. Many practices invested in the technology to remotely talk to patients, and reimbursement was boosted to match that of an office visit. Everyone seemed to love the concept of expanded access and the convenience, except for one group.

“There’s still some degree of skepticism about telehealth, at
MEDPAC recommends no Medicare reimbursement raises for doctors

Doctors’ groups condemn recommendation, say it will impede patients’ access to care

The federal government probably won’t be raising Medicare reimbursements next year, and physician organizations are strongly objecting.

At its January 13 meeting, the Medicare Payment Advisory Commission (MedPAC), which advises Congress on issues pertaining to Medicare, recommended against increasing base payment rates to doctors in 2023. It justified its decision in part by noting that Congress temporarily raised Physician Fee Schedule Payment rates for the period 2020-2022, and that doctors have benefitted from “tens of billions of dollars in pandemic relief funds and more flexibility to provide telehealth.”

Leaders of several groups representing doctors have issued statements criticizing the commission’s recommendation and warning of its financial impact on them and the health consequences for patients. American Medical Association (AMA) President Gerald Harmon, MD said the decision “imperils patient access to high-quality care as the costs to practice medicine continue to rise.”

He added that the AMA’s research shows that, after adjusting for inflation, Medicare physician payment declined 20% between 2001 and 2020. “The discrepancy between what it costs to run a practice and payment is sparking consolidation and driving physicians out of rural and underserved areas,” he said.

George M. Abraham, MD, MPH, president of the American College of Physicians (ACP), said the recommendation would “jeopardize access to primary care physicians.” Despite knowing the importance of primary care, he added, the U.S. allocates between 4% and 6% of its health care resources to primary care, “significantly less than other countries and... what is needed for the United States to achieve a high-functioning health care system that delivers quality and value to individuals and communities.”

He said the ACP wants to work with MedPAC to develop an alternative that would result in stable and predictable reimbursement updates, protect patients’ access to care, and encourage payment and delivery reforms.

The American Academy of Family Physicians issued a statement calling the recommendation “misguided” in light of rising costs and staffing shortages, and noting that institutions such as hospitals and skilled nursing facilities receive annual Medicare reimbursement updates to account for inflation, but physician payment does not.

“A lack of updates to physician payments will worsen access to high quality care, drive consolidation and undermine the stability of primary care physician practices,” the academy said.

The recommendations will be included in MedPAC’s next report to Congress, which is scheduled for March.
least in Washington,” says Gilberg. Prior to the pandemic, Medicare only covered telehealth services in rural areas — and with restrictions on which technology a doctor could use to talk to a patient. Those restrictions were lifted as part of the public health emergency. When the emergency is over, the rules will revert to existing law and Medicare will not cover telehealth in most cases.

“A lot of private payers also cover Medicare or follow Medicare-type payment policies, so I would expect a contraction in coverage for telehealth as well,” says Gilberg. “It would be both a contraction in coverage as well as a reduction in the amount paid for telehealth services.”

He says that Congress has concerns that if the originating site restrictions are lifted to allow telehealth outside of rural areas, then Medicare spending might increase significantly, perhaps by billions. The idea is that easier access would promote greater utilization. In addition, there are concerns about privacy, fraud risks and the quality of services when physicians can’t actually lay hands on the patient.

“All of those things need to be sorted out before we would see a permanent telehealth expansion in Medicare,” says Gilberg. “My best prediction on this is after the public health emergency, I do see a residual demand for telehealth, but I don’t see Congress just permanently extending all this indefinitely.”

One possibility is that Congress will keep the expansion for a couple years to study the overall impact to Medicare. Private payers are also somewhat skeptical of it having a negative impact on their bottom lines.

“Private payers do like telehealth, especially for primary care services, (because) they can make sure that certain preventive care is delivered,” says Gilberg. “But that doesn’t mean that they’re necessarily going to just pay physicians in their network the exact same amount for telehealth visit.”

Bethke says he expects telehealth will remain in some form. “I don’t see how it makes sense to back off of telehealth and technology and evolving our care model,” he says. “It just seems like a backward approach of not helping evolve and transform out industry.”

The strategy some payers are using is to buy a telehealth company and only reimburse for telehealth if the patient uses their in-house service. “I’m a little contrarian about telehealth and that they’re just not going to open up the floodgates for telehealth on the public or private side,” says Gilberg. “They’re going to kind of assess the situation and then move forward based on findings.”
ultimately (are what create) their network and those are the people who are buying their product.”

To be successful with payers, practices are going to have to not only improve outcomes, but also the consumer experience. This means understanding what the practice does well and marketing that to both payers and patients, Bethke says.

“That doesn’t mean you have to be the cheapest provider or the least expensive because if you think about that in retail, that’s not always a good thing,” Bethke says. “You don’t want to be the most expensive, but you want to create a brand and market to the individuals that you want to come to your practice.”

That same information used to promote the practice to patients can be used to show payers where the practice fits in the market and how it adds to the overall patient experience when it comes time to renegotiate, according to Bethke.

Value-based contracts in 2022

Many practices with value-based contracts fared better than those on fee-for-service deals, mainly because many of the value-based ones offered a monthly fee per month for payment or a set amount of money to manage a patient population. As a result, value-based practices saw less disruption to their revenue.

“Where it’s become a little tricky with value-based care in the middle of the pandemic is that a lot of quality measures and measures of cost are based on benchmarks,” says Gilberg. “And because of the disruptions that we’ve seen as a result of the pandemic, the benchmarks have a lot of anomalies or aberrations in the benchmarks. It’s always tricky, for example, if volumes went down significantly in 2020, only to rebound in 2021.”

As the country emerges from the pandemic, value-based measures may have to deal with some anomalies as care returns to more normal levels. Practices probably won’t see a huge surge in value-based contracts, at least for now. “The measurement of both costs and quality has been affected by the pandemic,” says Gilberg. “It’s hard to envision a situation where you are going to see significant growth in value-based care until we emerge from the pandemic and kind of normalize the benchmarks for cost and quality.”

Smaller practices and reimbursement challenges

With so much economic pressure hitting smaller practices harder than most, can an independent practice with limited resources survive in a post-pandemic health care world with so many reimbursement obstacles?

Bethke says without scale, smaller practices will have a challenging time keeping up with the demands of the evolving health care industry. “That doesn’t mean those small shops have to close and go join the biggest system,” he says. “There are ways around that — they can join clinically integrated networks, and there are other ways to collaborate.” A smaller practice may have to join an accountable care organization or similar group to help with the logistical challenges and the data many payers now require. But being small can be a good thing too.

“I think the advantage that smaller practices have is that they’re nimble and they can adapt quickly,” says Gilberg. “And we are seeing a positive trend in terms of their ability to recover. If we can get beyond some of these near-term staffing shortages, then I think that will be a very positive thing. The fact remains, and most studies show that, especially either independent practices or just practices that are smaller in size, they tend to be able to deliver more personalized care and also at a lower cost than some of the larger institutional systems.”

For the best financial results, practices need to decide how they want to be reimbursed and then build from there. “Don’t focus on how you’re currently reimbursed; focus on what you think it should be,” Bethke says. “Once you’ve determined that based on the data, your history, where you believe you are valuable to the system and thinking about that part differently — maybe in the past you were in the fee-for-service world — then and only then can you think about what the right payment model to live in is.

“Change the order of operations about how you think about payment models.”
Why doctors need a buy-sell agreement

A private practice physician’s career, as with many other professionals and entrepreneurs, is focused on growing their practice and serving their patients. Considering when and how they will inevitably exit their careers and, more importantly, create a “strategic exit plan” doesn’t tend to be the highest priority.

Certainly, focusing on serving patients is to their credit, but many doctors over time slip into a “die at the desk” mentality. Their practice is who they are, and their last day in the office has a greater chance of ending with their being carried out than exiting gracefully with a retirement party.

During their lifetime work, doctors do everything in their power to keep patients healthy, but they also know more than most that life is not always predictable; yet, successful practitioners often don’t make any preparation for ending their practice if their lives end earlier than expected.

If we have learned anything during the COVID-19 pandemic, stuff happens — many times outside of what we planned. Doctors and other medical professionals were frequently exposed to danger. What happens if we don’t make it to the office tomorrow? Our patients, staff and a lifetime of work dissipates into the air?

Having a contingency plan isn’t a planning option. It is a necessity.

Whether you are a solo practitioner or part of a large, complex medical group, a “buy-sell” arrangement is a must-have for private practices to protect their family, employees and patients. Your family deserves the economic value of your life’s work, your employees deserve the assurance they will remain employed and your patients need to know that their medical needs will be met.

We encourage our clients to have a buy-sell agreement that addresses the five Ds:

<table>
<thead>
<tr>
<th>Death</th>
<th>Premature death is the most common item in a buy-sell, whether a solo practitioner or part of a group.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disability</td>
<td>If you can no longer perform in your area of practice, disability insurance may cover a portion of your income and overhead, but what if you can never return to the practice of medicine? Make sure your agreement covers this possibility.</td>
</tr>
<tr>
<td>Divorce</td>
<td>In the event of a partner’s divorce, the shares of the practice cannot be left in jeopardy of going to the person who divorced a partner.</td>
</tr>
<tr>
<td>Disagreement</td>
<td>If partners can’t agree on major business decisions, a clause must be exercised to settle the agreement and potentially divide the practice.</td>
</tr>
<tr>
<td>Departure</td>
<td>If one doctor decides to retire while others want to continue, what is the valuation method and payout structure for the doctor who is retiring?</td>
</tr>
</tbody>
</table>

I have had the privilege in my 17-year career in financial services of working with many family medicine groups, dental practices and specialized doctors such as aestheticians. What I have found is that many are great businesspeople and certainly highly educated. But most don’t realize the inherent value of the practice they have created. It’s also important to recognize the value of the after-tax income the business produces — and that it may be your largest asset.

It’s critical to plan the eventual exit of your medical practice, just as you would a business. The appropriate time, attention and team are necessary to ensure maximum value.

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Interested in more content like this?
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A good adviser can offer more than just financial advice

by Steven Podnos, M.D., MBA, CFP

Having a relationship with a good financial planner brings a “best of” team of advisers to help you achieve your life goals.

As a physician, I’m frequently asked to make referrals to specialists by friends, family and patients. It certainly helps that I know who is good and who is not from direct working relationships, as well as being able to contact trusted physicians elsewhere for recommendations in their fields and geographic areas. This type of benefit extends to financial consulting as well.

Traditional reasons for hiring a fiduciary financial planner include to receive a review of one’s financial situation, obtain advice on the best ways to avoid financial mistakes and learn how to attain financial independence. An ongoing relationship with an experienced planner provides all this as well as long-term strategies for increasing wealth in a diversified and disciplined manner.

But a good financial adviser brings much more to the relationship in the form of the other professionals they know and work with. A seasoned planner usually will have a large team of consultants that they can tap for information and advice on behalf of their clients. These consultants have been vetted and found to provide the best fiduciary advice and help, as opposed to those who recommend risky, sales-driven tactics.

Let’s look at some examples ...

The field of life insurance is rife with agents trying to persuade young physicians to buy various types of expensive whole-life insurance products that they don’t need. I see it over and over. Closely aligned are annuity salespeople cramming expensive and underperforming products into portfolios to line their own pockets.

A good financial advisor will align with a great insurance agent who knows that most families just need some term policies that expire as financial independence is achieved. A great agent will also know the underwriting personnel and practices of various life insurance companies, which will, in turn, guide the best choice of policies for an individual in terms of cost and coverage. When necessary, a great agent will offer guidance on actions to take before applying for coverage, such as clearing up a resolved medical issue that is still on your records.

All this is true for having a great agent when purchasing disability insurance. The great agent knows the underwriting proclivities of the different companies and can help guide the young physician through the intricacies of applying. Such an agent knows that adding a catastrophic rider is a good value and that expensive extras like “return of premium” riders usually are not.

In short, the great agent knows that getting maximal coverage in one’s early years is the overriding goal. The good financial adviser knows who the good accountants are. Many accountants, however, are not much better than using a software program like TurboTax. Fortunately, there are still great accountants with deep experience, knowledge and creative ideas. A good financial planner has found and worked with these professionals, and the planner’s clients benefit greatly from this.

Working with attorneys on estate planning issues, contract reviews and even in litigation (malpractice or other) can be a scary crapshoot. It is difficult to know which attorneys are the best in their field and for your situation and personality. A good financial planner has worked with many attorneys over many years and can be extremely helpful when it comes to making the appropriate choices.

So having a relationship with a good financial planner brings a best-of team of advisers to help you achieve your life goals. Think of your own experience in medicine: When a relative or friend asks you to recommend a physician, you often know exactly whom to steer them to and whom to have them avoid. Having a guide to the best financial and legal advice is just as valuable.

Steven Podnos, M.D., MBA, CFP, is founder and principal of Wealth Care LLC in Merritt Island, Florida. He can be reached at Steven@wealthcarellc.com or at www.wealthcarellc.com.
You’ve received a request for medical records from a payer who is going to conduct an audit on your claims. Your electronic health record (EHR) system is excellent, the notes are voluminous and your providers are well-versed at coding. If anything, you undercode! You provide excellent care for your patients and achieve great outcomes. No one has ever given you any trouble before.

Nothing to worry about, right?

Several months pass, and you get a letter from the payer. It’s the results from your audit. You open it up and see:

- “Medical necessity not supported.”
- “Notes are cloned.”
- “Records include conflicting data.”

It also says that you owe an astronomical amount of money due to “overpaid claims” and that they are putting you on prepayment review until things improve.

What just happened? Why are they doing this? Can they legally do this?

Welcome to the world of billing and coding — where black and white is often eclipsed by gray, where the “obvious” is rarely so and where sometimes less is more.

Below are recent trends in medical audits and what physicians can expect, especially after the Centers for Medicare & Medicaid Services’ (CMS) overhauled the documentation of evaluation and management (E/M) codes a year ago.

Most providers have an EHR system and fill in pertinent patient information as prompted by the system. Is there anything they need to be on the lookout for?

An EHR system is supposed to make your life easier. It provides accurate, up-to-date information about the patient. Its purpose is to facilitate coordinated access and information sharing among physicians. It helps providers more efficiently diagnose patients, reduces errors, provides safer care and facilitates quality. And, by the way, it does a bang-up job of capturing essential billing elements. Pop in the right template, maybe tweak it a little, and you’re good to go.

So where do things go astray? Well, to understand how something like the earlier scenario can happen, you first need to understand how the patient’s medical record influences medical necessity. Per CMS, medical necessity is the overarching criterion for payment. Inaccurate information in the chart, especially when carried forward from a previous service date or entry without necessary editing, often does not afford an auditor the ability to understand if you needed to see that patient, perform that test, order that script, etc.

Often the information obtained from a patient has not changed from the prior visit. So what is the potential problem with just carrying information forward?

Auditors across the nation, both private and public, love to deny claims based on allegations that the provider simply copied and pasted prior notes. A copy/paste-type operation that occurs without needed modifications to content is a process infamously known as “cloning.” And that doesn’t just refer to the entire progress note as a whole; it can refer to pieces...
of a progress note that are inaccurate. Those pieces could be integral to billing a distinct procedure or a crucial element associated with an office visit code. If one or more pieces never, or almost never, change from one visit to the next, the auditor doesn’t know if the information simply didn’t change or whether it may have changed but just wasn’t edited.

Lately, auditors seem to assume the latter.

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Is there anything else that auditors look for when they believe a note is cloned?
The presence of conflicting information is another giant red flag. If the history indicates the patient has severe dementia but the review of the systems template indicates that “all systems were reviewed and negative,” well, that could be a problem. One error of this nature can lead to a reviewer casting aspersions on the integrity of your note. “What else could be wrong with this chart?” thinks the auditor.

Truth be told, these are usually just innocuous mistakes that do not represent any intent to commit billing fraud. But the payers don’t see it that way. They don’t know if you forgot to revise that review of systems because you’re up until 11:30 p.m. signing off on your notes or if you’re trying to pad the record with billing elements. All they know is there is a conflict or redundancy that could represent something fraudulent.

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Are there any other potential pitfalls that are low-hanging fruit for auditors?
Another pitfall that may come back to haunt you is the overstuffed progress note. This occurs when the sheer quantity of the displayed items seems wildly disproportionate to the nature of the presenting problems.

Taken at face value, a single, self-limiting medical condition would not normally warrant a complete review of past medical, family and social history; a full review of systems; and a comprehensive exam. Although there may be times when circumstances do require a more intensive evaluation than meets the eye, the payers expect this to be the exception, not the norm.

All this leads to a presumption that the information in your charts is questionable. Once that notion is planted in an auditor’s head, it colors their perspective. If you happen to be a “high volume” provider with disproportionately more billing of any particular code or modifier, the notion that there must be something disingenuous going on becomes solidified. This thinly veiled ethical challenge can be insulting and infuriating to hard-working providers who would never, in a million years, intentionally submit an unsupported health claim.

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Will providers have to completely change the way they document medical necessity?
A gift horse arrived a year ago in the form of the 2021 E/M guidelines. These are rules created by the American Medical Association and adapted by CMS and other payers for outpatient office visit codes (codes 99202-99215 only).

The guidelines effectively remove those preexisting requirements to “quantify” the history and physical examination; you no longer need to worry about having “enough” of that review of symptoms anymore. However, you should continue to document those aspects of history and exams that lend support to your clinical decision-making and any tests or treatments ordered. E/M coding has historically been associated with EHR misuse, in part due to the confusing and onerous documentation requirements imposed by the CMS.

The 2021 rules allow physicians to document the most salient points relevant to the medical decision-making or time spent. It is coding, so there are charting nuances you still need to know.

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Is there anything else providers should keep in mind when documenting medical necessity?
Another very simple rule to bear in mind is: Change what changes. Your notes should always have an interval history of present illness (HPI). This is the history of the problem, but there is usually something unique to say about the patient’s status spanning the period between the last appointment and the current one.

Also, make a point to label it “interval HPI.” Don’t blend it in with the other history because that combination of new and old data sometimes doesn’t sit well together. You want unique documentation for each encounter, and it should stand out in your progress note. Taking the interval HPI concept one step further, you need to understand that encounter-specific charting is king. With the E/M changes comes a flexibility that has not existed in many years.

The rigidity of cookie-cutter, awkward-appearing templating is, from a billing standpoint, now inferior to an old-school, 1985-ish, free-text paragraph or two (yep, I remember those).

Everything has come full circle. Less is more.

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Do these documentation changes apply to all current procedural terminology (CPT) codes?
To be clear, the E/M documentation changes do not apply to all CPT codes. Certain services, such as wellness visits, chronic care, transitional care, etc., require more rigidity in capturing essential elements. However, you do want to
infuse encounter/patient specificity into those templates too. Despite the redundancies, you still need to personalize those notes to render them unique to the patient. A little TLC goes a long way.

Any parting advice for physicians?
Spend an extra five to 10 minutes proofing those notes before you close them. As my mom once said, “An ounce of prevention is worth a pound of cure.” The immense benefits of such diligence can truly be worth its weight in gold.

In the unfortunate event that you do receive one of those nasty over-payment demand letters someday, don’t acquiesce without conducting an analysis first. Let’s face it: They call them “procedure” codes because there are commonalities. Certain things may not change, or change much, from one service date to another. If you’ve changed the things that change and still got dinged in an audit, you may have sufficient basis to challenge the results.

There is no requirement to rephrase verbiage in your charts just for the sake of making it look different. That’s a level of insanity we hope we’ll never reach.

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As an associate in Frier Levitt’s health care department, Robert focuses on civil health care fraud litigation matters, government investigations, payor audits and overpayment demands, Office of Inspector General exclusions and CMS revocation of billing privileges. Prior to joining Frier Levitt, Roberts was a criminal defense counsel in the United States Army Judge Advocate General Corps, handling trials for felony-level federal criminal offenses and appealing agency decisions on behalf of soldiers. He also served as a trial counsel and prosecuted federal criminal offenses and as an administrative law attorney, advising senior-level commanders and agency heads on matters such as the Freedom of Information Act, whistleblower protections, administrative investigations and environmental law-related issues.

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If you’re interested in being notified when the registration for this event goes live, please email bootcamp@medicaleconomics.com

Check out the October 2021 Bootcamp content!
Scan or visit: www.medicaleconomics.com/2021-physician-bootcamp
Effective January 1, 2022, Medicare began accepting four new current procedural terminology (CPT) codes for principal care management (PCM) and discontinued two Healthcare Common Procedure Coding System G codes. Experts say the new codes, which are paid at a higher rate than the G codes, afford physicians the opportunity to improve outcomes while simultaneously generating additional revenue.

What is PCM?
PCM is similar to chronic care management (CCM) in that both services are for patients who require ongoing clinical monitoring and care coordination. However, unlike its CCM counterpart, PCM only requires patients to have one complex chronic condition; CCM requires three or more.

For example, PCM could be appropriate for a patient with uncontrolled diabetes or uncontrolled hypertension or a high-risk patient with severe asthma who has frequent hospital readmissions, says Terry Fletcher, B.S., CPC, a healthcare coding and reimbursement consultant. It could also be necessary for someone with hepatitis C, fibromyalgia, long-haul COVID-19 or a variety of other complex chronic conditions, she adds.

“Many practices are already doing this work to take care of these patients,” says Lori Foley, CHC, CMA, principal of compliance advisory services at PYC, P.C., a professional services firm specializing in health care consulting and certified public accounting. “They just need to capture the right information so they can bill for it compliantly.”

Experts provide these five considerations for internists who plan to offer PCM in the months ahead:

1. **PRINCIPAL CARE MANAGEMENT BILLING CRITERIA**
   
   To bill for principal care management (PCM), patients must have one complex chronic condition that meets the following six criteria:
   
   1. Is expected to last at least three months.
   2. Puts the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline or death.
   3. Requires development, monitoring or revision of a disease-specific care plan.
   4. Requires frequent adjustments in medication regimens, and/or the management of the condition is unusually complex due to comorbidities.
   5. Requires ongoing communication and care coordination between relevant practitioners furnishing care.
   6. Requires at least 30 minutes of PCM services per calendar month.

   Internists who treat a high volume of Medicare patients should definitely consider providing and billing for all care management services, including transitional care management (TCM), CCM and PCM because this population tends to struggle with at least one chronic condition and frequent hospitalizations, says Don McDaniel, CEO of Canton & Company, a health care growth and strategic services firm.

   Consider a patient who is admitted to the hospital with uncontrolled hypertension. The patient may require TCM for 30 days after discharge, followed by PCM for an additional 30 days or more. If the patient develops an additional complex chronic condition that requires ongoing monitoring, they may even be eligible for CCM instead of PCM.

   Note that CCM is also a 30-day service for a patient with two or more chronic conditions expected to last at least 12 months that place the patient at significant risk of death, acute exacerbation/decompensation or functional decline.

   “PCM is one tool in a toolbox of different options that practices can piece together to support building the right kind of infrastructure and surveillance needed to support patients,” says McDaniel.

   **How can internists provide PCM effectively?**

   Experts provide these five considerations for internists who plan to offer PCM in the months ahead:
Choose the right patients
Not every patient with a complex chronic condition requires PCM. “Make sure you're documenting that the condition is severe enough that the patient is at risk for hospitalization or was recently hospitalized several times due to that condition,” says Fletcher.

Fletcher audits CCM claims on behalf of various insurance companies and says the biggest reason for recoupment is that diagnoses for which CCM is performed don't meet billing criteria or Medicare program integrity rules; she suspects the same may be true for PCM. For example, physicians can’t bill PCM for patients with a well-controlled chronic condition, she says. (See the sidebar on page 29 for PCM billing criteria).

Bill the right codes
Report CPT codes 99424 and 99425 when a physician or nonphysician provider performs the PCM, and report CPT codes 99426 and 99427 when clinical staff under the direct supervision of a physician or other qualified health care professional provide the service.

Fletcher says examples of clinical staff might include an RN, clinical psychologist or medical assistant. However, she cautions physicians to check with payers and state nursing boards before billing because every state is different.

Document patient consent
And be sure to document that you’ve notified the patient that their coinsurance applies, says Foley.

Document who did what and for how long
“We promote a log that’s very clear: name, time spent, what they did specifically and their credentials,” says Foley. “The good news is that EHRs (electronic health records) have come a long way since 2016 when CCM rolled out, and many have integrated tools for time aggregation that facilitates the billing process.”

McDaniel agrees, adding that physicians intending to bill PCM should ask their EHR vendor whether it supports a care management workflow.

Determine whether you’ll outsource PCM
McDaniel says to ask these questions: What type of PCM services are you currently providing but not billing? Are you able to bill for those services and potentially cover the cost of hiring an additional staff member who might also be able to provide other types of care management services such as CCM and TCM?

“Do the research and find out if you can afford to hire someone,” says McDaniel. “If you find out you can’t do it, you still have the ability to hire a third party to support the activity.”

Lisa A. Eramo, M.A., is a contributing author. Send your coding questions to medec@mjhlifesciences.com.

Principal care management codes and reimbursement

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
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<tr>
<td>99424</td>
<td>Principal care management (PCM) performed by a physician or nonphysician provider 30 minutes per calendar month</td>
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<td>99425</td>
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<td>$58.46</td>
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<td>99426</td>
<td>PCM performed by clinical staff under the direction of a physician or other qualified health care professional 30 minutes per calendar month</td>
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<td>99427</td>
<td>Additional 30 minutes per calendar month</td>
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</table>

“PCM is one tool in a toolbox of different options (that) practices can piece together to support building the right kind of infrastructure and surveillance needed to support patients.”

Don McDaniel, CEO of Canton & Company
The road to a more perfect EHR

by Keith A. Reynolds Editor

Physician frustration with electronic health record (EHR) systems has been around as long as the systems have been in use, but with developers striving to make improvements and public health emergencies taking center stage, EHRs have become less of a burnout-inducing boogeyman.

With so much of the health care industry in flux and new regulations soon being implemented by the Office of the National Coordinator for Health Information Technology, it’s important to look at the current state of EHRs and where they might be going in the future.

The state of EHRs

The nation’s physicians have widely adopted certified EHR systems after a decade of heavy investment in incentivizing the switch.

Micky Tripathi, national coordinator for health information technology at the U.S. Department of Health & Human Services (HHS), says that just on the public side, $40 billion was spent on incentives to push physicians toward the new technology. He says the move was largely successful.

“We’ve got something like 90% of providers across the country who are using certified EHR systems,” he says. “That’s, in a 10-year span roughly, sort of a tremendous change in a relatively small period of time for a really complicated part of our economy.”

According to Tripathi, this gives most practices baseline functionality to document things consistently and create a base of electronic information that did not exist 10 years ago. This has allowed EHR manufacturers to innovate.

Andrew Swanson, M.P.A., CMPE, vice president of industry insights at the Medical Group Management Association, says that the current state of EHR technology is better than it has ever been.

“What’s interesting to me in the (EHR) landscape is that (developers have) done their part to create more flexible platforms to make workflow as flexible as it can be,” Swanson says.

Even with the technology being widely adopted, frustrations persist among physicians — but they aren’t the same agitating factors that irked doctors earlier in the EHR era. Swanson attributes this to the EHR market winnowing to only include reputable developers.

“There’s a reason why you can name the top (EHR) providers on a couple of hands, and (before) you couldn’t do a list of 100 and get them all,” he says. “The cream has risen to the top, and they have taken market dominating positions, either by specialty or by care setting, and that’s helped groups, although there’s less selection.”

He says the complaints he hears now about EHR systems are more related to workflow, ease of use, and downstream and upstream applications of the technology.

“So now it’s no longer, ‘Do we need to use it?’” Swanson says. “Now it’s, ‘How do we make this the most effective tool in our arsenal?’ because we know it’s not going anywhere.”

Leigh Burchell, vice president of policy and government affairs at the practice management and EHR technology company Allscripts and former chair of the Electronic Health Record Association, says that developers have been making efforts to ease physician frustrations with the technology, but a lot of that frustration stems from the wide
range of requirements that must be accommodated by the software.

“So when we are told that we have to ask 13 different questions of a provider or that they now have to gather significantly more information from the patient and then turn that around and report it to four different new places, that is justifiably frustrating to either the doctor in their workflow or to their organization more largely,” she says.

Tripathi says that although many physicians are frustrated with their EHR system, practically no physician is seeking a return to paper. “Everyone recognizes that the move from paper to electronic is the move that we all needed to make,” he says.

Achieving interoperability

The quest for interoperability between EHR systems has been a goal of developers and the government, but Tripathi says that it is more of a moving target than it may seem.

“The truth is that we have a ton of interoperability today,” he says. “And interoperability is always going to evolve; we’re going to always kind of have incrementally more interoperability over time. It’s going to let us do more things than we’re able to do today.”

Burchell agrees that the industry has made strides in interoperability, but there is still more work to be done.

“I think we’re further down the road than a lot of people think we are,” she says. “That said, we are not at our final destination of being truly connected with a liquid state of information.”

Swanson questions whether interoperability is even worth chasing, considering how health information technology is developing.

“We are in a world now where data (are) king, and if outputs of (EHRs) and other patient records (are) still sacred and secure but (become) more shareable, is interoperability even necessary?” he says. “If we have the ability to move massive amounts of data securely, then do I need to hook up one system with the other with an API (application programming interface)?”

What’s on the horizon?

Burchell says she doesn’t know exactly what the EHR of the future will look like but that market leaders are hard at work making these future systems a reality by pushing boundaries of what is currently possible in them. She says there are still restrictions, though, based on how systems are set up.

“The way an EHR functions is tied, at least in some part, to the way the U.S. health care system functions, and a great deal of how an EHR works is driven by the strictures of our payment system,” she says. “That really does have some impact on what we can or can’t do in trying to move away from some of the things that frustrate our clients.”

Swanson sees EHRs adopting new, smarter technology that is easier to use for all practice staff — a move that’s become more important due to staff shortages resulting from the COVID-19 pandemic.

“If you’re new to the front office and medical review and somebody hands you an (EHR) and says, ‘Get in there, record vitals and get this patient roomed and ready to see me’ and you stare at a screen that’s impossible to figure out, you’ll go down the street and work for somebody else who can pay you the same amount of money and not have to deal with this technology challenge,” he says.

Tripathi would like to see EHRs keep developing with open approaches and open industry standards so that innovation can move in the directions dictated by physicians, patients and facilities. As developers continue to build on their own functionality, Tripathi says they should also be supporting a platform-type approach using open APIs or open interfaces that are not proprietary. He sees EHRs becoming almost like iPhones, with base functionality and then a host of specialized apps adding specific functionalities.

“So now it’s no longer, ‘Do we need to use it?’ Now it’s, ‘How do we make this the most effective tool in our arsenal?’ because we know it’s not going anywhere.”

Andrew Swanson, M.P.A., CMPE

“From a federal government perspective, we certainly don’t want to be dictating how EHRs evolve or how software is designed to support providers,” he says. “We just want to make sure that there aren’t artificial constraints on the type of innovation that will emerge.”
Almost every physician practice maintains an employee handbook that sets forth the rules and policies it has established for its employees. However, physician practices need to be careful not to establish an unintentional contract with employees by making it clear that the handbook only contains “guidelines” or “policies” and is not a contract.

Although state law varies on how employee handbooks are interpreted, in an interesting, unpublished decision of the Illinois Appellate Court, a “no contract” handbook disclaimer was upheld and an employee’s breach of contract claim filed against his former employer (a hospital) was dismissed. In that case, the employee alleged that he had an “oral and implied” employment contract based on the hospital’s handbook and other personnel practices, memoranda, policies and procedures. In particular, the handbook established a detailed employee conflict resolution program, which the employee alleged created a formal administrative process for addressing employment disputes. The employee alleged in his lawsuit that the hospital breached the employment agreement between the parties because he was terminated without a proper investigation or hearing as noted in the handbook.

In refuting the claims, the hospital argued that the worker was only an at-will employee and that the handbook did not create a contract. Although the lower court agreed with the hospital and dismissed the complaint, the appellate court recognized on appeal that even at-will employment relationships can become contractual if the elements of a contract are established by an employee handbook or other set of policies. The only way to prevent this from occurring is to include a disclaimer in the handbook, which clearly states that the handbook promises nothing and does not act as a contract.

In this particular case, the hospital’s handbook expressly provided that its “policies and procedures serve as guides” and that the hospital reserves “the right — at its sole discretion — to change, suspend or cancel with or without notice, all or any part of the policies, procedures, programs and benefits discussed in this handbook.” Even more importantly, the handbook contained a specific statement that the handbook did not establish contractual rights, in whole or in part, between the hospital and its associates.

The Appellate court found the hospital’s disclaimer to be clear and unambiguous. The appellate court also contrasted the case with other similar cases and pointed out that employers need to be careful because even when disclaimer language is properly used, it must be sufficiently set off from the rest of the handbook text; otherwise, the disclaimer might be insufficient, and a contract could be deemed to have been created.

To make sure that your employee handbook does not unintentionally create a contract with your employees, consider the following steps:

1. Make sure to include a specific disclaimer in the handbook that no contract is being created.
2. Be sure the statement is clear and conspicuous by using bold and capital letters or even enlarging the font.
3. Set off the disclaimer from the rest of the handbook provisions. Use a title to identify the disclaimer, such as “NO CONTRACT CREATED.”
4. Make sure your handbook describes your policies and procedures as guidelines and expresses that disciplinary action “may or may not” result.

Because the law varies from state to state, review your practice’s handbook, rules and policies with counsel on a regular basis. The above protections may or may not be sufficient in your state to prevent your handbook from becoming a contract.

Ericka L. Adler, J.D., LL.M., has practiced regulatory and transactional health care law for more than 20 years. Send your legal questions to medec@mylifesciences.com.
So, you want to be a doctor?” my pre-med preceptor asked, cocking an eyebrow. “My advice, kid? Don’t do it. Go to business school instead—anything else.” But I was 18, and like most teenagers, I knew better. “He’s just jaded,” I thought. “It won’t be like that for me.”

Thirty years and a global pandemic later, I find myself reflecting more than ever on that conversation. I feel privileged to be a physician, and I love my relationships with my patients (most of the time), but the daily aggravations often feel like death by a thousand paper cuts. And even though I’ve escaped much of the reimbursement rat race by converting to direct primary care, I still find myself frustrated daily by nonsensical demands, such as prior authorizations for generic medications and prolonged peer-to-peer phone calls to get necessary tests approved.

And, of course, add COVID-19 into the equation. Even before the pandemic, doctors were reporting high rates of burnout, with almost half making active plans to leave the profession. Tack on more than a year of full hospitals, social isolation and emotional angst, and some doctors have simply had enough.

But at our first in-person county medical society meeting in nearly two years, I found a balm for my jaded thinking, and it came straight from the Collier County Medical Society’s Physician of the Year, nephrologist, Mark Russo, M.D. His words of wisdom were just what I needed to hear.

“Remember where you started”

Before he became a physician, Russo started working at the bottom rung of the hospital system. “I was a patient transporter, nurses’ aide and psychiatric attendant, and one of my jobs was to walk around and light the patients’ cigarettes,” he said. This made me think about my own days of volunteering in hospitals and clinics to boost my medical school application. I remember how excited I was when a nurse let me check a patient’s blood sugar—I even wrote about it my diary. That pre-med student would be thrilled to know she would one day not only routinely check blood sugars but help patients manage their diabetes.

Take a moment to consider who you were before you started medical school. What motivated you to want to become a physician? What did you write on your medical school application personal statement? Most likely, you talked about wanting to help, to heal and to make a difference in someone’s life. I bet you’re doing exactly that.

Look how far we’ve come

Russo obtained a doctorate in molecular biology but found himself urged to attend medical school by his research mentor and discoverer of the Philadelphia chromosome, Peter C. Nowell, M.D. Recollecting the early days of his medical career, he pointed out how much medicine has improved in the past 20 to 30 years. “Isn’t it great to be practicing medicine now?” he asked. “We have been blessed with improved treatments for cancers, hepatitis C, immunosuppressants [and] mRNA vaccines...”

As a nephrologist, he is ecstatic about research on xenograft transplants. “We may even put dialysis out of business in our lifetime,” Russo said. This outlook resonated with me. Although we’ve struggled with COVID-19, the mRNA technology perfected to prevent the disease may change the trajectory of vaccines for many diseases and even cancer. Although it’s
It’s not all about doctoring

As physicians, we truly do make a difference in the lives of our patients, but we make an impact in other ways, too. Russo talked about the three years he spent working as a wrestling coach before medical school, and he recalls this as one of his favorite jobs. “I was able to help kids become outstanding citizens in their respective communities by instilling the discipline they needed, and they still call or write me, thanking me for teaching them,” he said.

It’s easy to focus on our shortcomings. Instead, take a moment to think about all the people you have helped and inspired over the years. Maybe it was through your work as a doctor, but maybe it was just through a kind word or deed. Know that you make a positive impact on the lives of others every day.

Oftentimes, just being there for someone is enough. “Sometimes we cannot cure or treat. All we may have is our human touch.” Russo said, noting that medicine has been moving away from touch over time. “It’s OK to hug. It’s OK to just hold their hand and comfort them.”

Focus on your friends and family

An entourage of family members accompanied Russo to celebrate his award, and his family’s pride truly touched me. “Mark is the smartest person I know,” his older brother said. “The kid always had his head in a book. I remember the rest of us had to be quiet because he was always studying for some kind of test.”

Rather than focusing on people who don’t matter, such as social media trolls or anonymous reviewers, let’s give our attention to the people who really matter. Remember that we all have our own cheering section of friends and family who want to see us succeed and will be proud of us no matter what.

Own yourself

“My entrepreneurial spirit began when I was around 13 years old,” Russo said. “Everyone in the neighborhood was getting an allowance of $2 to $3 per week, so I asked my dad if I could have an allowance, too. My dad thought about it for a while and finally answered, ‘Yes. I’ve decided I’m going to allow you to continue to live here.'”

Cures for the jaded practice staffer

by Pamela Ballou-Nelson Contributing Author

If they aren’t happy, they’ll leave.

That’s the mantra all employers, including physicians and practice owners, should take to heart. Especially today, during the “Great Resignation” in the wake of the COVID-19 pandemic.

If employees don’t feel valued, they will leave.

Nowhere is this more apparent than in the medical office, where support staff are often under intense pressure to perform and face a daily onslaught of incoming calls, patient visits and other tasks. The typical primary care front desk employee fields 30 inbound calls per day and handles over 1,500 patients and 4,300 total encounters per year, according to the MGMA DataDive Financials and Operations datasets.

It’s a difficult job, and the turnover numbers reflect that. Annual turnover among front office support staff in primary care offices exceeds 18%, and in surgical practices, it’s above 20%. For clinical support staff, these figures are 16% in primary care and 25% in surgical.

This constant upheaval can be draining on the staff that does stay, as they are often forced to pick up the slack and train new employees year after year. But it’s also a financial drag on the practice overall. Hiring over and over again for the same positions is an expensive proposition, not to mention the fact that without effective support staff around them, clinicians can’t do their best work.

Faced with these challenges, many employers turn to employee appreciation programs — handing out performance bonuses, awarding extra vacation time and even providing premium parking options — in hopes of improving the situation. But it turns out these programs can often have the opposite of their intended effect.

In primary care offices that offer employee appreciation programs, front desk turnover is higher than in those without such programs, exceeding 24% annually. Even those categories that see improvements, turnover remains high. With appreciation programs in place, primary care clinical support staff turnover falls to 14%, and front office support staff turnover falls to 15%. We aren’t getting to zero.

What’s the disconnect?

In my experience, it’s that these appreciation programs
So Russo started his own business with his friends, mowing lawns and making $20 to $30 per week. He continued his entrepreneurship as a physician, opening a solo practice, Naples Nephrology, in 2002. In 2007, he added a partner “who is like a sister to me.”

Russo encourages physicians to take a chance on self-ownership, and I couldn’t agree more. After 15 years of employment, opening my own practice was the best thing I ever did. I never thought I could run a business but having physician mentors like Russo helped me realize I could—and you can, too. Talk to colleagues who have opened practices or check your state medical society for resources.

As Russo says, “Follow your dreams!”

6 Don’t be afraid to speak out
“During the pandemic, I was saddened to see mostly politicians speaking about the illness. I yearned to see more physicians,” Russo said. “Many of us answered the call and educated our citizens, leading us to have a strong response to [COVID-19], but when we tried to stand up and guide our leaders, we were pushed aside.” In addition, doctors who tried to speak up were harassed, heckled, and even threatened and abused, which I experienced first-hand when I attended county commissioner and school board meetings on behalf of our medical society.

“We need more voices. We need to be louder,” Russo said. “We need to take back control. This is our lane. This is our automobile. We know how to drive it, not the politicians.”

7 Give back to your community
Russo reminds us that as physicians, we all trained at top-notch, highly competitive universities. “We bring special skills and experience from these tertiary centers into our own communities. We must continue to recruit new physicians to meet the needs of the community,” he said. Consider precepting medical students or residents and taking newer doctors under your wing to show them the ropes and provide support.

Russo also challenges physicians to serve the community outside of medicine. Volunteer work has been shown to lead to improved physical and mental health, and also allows us to be a part of molding the community we want to live in.

Rebekah Bernard, M.D., is a family physician practicing in Fort Myers, Florida, and is the author of “How to Be a Rock Star Doctor.”

—are not aligned with what workers truly value. Yes, having an employee appreciation program is important, but it must go beyond just platitudes and handouts to be effective at reducing turnover. It must offer more than bonuses and instead provide employees with real value.

Effective employee appreciation programs usually offer some combination of the following:

**Connection** Everyone needs to feel like they are part of a team and that their contributions to the office are valued. In well-run practices, everyone talks. They meet on a regular basis and discuss everything that is going on in the practice. This ensures the front desk staff knows what’s happening in the back and better understands why they do things the way they do and vice versa. That way, everyone on the team is part of the patients’ care. They aren’t just there to answer phones and greet people.

**Trust** Too often, support staff feel like their ideas and input aren’t valued and that they can’t share what they want to share with the rest of the team. Assuming the meetings required to facilitate connection are happening, trust means taking the good ideas that come from those meetings and putting them into practice.

**Training** Clinicians must be willing to spend money on training their staff comprehensively, which includes communication skills, technology tools, and organization and project management. This not only helps workers feel comfortable in their day-to-day work, but it also assures them that they’re providing real value and are contributing to the success of the organization as a whole.

**Comfort** No one wants to spend their day crammed into a small cubicle, sitting behind a sliding glass window. Does your support staff have enough space to work comfortably? Do they have space to eat lunch? Is there a staff lounge area? The entire atmosphere of the office is a way to show appreciation.

**Room for advancement** Many people start working in health care because they want to make a difference and help people. Maybe that means moving from the front office to take on more of a clinical role as a medical assistant. Having an interest in health care doesn’t have to end at the front desk, especially for those who are interested in progressing in the field.

Working in a private medical practice can be challenging, with heavy workloads, endless patient demands and near-constant interruptions. A basic employee appreciation plan isn’t going to make the day-to-day any easier for support staff. But an appreciation plan that does more — that shows employees how much you truly trust and respect them — can make all the difference in the world, turning employees into real team members who excel and, just as important, stick around.
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