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 (e.g., 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
- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%)

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SGX:RNA190019 July 2019 
Produced in the USA.
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 (e.g., 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.

• Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%).

• Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%).

• SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion.

• Vaccination with SHINGRIX may not result in protection of all vaccine recipients.

Please see Brief Summary of Prescribing Information for SHINGRIX on the following pages.

BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

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

1 INDICATIONS AND USAGE

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

Limitations of Use:

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE AND ADMINISTRATION

2.2 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 anytime between 2 and 6 months later.

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

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

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

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

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

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX; n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%), respectively.

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

<table>
<thead>
<tr>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
<td><strong>Local Adverse Reactions</strong></td>
<td><strong>Local Adverse Reactions</strong></td>
</tr>
<tr>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td>88.4</td>
<td>14.4</td>
</tr>
<tr>
<td><strong>Pain, Grade 3</strong></td>
<td>10.3</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Redness</strong></td>
<td>38.7</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>Redness, &gt;100 mm</strong></td>
<td>2.8</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Swelling</strong></td>
<td>30.5</td>
<td>0.8</td>
</tr>
<tr>
<td><strong>Swelling, &gt;100 mm</strong></td>
<td>1.1</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>General Adverse Events</strong></td>
<td><strong>General Adverse Events</strong></td>
<td><strong>General Adverse Events</strong></td>
</tr>
<tr>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
</tr>
<tr>
<td><strong>Myalgia</strong></td>
<td>56.9</td>
<td>15.2</td>
</tr>
<tr>
<td><strong>Myalgia, Grade 3</strong></td>
<td>8.9</td>
<td>0.9</td>
</tr>
<tr>
<td><strong>Fatigue</strong></td>
<td>57.0</td>
<td>19.8</td>
</tr>
<tr>
<td><strong>Fatigue, Grade 3</strong></td>
<td>8.5</td>
<td>1.8</td>
</tr>
<tr>
<td><strong>Headache</strong></td>
<td>50.6</td>
<td>21.6</td>
</tr>
<tr>
<td><strong>Headache, Grade 3</strong></td>
<td>6.0</td>
<td>1.7</td>
</tr>
<tr>
<td><strong>Shivering</strong></td>
<td>35.8</td>
<td>7.4</td>
</tr>
<tr>
<td><strong>Shivering, Grade 3</strong></td>
<td>6.8</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Fever</strong></td>
<td>27.8</td>
<td>3.0</td>
</tr>
<tr>
<td><strong>Fever, Grade 3</strong></td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>GI</strong></td>
<td>24.3</td>
<td>10.7</td>
</tr>
<tr>
<td><strong>GI, Grade 3</strong></td>
<td>2.1</td>
<td>0.7</td>
</tr>
</tbody>
</table>

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

a 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.

Placebo was a saline solution.

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

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

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.

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

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

There were no differences in the proportions of subjects reporting any Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 13.8%, respectively). Grade 3 solicited general adverse (continued on next page)
events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, 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 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

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

Serious Adverse Events (SAEs)

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

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

Deaths

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

Potential Immune-Mediated Diseases

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

Dosing Schedule

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

6.2 Postmarketing Experience

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

General Disorders and Administration Site Conditions

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

Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

For concomitant administration of SHINGRIX with inactivated influenza vaccine [see Clinical Studies (14.9) of full prescribing information].

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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

8.2 Lactation

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

8.5 Geriatric Use

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (48.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

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

17 PATIENT COUNSELING INFORMATION

• Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.

• Inform patients about the potential for adverse reactions that have been temporally associated with administration of SHINGRIX.

• Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Storage:

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

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CHAIRMAN’S LETTER

Code telehealth right to get paid

Telehealth and other forms of remote care are surging in popularity as the country remains tight in the grip of the COVID-19 pandemic. Right now, technology is the lifeline that is connecting physicians and patients.

The growth of these platforms is simply stunning. In April alone, the volume of telehealth claim lines increased more than 8,000%, according to a study by nonprofit group FAIR Health.

On the physician side of the equation, there’s another wrinkle beyond setting up your webcam and making sure your patients are ready and comfortable: getting paid for providing telehealth services.

As always, getting paid requires coding and documenting your encounters clearly and accurately.

This month, our cover story is about coding for telehealth and other remote care. It’s the first half of our two-part coding guide, which will conclude in September. The guide breaks down accurate coding for other important programs, including evaluation and management services, chronic care management, transitional care and more.

We also take a close look this month at value-based care models and how the pandemic is affecting them. The highlight is an interview with Farzad Mostashari, M.D., who has some interesting things to say about how value-based care can save primary care practices from financial ruin — you won’t want to miss it.

Other important articles in this month’s issue include:

- How practices can prepare for double jeopardy this fall, when COVID-19 cases combine with cases of the seasonal flu.
- Rebekah Bernard, M.D., wrote a passionate and heartfelt column on bias and how physicians can deal with their own. As our country confronts important issues concerning racial disparity, Bernard’s piece is a must-read and provides tips on how physicians can look inside and change for the better.
- The COVID-19 pandemic is changing many things, including the malpractice landscape. This issue also features an interview with Sean P. Byrne, J.D., a malpractice defense lawyer who has a lot to say about what physicians can do to protect themselves.

We hope the content in this issue helps you, your practice and your patients get through this tough time. As always, stay healthy!

Mike Hennessy Sr.
Chairman and Founder of MJH Life Sciences™
What are the risks associated with telemedicine?
We’re barely making payroll, what if we can’t make a payment?
I’m a retired doc that wants to help, will I be covered?
Will my premium be lower while I’m closed or not doing certain surgeries?
What do you do to help burned out physicians serving on the frontline?
Am I covered if I get infected?
How do we keep our practice safe?

Visit the ProAssurance COVID-19 Information Center to find frequently updated information gathered to support your medical professional liability coverage decisions.

You’ll find helpful risk guidelines, policy updates, and crisis support at ProAssurance.com/COVID-19.

For ProAssurance policyholder information and resources

ProAssurance.com/COVID-19
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   What practices must do to ensure they have the PPE and staff to treat patients this fall.

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Our exclusive survey shows how recent economic fallout is harming practices.

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COVID-19 COVERAGE CENTRAL

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

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

To read all of our ongoing coverage, go to [MedicalEconomics.com](http://MedicalEconomics.com)

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**Perfect your telehealth program**

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

Watch this video and others at: [bit.ly/MedEcVideo](http://bit.ly/MedEcVideo)

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Have a question for our advisers? medec@mmhgroup.com
Walgreens will open hundreds of primary care clinics

Walgreens will open 500 to 700 primary care, full-service clinics in their stores within the next five years, with plans to open hundreds more afterward.

According to a news release, the move comes after a successful pilot program last year in Texas. The clinics will be called Village Medical at Walgreens and will be part of a $1 billion investment the drugstore chain is making in its partnership with VillageMD. They will integrate Walgreens pharmacists into a group of 3,600 physicians recruited by VillageMD.

“This rollout is a major advancement of one of Walgreens Boots Alliance’s four key strategic priorities, Creating Neighborhood Health Destinations,” says Stefano Pessina, executive vice chairman and CEO of Walgreens Boots Alliance, in the release. “These clinics at our conveniently located stores are a significant step forward in creating the pharmacy of the future, meeting many essential health needs all under one roof as well as through other channels.”

The clinics will accept an array of health insurance providers and will “offer comprehensive primary care across a broad range of physician services,” according to the release. They will offer 24/7 care through telehealth and in-office visits, and more than 50% of the clinics will be in areas with physician shortages, according to the release.

“In the U.S., we spend $4 trillion per year on health care, over 85% of that is tied to patients with chronic diseases. To improve our health care system and reverse the trajectory of health spending, we must meet the needs of all patients. This partnership allows us to unleash the power of primary care doctors and pharmacists, enabling them to work in a coordinated way to enhance the patient experience,” says Tim Barry, chairman and CEO of VillageMD.

— Keith A. Reynolds, associate editor

Patients happy with virtual care, survey shows

Results of a survey by medical software provider Kyruus of 1,000 adult patients found that nearly three quarters had tried virtual care during the COVID-19 crisis and more than 75% were very or completely satisfied with their experience.

However, the results suggest that health care organizations can take steps to enhance the experience and make it more seamless for patients. Key findings include:

- **Patients want to keep using virtual care.** Patients reported being very or extremely likely to use virtual care for a wide variety of appointments, with the top three being wellness check-ins (60%), surgery/procedure-related visits (58%) and visits for COVID-19 (58%).

- **There is a high demand for online scheduling.** While only 30% of respondents booked their virtual visits online, 54% would prefer this booking method in the future. Online is the clear preference among both members of Generation X at 72% and millennials at 64%, respectively.

- **Awareness about how to access virtual care is relatively low.** Fewer than half of respondents said they understood clearly how to access virtual care visits.

- **Patients will use virtual care even if they have to pay.** Almost half of respondents said they would still use virtual care to some degree in the future even if their insurance did not cover it. 25% whenever possible and 21% on a limited basis.

— Todd Shryock, managing editor
How value-based care can save your practice

by Chris Mazzolini, M.S., editorial director

Primary care is in the midst of a crisis. Many practices face the possibility of closure as they deal with fallout from the COVID-19 pandemic. So what can physicians do to save their practices and treat their patients effectively? Farzad Mostashari, M.D., says physicians should embrace risk.

And by risk, he means value-based care. Mostashari contends that the fee-for-service system has exacerbated these financial struggles and that the way forward is to accelerate the evolution of how physicians are paid for providing care. In a wide-ranging conversation, we discuss value-based care, telehealth and what the ideal primary care practice of the future should look like.

Mostashari is the former director of the Office of the National Coordinator for Health IT and current CEO of Aledade. Based in Bethesda, Maryland, Aledade assists small practices with transitioning to value-based care models. This interview has been edited for length and clarity.

Medical Economics®: What is the state of primary care right now? What are practices going through and how do we fix primary care so that they can succeed in the future, given the challenges?

Mostashari: Primary care has never been more needed. We have obviously a lot of need for primary care on the front lines of COVID-19. We all hear about hospital workers who are at risk of being infected with COVID-19, but those patients who end up in the hospital first went to their primary care practices. And those primary care doctors aren’t like you and me, who get to stay home and socially distance ourselves. Those primary care practices are exposed to every patient who walks in the door, and they care for them. They close the door, they’re in a room with them, often with inadequate personal protective equipment, because the supply chain for those small practices is broken, they could not order masks.

These primary care heroes have been caring for patients, helping patients stay home and healthy and telling them, “Don’t come in if you don’t need to.” But that means under their current business model of primary care, they are struggling financially, because the only way they had been getting paid is by doing visits — not by answering phone calls or reaching out to patients. And so, at the very time we need primary care the most, we see more and more practices that were fee-for-service threatened with going out of business.

So it’s not a good time for primary care. They’re worried about themselves. They’re worried about their family members. They’re worried about their staff, and they’re worried about how to make payroll.

Medical Economics®: What is the state of primary care right now? What are practices going through and how do we fix primary care so that they can succeed in the future, given the challenges?

Mostashari: This is quite topical. [Recently] BlueCross BlueShield of North Carolina announced a program that we’ve been working with them on for some time now, where they are leading the way on this issue for any health plans, in terms of thinking of what should be done to save these independent primary care practices. Quite simply, what they’re saying is, we
will give you a lump sum payment to make up the loss of revenue that you had this year. There’s no clawback, if they miscalculate; there are no additional reporting requirements.

The one requirement is that you enter into a total cost-of-care accountability contract. Aledade is honored to be the partner helping support those practices and succeeding in these value-based contracts.

And guess what? If you’re in one of those value-based contracts now you’re less dependent on fee for service. Our North Carolina practices, like those in other parts of the country, are getting hundreds of thousands of dollars in payments — not for patients walking in the door, but for patients being healthy and at home and not having to go to the hospital. That is what we should be doing. We should be keeping independent primary care practices whole and using this as an opportunity to move toward value-based care.

How do you see value-based care approaches evolving, given this cataclysmic event?

Mostashari: It’s a cataclysmic event as far as fee for service goes, with hundreds of billions of dollars of bailouts required to compensate hospitals and others for lost revenue from people not walking in the door for fee for service. Value-based care is fine. It hasn’t needed a bailout. The ACO [accountable care organization] models are pretty robust. You have to say, “Can we be better than if we weren’t in an ACO? Can we respond faster to the needs of the patients? Can we educate the patients? Can we take care of their preventive care? Can we deal with care transitions? Can we deal with our medication issues?” All of the things that we are working on with our practices to do a good job on the value-based contract is exactly what you would want to do for your mother at the time of COVID-19. Right? You would want her primary care practice to reach out and let her know she can call us first, we’ll see her on video, we’ll talk to her on the phone. If she has any problems, we’ll send her a 90-day prescription so she doesn’t have to go to the pharmacy in person. It’s all the things that you would want done for her. And if she does end up in the emergency department, we’ll call to see how she’s doing and follow up. That’s what we should be doing anyway. It’s just that the current payment system didn’t support it.

Q&A / PRACTICE MANAGEMENT

What does the ideal primary care system of the future look like?

“I think the key is to really break the fallacy that fee for service is a good way to pay for primary care.”

Mostashari: Telehealth has a long history of problems with reimbursement, because the concern on the part of the health plans and Medicare and others is it’s not going to substitute for face-to-face visits, that it’s just going to be additive, it’s going to increase costs, it’s going to be harder to trace for fraud and abuse purposes. All of those issues are suspended now, because we can’t get any face-to-face visits, and this is a substitution for the loss of care. But when things go back to normal — and things will go back to normal — the question is whether this [telehealth surge] is just a blip or whether this is going to be the new way of delivering care. And I think people are being too optimistic to assume that all the flexibilities and parity that have come with telehealth during this period will continue.

I think the solution is to take risks. The solution is saying to the health plan, “Hey, we’re not going to run up the bill on telehealth because we have an incentive to care about the total cost of care.” More risk is more freedom, in that sense, because if you’re on the same side as the payer, then they’ll say, “You’ll deliver the care however you want to deliver it, I don’t care, because you have the same incentives to keep the person healthy and out of the hospital, as opposed to running up the bill.”
ME: Things are starting to open up in much of the country while there also is a surge in cases in many places. So you have to navigate this fine line of doing what’s right in terms of not seeing patients in person while keeping your business afloat. What are some ways to navigate these challenges?

Mostashari: The good thing about working with independent practices is that the north star is what’s best for the patient, sometimes to the detriment of their business, right? But if you work for an organization that has a big finance department, then the finance people can tell you how you should practice medicine. That’s not the case with these independent practices; they do what’s right for the patient.

ME: What’s right for the patient in this case is: If we can deliver care to you remotely, we should do it that way. And if you have potential COVID-19, then we need to keep you and other people safe. So a lot of it has work done in terms of creating new workflows and protocols for how to do testing in the parking lot, how to keep separate entrances, how to put people behind [acrylic shields], how to keep the waiting room empty. We have to reopen the practices so that we can get primary care in person to the people who need in-person care, but we have to do it in a way that’s safe for the practice staff and safe for other patients.

ME: Let’s talk about the strain and mental toll this is taking on physicians. What do we need to do to take care of them?

Mostashari: I’m very worried about burnout. I’m very worried about the pressures that are on our frontline primary care doctors and their staff. The worry that that we all feel — that uncertainty is compounded when you’re a small-business owner. You’re worrying about your finances, you’re worrying about your employees, you may have to do layoffs, you worry about your safety and you’re worried about bringing COVID-19 home to your family. I don’t think it’s appreciated enough the daily toll it takes to go in, expose yourself and then come home. I talked to one primary care provider who told me, “I come home and just scrub myself raw.” Living with that is taking a toll.

Caring for those who care for us, right now we need to do that. And we need to go beyond bumper stickers or signs that say thank you for the essential workers. We actually need to, as a country, follow through on providing them with the support they need.

ME: Let’s get more optimistic. What do the ideal primary care system and practice of the future look like?

Mostashari: I think the key is to really break the fallacy that fee for service is a good way to pay for primary care. We’ve kind of limped along and made it work based on compassion and professional ethos. And now I think we’re seeing this is just no way to run the zoo. We shouldn’t be basing primary care payments on that. It should be on the value created and we need to move toward more person-based rather than transactional [encounters]. Primary care is very much a person-based, longitudinal relationship kind of work, and we should be paying for it based on person-based longitudinal care and holding people accountable for total cost, total quality, total experience of care.

And I think that’s the optimistic view, that we will get to the point where we’re going to have more freedom for primary care to deliver care the way they see fit.

ME: What do you think the pandemic has revealed about our health care system?

Mostashari: We’ve talked a lot about how broken fee for service is and how we don’t have the systems to really support these independent smaller practices. The plus side is you never thought you’d see things move so quickly. We saw change within days on policy, regulations, payment models, technology adoption and telehealth. We saw a change in days that you would have thought would take years under the normal course. So that to me is the positive. We have responded. It’s shown that our health care system [is] getting up, sprinting and realizing, “Oh, I didn’t realize I could still sprint!” It is a good reminder that we can do it when we need to.

But even as we’re in the midst of an emergency, we need to be thinking around the bend.
Preventing for a second wave of COVID-19

Practices must take these steps to ensure they are ready

by Keith Loria, contributing author

Even though the first wave of COVID-19 cases is still happening, health experts warn that once the weather gets cooler in the fall, a second wave of cases is likely to arrive.

And if the wave coincides with the start of flu season, it would put an enormous strain on doctors and their practices. That’s why practices should start preparing now.

With an increase in the number of patients with cough and fever symptoms, the problem lies in how to differentiate illnesses. Doctors will need to correctly and quickly distinguish COVID-19 from the flu, strep throat, or other viral illnesses.

Alicia Wright, M.D., a pediatrician for Holston Medical Group in Kingsport, Tennessee, says it’s important to keep patients who have symptoms of COVID-19 separate from those who do not.

“We are continuing to perfect our social distancing and virtual visit protocols so that it becomes second nature for our staff and providers,” Wright says. “This includes masking, temperature screening, call triage, making sure our lobbies are social distanced enough, as well as improving our survey questionnaires at the beginning of every visit. Perfecting these protocols practiced each day puts us and our patients in a safer position so whenever the illness does return, we are really prepared.”

Jeff Bullard, M.D., family medicine specialist at MaxHealth in Colleyville, Texas, notes his practice’s greatest challenge with the initial wave of COVID-19 was lack of preparedness.

“We have had to develop infection-control policies, navigate PPE [personal protective equipment] procurement and learn new ways to communicate with patients,” he says. “The most glaring challenge was how to deliver care. [COVID-19] required a rapid shift from brick and mortar to virtual care delivery, which for most of us was a new skill.”

Stock up on PPE

Coordinating PPE procurement was a big obstacle when the coronavirus first started spreading. It’s expected to continue to be a concern, as everyone needs the same equipment at the same time.

“Maintaining relationships with suppliers as well as leaning on the local community are two important factors in making sure practices maintain the appropriate amount of PPE,” Wright says.

For example, she suggests reaching out to the community to ask for donations of homemade face masks, face shields, and goggles. Some local manufacturers have shifted their production lines to make hand sanitizer.

Most practices don’t routinely maintain a stockpile of PPE to manage pandemic-level events. Bullard says the lack of PPE greatly affected his ability to see patients in the office early on and also hindered the practice’s ability to be a testing resource for patients.

“To prepare for a second wave, clinics must begin ordering PPE now,” he says. “Most distributors are allocating monthly supplies of PPE to outpatient clinics but only a limited amount with each order. By ordering frequently throughout the summer, you should be able to build a decent stockpile before flu season and what many believe will be the return of [COVID-19].”

For many practices, finding vendors that can sanitize N95 masks has been challenging, and this is where partnerships with state resources and national associations may be helpful in finding solutions.

Providing care

It’s also vital that physicians prepare for the next wave of COVID-19 by maintaining competencies gained during the first wave.

As the pandemic began and many facilities started closing, proactive physicians were finding alternative ways to care for and communicate with patients. If a second wave comes in the fall, physicians will find themselves once again experiencing closures and shelter-in-place orders.
Physicians will need to let patients know what options are available to contact them and spell out circumstances in which they may need an in-person visit versus a virtual encounter.

Telehealth and virtual visits help ensure the continued delivery of health care during times of high COVID-19 activity, which is particularly critical for individuals in high-risk groups.

During the upcoming flu season, doctors will need to leverage telehealth to virtually assess symptomatic patients and conduct drive-through flu and COVID-19 testing.

Practices should be building these protocols now, Bullard says. “Most doctors are now well down that path of optimizing and integrating this new delivery model,” he says. “At the same time, factors like the fear of a reversal of insurance parity and the need to rightsize the financial strain COVID-19 has placed on practices are tempting doctors to move back to what was comfortable and abandon televisits in favor of in-office visits.”

**Communication matters**

Excluding appointment reminders and lab follow-up, practice communication historically focused on managing incoming patient requests. The is not a winning strategy in the COVID-19 era.

In recent months, fear of infection and lack of information have left patients uncertain about how to address their health care needs, as shown by the reported 30% to 70% decrease in physician visits around the country, including a survey from the Commonwealth Fund.

Physicians must stay highly engaged with their patients as COVID-19 continues to disrupt health care delivery and traditional access. What may have once felt like overcommunicating...
COVID-19’s Second Wave / Practice Management

"I think the most important thing is for our staff and patients to know that their safety is our highest priority. We aim to take measures to ensure that patients and staff are confident that their well-being is being protected."

— Alicia Wright, M.D., pediatrician, Holston Medical Group, Kingsport, Tennessee

A decrease is physician visits around the United States since the beginning of the COVID-19 pandemic.

Source: The Commonwealth Fund

"They can be helped by assuring all PPEs are available, even the ones not used for [COVID-19], monitoring their quality so that they can feel as safe as possible," he says. “Front-line personnel should develop proper management strategies, including rigid time off and [standard procedures] developed during the first wave.”

A practice’s staff must feel prepared and have the appropriate resources to do their jobs each day, especially when dealing with COVID-19 situations.

“Look for every opportunity to communicate with your staff,” Bullard says. “Along with the ongoing worry about employment sustainability, workers are also concerned about their health and the health of their families. Keep your employees informed about the financial stability of the practice and all you are doing to assure their continued employment.”

Additionally, he says to develop a robust clinic safety plan. It should include work site cleaning, contamination prevention and patient triage protocols, along with infection control policies that will be followed if patients who test positive for COVID-19 receive care at the practice.

“Review the plan details, and the logic behind it, with all your employees,” Bullard says. “Take every opportunity to engage your employees as participants or even as monitors who are responsible for assuring plan adoption and success. This gives everyone an opportunity to hold some control over their environment. Even more, it lets them know that their safety is an important matter that you care about.”

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Content from
PHYSICIANS PRACTICE

Staff issues
Stuart A. Meyers, M.D., an internist in Woodbridge, Va., says that COVID-19 causes a very stressful scenario for those who work on the front line.

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Stuart A. Meyers, M.D., an internist in Woodbridge, Va., says that COVID-19 causes a very stressful scenario for those who work on the front line.
Telehealth coding guide:
Code it right, get paid

by Lisa A. Eramo, M.A., contributing author

There’s nothing more frustrating than rendering a service and not being paid. Nuanced coding rules are difficult to understand, and physicians aren’t taught this information in medical school.

Still, health care is a business. As business owners, physicians need to know how they’re paid, including what codes to use, what modifiers to append and what details to document.

Brushing up on common coding mistakes helps avoid costly recoupments and denials. We’ve asked several coding experts to provide their best advice on how physicians can maintain compliance and collect all of the revenue to which they’re entitled.

In part 1 of our two-part coding guide, we focused on coding for telehealth and other forms of remote patient care — important codes for physician practices’ short-term survival as the U.S. continues to grapple with the COVID-19 pandemic.
In times of social distancing, telephone services have become a practical way to improve patient access and prevent spread of COVID-19. Telephone services are ideal for straightforward problems (e.g., simple rash, asymptomatic cough, medication refills) that require a minimum of five minutes of medical discussion, says Toni Elhoms, CCS, CPC, chief executive officer of Alpha Coding Experts, LLC, in Orlando, Florida. Consider the following codes that Medicare accepts during the current public health emergency (PHE). Commercial payers may accept these codes, as well. Note that once the PHE has concluded, Medicare may only accept G2012 (virtual check-in) for telephone services.

Elhoms provides these tips to ensure compliance:

- **Document verbal consent, including patient acknowledgement and acceptance of any copayments or coinsurance amounts due.**
- **Only count time spent on the phone engaging in medical discussion with the patient or caregiver. Do not report these codes for conversations lasting less than five minutes.**

The best way to operationalize these codes is to set up an edit in the practice management system that pending claims for a manual review to determine whether and which services are ultimately billable, Elhoms says.

### CPT Codes for Telephone Services

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
<th>TIME</th>
<th>2020 NATIONAL AVERAGE MEDICARE PAYMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>99441</td>
<td>Telephone evaluation and management (E/M) service by a physician or other qualified health care professional</td>
<td>5-10 minutes of medical discussion</td>
<td>$14.44</td>
</tr>
<tr>
<td>99442</td>
<td>Telephone E/M service by a physician or other qualified health care professional</td>
<td>11-20 minutes of medical discussion</td>
<td>$28.15</td>
</tr>
<tr>
<td>99443</td>
<td>Telephone E/M service by a physician or other qualified health care professional</td>
<td>21-30 minutes of medical discussion</td>
<td>$41.14</td>
</tr>
<tr>
<td>98966</td>
<td>Telephone assessment and management service provided by a qualified nonphysician health care professional</td>
<td>5-10 minutes of medical discussion</td>
<td>$14.44</td>
</tr>
<tr>
<td>98967</td>
<td>Telephone assessment and management service provided by a qualified nonphysician health care professional</td>
<td>11-20 minutes of medical discussion</td>
<td>$28.15</td>
</tr>
<tr>
<td>98968</td>
<td>Telephone assessment and management service provided by a qualified nonphysician health care professional</td>
<td>21-30 minutes of medical discussion</td>
<td>$41.14</td>
</tr>
<tr>
<td>G2012</td>
<td>Virtual check-in</td>
<td>5-10 minutes of medical discussion</td>
<td>$14.80</td>
</tr>
</tbody>
</table>
In the last few months, providers have adopted telehealth to improve patient access and generate revenue during COVID-19. Among the services physicians can render via telehealth to patients with Medicare during the current PHE are Medicare annual wellness visits, new and established patient office visits, prolonged services, smoking and tobacco cessation counseling, annual depression and alcohol screenings, advanced care planning and more. Medicare covers more than 200 services via telehealth, many of which were added for temporary coverage during the current PHE. Commercial payer coverage of these services may vary, and it’s best to check with individual payers, Elhoms says.

Elhoms provides these tips for billing telehealth services:

- **Pay attention to audio-only vs. audio-visual requirements.** Medicare requires the use of audio-visual technology for certain telehealth services and permits audio-only for others. Commercial payers also may have specific requirements. For example, physicians can render a telehealth visit for advanced care planning using audio only, but they must use audio-visual technology for a new patient telehealth office visit.

- **Don’t render Medicare’s Initial Preventive Physical Exam via telehealth.** Medicare does not permit it.

- **Document verbal consent for telehealth, including patient acceptance of any copayments or coinsurance amounts due.**

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

- **Document, document, document.** Physicians need to prove they met all of the code requirements even when rendering the service via telehealth, Elhoms says. “Don’t pull in a problem list if you didn’t treat or manage all of those problems,” she adds. “Physicians need to link the diagnosis with the assessment and treatment plan. That’s imperative.” One caveat is that during the current PHE, physicians can bill 99201-99215 rendered via telehealth based on time or medical decision-making. “The total time in direct medical discussion with the patient is going to be critical,” Elhoms says.

“The best advice I can give anyone doing telehealth right now is to watch the CMS [Centers for Medicare & Medicaid Services] and commercial payer websites pretty much on a daily basis,” says Rhonda Buckholz, CPC, CPMA, owner of Coding and Reimbursement Experts in Pittsburgh, Pennsylvania. “The coding of services changes constantly, and practices really need to be careful.”

### Online digital E/M services

Though online digital E/M services are relatively new, they also can help practices increase patient access during COVID-19. Here’s how it works: An established patient initiates a conversation through a HIPAA-compliant secure platform (e.g., electronic health record portals, secure email, secure texting). A physician or other qualified health care professional reviews the query, as well as any pertinent data and records. Then they develop a management plan and subsequently communicate that plan to the patient or their caregiver through online, telephone, email or other digitally supported communication.
Consider the following codes that Medicare currently accepts during the PHE.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
<th>2020 NATIONAL AVERAGE MEDICARE PAYMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>99421*</td>
<td>Online digital E/M service for an established patient for up to seven days (cumulative time), 5-10 minutes</td>
<td>$15.52</td>
</tr>
<tr>
<td>99422*</td>
<td>Online digital E/M service for an established patient for up to seven days (cumulative time), 11-20 minutes</td>
<td>$31.04</td>
</tr>
<tr>
<td>99423*</td>
<td>Online digital E/M service for an established patient for up to seven days (cumulative time), 21 or more minutes</td>
<td>$50.16</td>
</tr>
<tr>
<td>G2061</td>
<td>Qualified nonphysician health care professional online digital E/M service for an established patient for up to seven days (cumulative time), 5-10 minutes</td>
<td>$12.27</td>
</tr>
<tr>
<td>G2062</td>
<td>Qualified nonphysician health care professional online digital E/M service for an established patient for up to seven days (cumulative time), 11-20 minutes</td>
<td>$21.65</td>
</tr>
<tr>
<td>G2063</td>
<td>Qualified nonphysician health care professional online digital E/M service for an established patient for up to seven days (cumulative time), 21 or more minutes</td>
<td>$33.92</td>
</tr>
</tbody>
</table>

*Commercial payers may accept these codes as well.

Commercial payers may also accept the following codes for qualified nonphysician health care professionals:

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
<th>PAYMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>98970</td>
<td>Qualified nonphysician health care professional online digital E/M service for an established patient for up to seven days (cumulative time), 5-10 minutes</td>
<td>Payment varies depending on commercial payer.</td>
</tr>
<tr>
<td>98971</td>
<td>Qualified nonphysician health care professional online digital E/M service for an established patient for up to seven days (cumulative time), 11-20 minutes</td>
<td>Payment varies depending on commercial payer.</td>
</tr>
<tr>
<td>98972</td>
<td>Qualified nonphysician health care professional online digital E/M service for an established patient for up to seven days (cumulative time), 21 or more minutes</td>
<td>Payment varies depending on commercial payer.</td>
</tr>
</tbody>
</table>

Elhoms provides these tips to maintain compliance:

- Use these codes when physicians or other qualified health care professionals make a clinical decision that would otherwise occur during an office visit. Do not use them for scheduling appointments or nonevaluative communication of test results.

- Use these codes only for established patients.

- Do not use these codes for fewer than five minutes of E/M services.

- Document verbal consent, including patient acknowledgement and acceptance of any copayments or coinsurance amounts due.

- Do not report these codes when the online digital E/M service ends with a decision to see the patient in 24 hours or the next available urgent visit appointment.

- Do not report these codes when the online digital E/M service relates to a related E/M service performed within the previous seven days or within the postoperative period of a previously completed procedure.

Promoting these services is often the biggest barrier, says Elhoms, who suggests putting up signs letting patients know they can access their provider electronically for nonurgent medical issues.
Remote patient monitoring (RPM) is a relatively easy way for physicians to keep tabs on patients without requiring them to come into the office. Medicare covers RPM for patients with one or more acute or chronic conditions, and commercial payer coverage may vary. During the PHE, physicians can initiate RPM on new and established patients. Normally, Medicare permits it only for established patients.

RPM consists of two forms: monitoring data through either a non-manual or manual data transfer, says Jim Collins, CPC, CCC, consultant at CardiologyCoder.com, Inc. in Saratoga Springs, New York.

For example, physicians can remotely monitor a patient’s pulse oximetry, weight, blood pressure or respiratory flow rate using a device that transmits daily recordings or programmed alerts. Physicians can purchase them directly from manufacturers or patients can purchase the devices themselves. Collins says patients should look for Bluetooth-enabled devices or ones that include a built-in Global System for Mobile Communications (GSM) transmitter. The former requires an Internet connection, and the latter automatically transmits data to an internet cloud service through an encrypted bandwidth. Physicians can bill for the initial setup, cost of the device itself (when applicable) and data monitoring.

Another example is self-measured blood pressure monitoring. When patients supply their own blood pressure device that a physician calibrates, physicians may be able to bill for patient education, device calibration, reviewing the data that the patient provides and communicating a treatment plan to the patient or caregiver.

Consider the following relevant codes:

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
<th>2020 NATIONAL AVERAGE MEDICARE PAYMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>99453</td>
<td>Initial device setup and patient education</td>
<td>$18.77</td>
</tr>
<tr>
<td>99454</td>
<td>Rental fee for devices that supply daily recordings or programmed alert transmissions for 30 days</td>
<td>$62.44</td>
</tr>
<tr>
<td>99457</td>
<td>RPM treatment management service by clinical staff, physicians or other qualified health care professionals requiring 20 minutes of live, interactive communication with the patient or caregiver during a 30-day period</td>
<td>$51.61</td>
</tr>
<tr>
<td>99458</td>
<td>[Each additional 20 minutes]</td>
<td>$42.22</td>
</tr>
<tr>
<td>99473</td>
<td>Self-measured blood pressure using a device validated for clinical accuracy (including patient education/training and device calibration)</td>
<td>$11.19</td>
</tr>
<tr>
<td>99474</td>
<td>Collection and review of separate self-measurements of two readings, one minute apart, twice daily over a 30-day period (minimum of 12 readings), and communication of a treatment plan as well as average systolic and diastolic pressures to the patient</td>
<td>$15.16</td>
</tr>
</tbody>
</table>

“Monitoring physiologic data on a regular basis substantially reduces hospitalizations, trips to the emergency room and exacerbations of chronic conditions,” says Collins. “It can also be a huge chunk of revenue.”

Collins provides these tips for compliant RPM billing:

- **Document patient consent.** Patients must opt in for these services.
- **Document total time spent rendering these services to support time-based requirements.**
- **Know when these codes are appropriate.** It’s unclear whether Medicare will pay physicians for monitoring physiologic data derived from internal devices (devices placed within the patient’s body) or data derived from wearable fitness devices.
- **Only bill 99457 when the provider renders at least 20 minutes of live, interactive communication with the patient or caregiver.** “It’s not going to be medically necessary to spend 20 minutes every month on every patient,” Collins says. “Patients could go for several months without physicians needing to do anything for them.”
You’ve controlled their A1c and blood pressure. But your patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) are still at risk.1-3

**Inflammation and Fibrosis Are Destroying Your Patients’ Kidneys**

CKD progression in T2D is influenced by 3 major drivers1-4:

**METABOLIC DRIVERS**
- Elevated blood glucose (A1c) levels

**HEMODYNAMIC DRIVERS**
- Rise in blood pressure
- High intraglomerular pressure

**INFLAMMATORY AND FIBROTIC DRIVERS**
- Proinflammatory cytokines
- Fibrotic proteins

Today, the treatment of CKD in T2D does not adequately address inflammation and fibrosis, a major driver of CKD progression1

It’s time to explore an unaddressed driver of CKD in T2D at CKD-T2D.com

Improve medication adherence with technology

When considering the importance of medication adherence, former U.S. Surgeon General C. Everett Koop said it best: “Drugs don’t work in patients who don’t take them.” That was 35 years ago, and the issue remains a major area of concern for clinicians today.

One-fourth of new prescriptions are never filled — and even when filled, up to 50% of patients with chronic conditions fail to take their medications as prescribed. These statistics reflect the situation before COVID-19 led to social distancing and stay-at-home orders that may be making the situation worse.

Medication nonadherence can lead to serious health consequences and higher medical costs. Each year, medication nonadherence results in approximately 125,000 deaths and up to 25% of hospitalizations, which is estimated to cost the American health care system nearly $300 billion.

As the number of coronavirus cases continues to grow across the U.S., medication adherence has never been more critical, especially for elderly patients and those with chronic conditions who are the most susceptible to complications, including death, from COVID-19, according to the Centers for Disease Control and Prevention. To protect the most vulnerable patients, physicians and pharmacists must work together to identify the underlying reasons patients aren’t taking their medications as prescribed and to provide solutions that improve adherence.

**Obstacles to medication adherence**

There are three primary reasons why patients don’t fill new prescriptions or take their medications as directed: high cost, lack of symptoms and forgetfulness.

**Financial concerns**

A major contributor to medication nonadherence is high out-of-pocket costs for prescription drugs, as shown by the results of a recent consumer survey. In the survey, 48% of respondents reported not filling a prescription within the last few years because of cost. The survey also found that even a $10 rise in copay increases the likelihood of prescription abandonment by as much as 19%.

Results of a study published in *Annals of Internal Medicine* also found a direct correlation between the amount of a patient’s copay and the likelihood of prescription abandonment. Patients with $50 copays were nearly four times more likely to abandon a prescription at a pharmacy than patients paying $10.

Today, millions of Americans have lost their jobs, their health insurance and the incomes they used to pay for out-of-pocket health care costs. One in seven report they would avoid seeking care for potential COVID-19 symptoms because of cost concerns, according to a recent Gallup-West Health poll. Unless patients find some financial relief, medication nonadherence rates surely will rise.

**Lack of symptoms and misunderstanding of disease**

Patients often do not understand why they need certain medications. It’s not uncommon for a person to say they don’t feel their blood pressure is high or that they don’t have any symptoms from high cholesterol. If they don’t feel sick, people may stop taking their medications, which can have serious consequences over time. This situation often leads to unnecessary visits to the emergency department and, occasionally, hospital admissions that could have been avoided.

During the current health crisis, we have all been encouraged to stay at home, limit trips to the grocery store and pharmacy and postpone nonessential medical care. This means patients may have less interaction with physicians and pharmacists who can educate them about prescribed therapies. Now is the time for care team members to adopt proactive measures to make sure patients understand what their medications are for, how to take them and why doing so as prescribed is important.

**Delaying or forgetting to pick up prescriptions**

Even in our former everyday lives, it was easy enough to put off a trip to the pharmacy for a prescription. Now, as many of us remain sheltered at home, it’s a challenge to recall what day it is, much less remember to pick up a prescription.

Using reminder tools that notify
patients when medications are prescribed and when they are ready for pickup, pharmacists and physicians can help reduce prescription abandonment. Many independent pharmacies and national chains are offering free delivery services for prescriptions, which is particularly beneficial for patients who feel leaving home could compromise their health. Additionally, health plans have eased restrictions on filling prescriptions in larger quantities, reducing trips to the pharmacy.

**Improving medication adherence with technology**

Care team members can improve medication adherence and health outcomes by leveraging technologies that provide price transparency, offer access to educational materials and send reminders directly to patients’ mobile devices. Technology also can facilitate secure communication between prescribers and pharmacists.

For example, when prescribers see patient-specific drug pricing details at the point of encounter within prescribing workflows, it empowers them to discuss formulary options and out-of-pocket costs with patients and potentially review financial assistance options if cost is a barrier. Real-time price transparency tools let patients know exactly how much their medication will cost before going to the pharmacy. These tools eliminate the “sticker shock” experienced when the pharmacist accesses the patient’s health plan benefits to discover the medication is unaffordable for the patient.

Care providers also can reduce financial barriers with new technology that gives patients direct access to copay assistance options. Emerging solutions may link patients to educational content about prescribed medications, giving them a better understanding of the prescribed therapy.

**Better communication between pharmacists and doctors**

Physicians and pharmacists can further drive adherence by sending automatic reminders to patients’ smartphones, for example, to notify them when a prescription is sent to the pharmacy or when a prescription is ready. Such tools may allow patients to set reminder notices to pick up their medication. By committing to a specific time, patients are more likely to pick up their prescriptions and more likely to take them.

Sometimes, prescriptions are not filled in a timely manner because the pharmacist needs additional clarification from the physician or the payer. A pharmacist may place a call to the physician and leave a message, which starts a time-delaying game of phone tag. To increase efficiency, improve coordination and ultimately fill prescriptions more quickly, a patient’s care team can communicate directly using secure texting, email or videoconferencing technology.

COVID-19 has affected every aspect of our lives and created tremendous financial and emotional strain for many of the most vulnerable patients. Health care professionals must help patients overcome any hurdles standing in the way of medication adherence, including financial and safety concerns. With the right communication and educational tools, providers can help ensure patients take the medicines they need, especially those managing chronic conditions or at the highest risk of complications.

Thomas E. Sullivan, M.D., is chief strategy officer and chief privacy officer for DrFirst. He is a board-certified cardiologist and internal medicine specialist with more than 40 years of clinical practice and is a past president of the Massachusetts Medical Society. Send your technology questions to medec@mjlifesciences.com.

“One-fourth of new prescriptions are never filled — and even when filled, up to 50% of patients with chronic conditions fail to take their medications as prescribed.”
What will COVID-19 mean for value-based models?

by Jeffrey Bendix, M.A., Senior Editor

Six months into the COVID-19 pandemic, its impact on medical practices is becoming clear: fewer in-person visits, more care provided via telehealth and, for many, lower revenue.

But even as doctors struggle with the day-to-day challenges of practicing under radically new circumstances, some health care policy makers, academics and payers are asking another question: What do the changes brought about by the pandemic mean for accountable care organizations (ACOs) and other value-based care models, under which doctors and practices are rewarded for keeping patients healthy while holding costs down?

The consensus among experts who spoke with Medical Economics® is that the pandemic will, in the long run, benefit ACOs and other value-based programs, as practices lessen their dependency on fee-for-service medicine as the sole source of their income.

“If you’re a small practice living on fee-for-service, and suddenly all your patients disappear, you realize how much risk you’re under, as opposed to those who have moved to some sort of capitation or bonus for quality arrangement covering at least part of their patient base,” says J.B. Silvers, Ph.D., a professor of health care finance at Case Western Reserve University’s Weatherhead School of Management in Cleveland, Ohio.

“What many thought was the less risky approach of just practicing fee-for-service turns out to be more risky when you have these...
unexpected ‘black swan’ events,” he says.

CMS addresses ACO worries
Early in the pandemic, as practices’ patient visits and incomes plummeted, value-based programs seemed anything but appealing, especially if they involved financial risk. A mid-April survey by the National Association of Accountable Care Organizations (NAACOS) found that 56% of ACOs in a two-sided risk program — i.e., one that requires sharing losses as well as gains — said they were “very likely,” “likely” or “somewhat likely” to leave the program due to fear of having to repay losses incurred as a result of treating patients with COVID-19.

Partly as a result of this sentiment, the Centers for Medicare & Medicaid Services (CMS) moved quickly to shore up its main value-based initiative, the Medicare Shared Savings Program (MSSP).

According to Silvers, CMS had little choice but to act quickly to ensure that ACOs remain in the MSSP program. “This [MSSP] is a big bet they’ve made, and if practices start to bail on them, the whole program goes down the tubes,” he says. “Having practices stay in it for the long run is really important, so they want to make it as stable and predictable as they can.”

Allison Brennan, MPP, senior vice president of government affairs for NAACOS, says the steps CMS has taken have helped allay members’ initial fears over the effects of the pandemic.

“The main reason they are taking these actions is to prevent ACOs from unfairly shouldering the burden of a pandemic over which they have no control, and so far it seems to be working,” she says, adding that “we still have to wait and see what the net effect will be in some of the hardest-hit areas.”

How value-based programs are responding to pandemic
Despite their initial fears, practices in value-based programs appear to be better positioned to survive the COVID-19 crisis, says Keely Macmillan, M.S., senior vice president of policy and solutions management at consulting firm Archway Health, which helps practices shift to bundled payments and other types of value-based models.

“The providers who had put infrastructure in place to achieve success in these models, like care coordination, patient tracking and telehealth, are able to respond more quickly and continue providing high-quality care to patients in the midst of this health emergency,” she says.

“That has proven true for CareMount, an ACO based in Mount Kisco, New York, with more than 600 providers in five counties and parts of New York City. It began participating in MSSP in 2013, and since 2018 it has been part of the Next Generation ACO program, where it shares in losses as well as cost savings. It also has performance-based contracts with many of its commercial payers.

Because of its long experience with value-based programs, CareMount understood the importance of population data in improving patient care, says Kevin Conroy, M.S., the group’s chief financial officer and chief population health officer. It had built an in-house data analytics department that performed functions such as alerting doctors when a Medicare patient was due for an annual wellness visit.

Once the severity of the pandemic became apparent, Conroy says, CareMount was able to use the data it had accumulated to quickly identify and contact its most vulnerable patients. “We already had a robust care coordination team, but we became more targeted with it,” he explains. “We looked at things like who was deferring care or missing a screening and who we needed to reach out to telephonically to make sure there’s no deterioration in their condition.”

CareMount also had a telehealth platform, Conroy says, although before the arrival of the pandemic it was rarely used. Beginning in mid-March, however, telehealth visits escalated rapidly, peaking at 1,500 per day, and they have been an important tool in enabling CareMount’s providers to stay in touch with patients and monitor their health.

In addition, Conroy says, CareMount is in the early stages of developing a home health program to augment telehealth visits. The goal is to send medical assistants to patients’ homes for tasks that can’t be done by phone, such as blood pressure screenings and checking
MONEY / VALUE-BASED CARE

Conroy predicts that the pandemic will heighten the appeal of value-based care models such as ACOs. “Groups that are using value models are positioned to create a more predictable revenue flow,” he says.

Telehealth’s impact
Another effect of COVID-19 on value-based programs is the increase in telehealth visits. A Commonwealth Fund study released in mid-June found that while telehealth visits were down from their mid-April peak, they were still about 8% higher compared with four months earlier. Meanwhile, numerous surveys have shown high levels of patient satisfaction with telehealth and a desire to continue using it, even post-pandemic.

The growth has been fueled in part by CMS’s decisions to allow Medicare to pay for more types of telehealth visits and raise reimbursements to match what it pays for in-person visits, and Congress’s loosening of restrictions on how and where telehealth visits can take place. And while it’s not known if these changes will be permanent, they will likely remain in effect at least for the duration of the public health emergency, according to Travis Broome, MBA, MPH, senior vice president for policy and

How the Medicare Shared Savings Program is adapting to COVID-19

by Jeffrey Bendix, M.A. Senior Editor

Since March, when COVID-19 was declared a public health emergency (PHE), CMS has sought to minimize the pandemic’s financial impact on the 517 accountable care organizations participating in the Medicare Shared Savings Program. Most notably, it invoked what’s known as the “severe and uncontrollable circumstances” policy to change some of its methodology for setting ACO performance benchmarks and rules regarding sharing of downside risk.

Among the changes CMS has made:

- Removing the costs of COVID-19 treatments from Medicare spending data used to calculate an ACO’s performance during 2020 and for setting future performance benchmarks.
- Giving ACOs with agreements that expire at the end of 2020 the option of extending the agreement period through the end of 2021, while remaining under their 2020 benchmarks.
- Allowing ACOs in the BASIC track (without downside financial risk) the option to remain through 2021, so as to not incur higher levels of risk.
- Reducing any shared losses incurred by ACOs in the Next Generation model in 2020 according to the proportion of months of the PHE, thereby limiting financial risk.
- Easing regulatory requirements for COVID-19 testing while making it easier to get reimbursed for testing.
- Making the pandemic’s status as a PHE retroactive to the start of 2020 and extending it at least through July 2021.
- These changes have helped to reassure ACOs and their member practices that had been worried about the financial consequences of the pandemic, says Steve Nuckolls, a board member of the National Association of Accountable Care Organizations and the CEO of Coastal Carolina Health Care in New Bern, North Carolina.

“Initially there were a number of ACOs concerned that the benchmarking process would hurt them and were considering dropping out of the program.” Nuckolls says. “So when CMS invoked the severe and uncontrollable clause, these groups felt relief that they wouldn’t be penalized for factors outside of their control.”

*Sources: CMS and the National Association of Accountable Care Organizations
“Everyone agrees we have enough money in the health care system to take care of everyone, we’ve just been spending it in the wrong things and in the wrong places.”

— Mark Fendrick, M.D., director of the Value-Based Insurance Design Center, University of Michigan

Value-focused care at Aledade, a consulting firm that helps practices form and join ACOs.

Broome notes that ACOs and other value-based programs are a good environment for testing whether more telehealth visits improve patients’ health, and, if so, under what circumstances. “Under these models, the providers are incentivized to find and do just the parts of telehealth that really add value, because they’re on the hook for the total cost of care,” he says. In other words, practices will incur financial penalties if telehealth leads to more visits without improved outcomes.

Mark Fendrick, M.D., director of the Value-Based Insurance Design Center at the University of Michigan and a professor of health management and policy at the university’s School of Public Health, echoes Broome’s prediction and thinks it will also extend to fee-for-service medicine.

“I’m hopeful [with telemedicine] that the volume of these low-value services will fall and free up funds to invest in the areas where we really need to be spending money,” he says.

The drop-off in health care spending
Another significant question for practices in value-based models, especially those that are part of the MSSP, is the effect of the steep decline in health care spending due to patients delaying or foregoing care, both elective and necessary. Results of a study from the insurance and consulting firm Milliman, released in April, estimate that health care spending in 2020 will be down by at least $75 billion, and possibly as much as $575 billion, due to deferral or elimination of care related to COVID-19.

The spending drop-off has both short- and long-term implications for ACOs in the MSSP, according to Archway’s Macmillan. In the short term, it has caused CMS to adjust the formulas it uses to set spending benchmarks for some shared savings programs.

Looking ahead, Macmillan says, the big question for ACOs and other value-based programs concerns medically necessary care that has been deferred because of the pandemic. “A lot of patients with chronic conditions haven’t been well managed in the past few months because they’ve stayed home, which means their diseases may have progressed more quickly than normal,” she says. The result would be more severe acuity when these patients do finally venture out, leading to higher costs of care.

“CMS is going to have to figure out how to address that issue fairly, and I don’t think there’s enough data yet to measure the impact this [deferred care] has had,” Macmillan says. “But going forward they have to make sure their benchmarking methodologies reflect the circumstances of COVID-19.”

Fendrick says the changes in care delivery wrought by the pandemic could result in a wholesale rethinking of spending priorities.

“Everyone agrees we have enough money in the health care system to take care of everyone, we’ve just been spending it in the wrong things and in the wrong places. “

— Mark Fendrick, M.D., director of the Value-Based Insurance Design Center, University of Michigan

Medical Economics.com
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 $330.98 for 120 1g capsules and $387.24 for 240 0.5g capsules. Commercially insured patients can save with the VASCEPA Savings Card. VASCEPA Savings Card may not be used to obtain prescription drugs paid in part by some Federal or State Programs; see vascepahcp.com for more information. There is no generic equivalent for VASCEPA.

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.

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• It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA.

• 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.

• Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding events.

• Common adverse reactions in the cardiovascular outcomes trial (incidence ≥3% and ≥1% more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%) and atrial fibrillation (5% vs 4%).

• Common adverse reactions in the hypertriglyceridemia trials (incidence ≥1% more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%).

• Adverse Events, Product Complaints, or Special Situations may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

• Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding events.

**IMPORTANT SAFETY INFORMATION (cont’d)**

• VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.

• Common adverse reactions in the cardiovascular outcomes trial (incidence ≥3% and ≥1% more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%) and atrial fibrillation (5% vs 4%).

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• Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding events.

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

*RRR-relative risk reduction.

*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, or TRICARE. 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, 2020.

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

VASCPEPA (icosapent ethyl) Capsules, for oral use

Brief Summary of Prescribing Information

Please see Full Prescribing information for additional information about VASCPEPA.

1 INDICATIONS AND USAGE

VASCPEPA® (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.
- as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

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

2 DOSAGE AND ADMINISTRATION

2.1 Prior to Initiation of VASCPEPA

- Assess lipid levels before initiating therapy. Identify other causes (e.g., diabetes mellitus, hyperthyroidism, or medications) of high triglyceride levels and manage as appropriate.
- Patients should engage in appropriate nutritional intake and physical activity before receiving VASCPEPA, which should continue during treatment with VASCPEPA.

2.2 Dosage and Administration

- The daily dose of VASCPEPA is 4 grams per day taken as either:
  o four 0.5 gram capsules twice daily with food; or
  o two 1 gram capsules twice daily with food.
- Advise patients to swallow VASCPEPA capsules whole. Do not break open, crush, dissolve, or chew VASCPEPA.

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Atrial Fibrillation/Flutter

VASCPEPA 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 12.9% of patients treated with VASCPEPA compared to 8.4% (p < 0.001) of patients receiving placebo (HR: 1.5, 95% CI 1.1, 1.9). 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

VASCPEPA contains ethyl esters of the omega-3 fatty acid, eicosapentaenoic acid (EPA). 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 VASCPEPA. Inform patients with known hypersensitivity to fish and/or shellfish about the potential for allergic reactions to VASCPEPA and advise them to discontinue VASCPEPA and seek medical attention if any reactions occur.

5.3 Bleeding

VASCPEPA is associated with an increased risk of bleeding. In a double-blind, placebo-controlled cardiovascular outcomes trial of 8,179 patients, 482 (12%) patients receiving VASCPEPA experienced a bleeding event compared to 404 (10%) patients receiving placebo. Serious bleeding events occurred in 111 (3%) of patients on VASCPEPA 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 are not 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 VASCPEPA 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% were Black, and 4% identified as Hispanic ethnicity. Common adverse reactions (incidence ≥ 2%) on VASCPEPA and a ≥1.5 more frequent than placebo included musculoskeletal pain, peripheral edema, constipation, gout, and atrial fibrillation.

Hypertriglyceridemia Trials

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 VASCPEPA at an incidence ≥1% more frequent than placebo based on pooled data included arthralgia and oropharyngeal pain.

6.2 Postmarketing Experience

Additional adverse reactions have been identified during post-approval use of VASCPEPA. 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 these studies has not exceeded normal limits and did not produce clinically significant bleeding episodes. Monitor patients receiving VASCPEPA and concomitant anticoagulants and/or antiplatelet agents for bleeding.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.1.1 Risk Summary

The available data from published case reports and the pharmacovigilance database on the use of VASCPEPA in pregnant women are insufficient to identify a drug-associated risk for major birth defects, miscarriage or adverse maternal or fetal outcomes. In animal reproduction studies in pregnant rats, non-dose-related imbalances for some minor developmental findings were observed with oral administration of icosapent ethyl during organogenesis at exposures that were equivalent to the clinical exposure at the human dose of 4 g/day, based on body surface area comparisons. In a study in pregnant rabbits 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 from gestation day 7-17, icosapent ethyl did not affect viability in fetuses (F1 or F2). Non-dose-related imbalances in findings of absent optic nerves and unilateral pes anserine at birth are observed at human exposures based on the maximum dose of 4 g/day and body surface area comparisons. Additional variations consisting of early incisor eruption and increased percent cervical ribs were observed at the same exposures. Pups from high dose treated dams exhibited decreased coaptation rates, delayed estrus, decreased implantations and decreased surviving fetuses (F2) suggesting potential multiplegenerational 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 rabbits given oral gavage doses of 0.1, 0.3, and 1 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/day, based on body surface area comparisons), 50% of the live born and dead fetuses were noted in the 1 g/kg/day group, but these were not significantly 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 exposures at a maximum dose of 4 g/day based on body surface area comparisons.

8.2 Lactation

8.2.1 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 in 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 breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for VASCPEPA and any potential adverse effects on the breastfed child from VASCPEPA 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 VASCPEPA, 45% were 65 years of age and over. No overall differences in safety or effectiveness were observed between these patients and younger groups. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

8.7 Hepatic Impairment

In patients with hepatic impairment, alaminaminotransferase (ALT) and asparateaminotransferase (AST) levels should be monitored periodically during therapy with VASCPEPA.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling before starting VASCPEPA (Patient Information).

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VASCPEPA® (icosapent ethyl)

Manufactured by: Amarin Pharma, Inc.
Amarin Pharmaceuticals Ireland Limited
Bridgewater, NJ, USA

Distributed by:
Amarin Pharma, Inc.
Bridgewater, NJ, USA

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VAS-02464 01/20
Updated COVID-19 coding: What you need to know

On April 1, 2020, the Centers for Disease Control and Prevention (CDC) updated the International Classification of Diseases, Tenth Revision (ICD-10) coding guidance for COVID-19 coding.

Codes for diagnosing COVID-19 (April 1, 2020 - September 30, 2020)

For diagnosis coding, consider the following:

- If COVID-19 is confirmed or if testing is negative, the following encounter codes should be used:
  - Encounter for observation for suspected exposure to other viral communicable diseases (possible exposure to COVID-19 ruled out): Z03.818.
  - Contact with and suspected exposure to other viral communicable disease: Z20.828.
  - Encounter for screening for other viral diseases, asymptomatic, no known exposure, results unknown or negative: Z11.59.

- For confirmed COVID-19 diagnosis: U07.1. Use additional codes to identify pneumonia or other manifestations. For example: pneumonia confirmed as due to COVID-19 would use U07.1 (COVID-19) and J12.89 (other viral pneumonia).

Additional manifestation codes
- Acute bronchitis: J20.8 or J40 if unspecified bronchitis.
- Lower respiratory infection: J22.
- Respiratory infection not otherwise specified: J98.8.
- Acute respiratory distress syndrome: J80.

Additional coronavirus codes not due to COVID-19
- Coronavirus infection, unspecified: B34.2.
- Coronavirus as the cause of diseases classified elsewhere: B97.2.
- Pneumonia due to severe acute respiratory syndrome-associated coronavirus: J12.81.

Correction
Guidance for coding COVID-19 is evolving quickly. In our June 2020 issue, Medical Economics published outdated COVID-19 codes in a box on page 17. The codes on this page are the most current codes for COVID-19, and were accurate as of press time. For the latest guidance and information, visit the CDC at: https://bit.ly/Covid19codes.

Bill Dacey, MHA, MBA, CPC, is principal in The Dacey Group, Inc., a consulting firm in Palm Harbor, Florida, dedicated to coding, billing, documentation and compliance concerns for physicians. Dacey is an AAPC-certified coding instructor and has been active in physician training for more than 25 years. Send your coding and billing questions to medec@mjhlifesciences.com.
COVID-19 financial impact

by Medical Economics® Staff

The COVID-19 pandemic has created numerous challenges for physician practices, among them severe losses to patient volume and revenue. MJH Life Sciences™, the parent company of Medical Economics®, recently conducted a survey of our physician audience to learn about these financial challenges. We present the data below.

How has the COVID-19 pandemic affected your current staffing plan?

### Physicians

<table>
<thead>
<tr>
<th>No change</th>
<th>Furloughed/temporary leave</th>
<th>Permanent staff reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>73%</td>
<td>20%</td>
<td>7%</td>
</tr>
</tbody>
</table>

### Non-physician clinical staff

<table>
<thead>
<tr>
<th>No change</th>
<th>Furloughed/temporary leave</th>
<th>Permanent staff reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>60%</td>
<td>32%</td>
<td>8%</td>
</tr>
</tbody>
</table>

### Non-clinical support staff

<table>
<thead>
<tr>
<th>No change</th>
<th>Furloughed/temporary leave</th>
<th>Permanent staff reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>48%</td>
<td>38%</td>
<td>14%</td>
</tr>
</tbody>
</table>
**COVID-19 FINANCIAL IMPACT / MONEY**

**What is your anticipated loss in revenue for 2020 as a result of COVID-19?**

<table>
<thead>
<tr>
<th>Loss Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No loss</td>
<td>9%</td>
</tr>
<tr>
<td>1% to 20% loss</td>
<td>23%</td>
</tr>
<tr>
<td>21% to 40% loss</td>
<td>36%</td>
</tr>
<tr>
<td>41% to 60% loss</td>
<td>20%</td>
</tr>
<tr>
<td>More than 60% loss</td>
<td>10%</td>
</tr>
</tbody>
</table>

**Do you expect your headcount to change once your locality reopens?**

- We’ll return to same levels of staff members: 34%
- We won’t return to the same headcount: 37%
- We haven’t decreased staff and don’t expect to: 23%
- Other: 6%

**One your area reopens fully, what is your expectation of patient volume by type of interaction?**

**In-person appointment**

- Likely to decrease: 47%
- Likely to stay the same: 18%
- Likely to increase: 26%

**Telemedicine visits**

- Likely to decrease: 25%
- Likely to stay the same: 16%
- Likely to increase: 42%
Who took the survey?

Practice type
- Private/independent: 53%
- Hospital/health system: 22%
- Group practice: 16%
- HMO-based practice: 1%
- Other: 7%

Specialty
- Pediatrics: 22%
- Primary care (family practice/internal medicine): 19%
- Dermatology: 5%
- OB/GYN: 11%
- Psychiatry: 14%
- Neurology: 2%
- Ophthalmology: 7%
- Oncology: 2%
- Rheumatology: 1%
- Urology: 2%
- Other: 15%

Provider type
- Physician: 82%
- Nurse practitioner/physician assistant: 6%
- Nurse: 2%
- Practice administrator: 3%
- Other: 7%

About the survey
The data in this survey was collected between May 29 and June 3, 2020, via pop-up alerts on MJH Life Sciences™ websites. More than 1,500 health care providers participated in the survey.
Atherosclerotic cardiovascular disease (ASCVD), the leading global cause of morbidity and mortality in the United States is largely attributed to a variety of cardiovascular risk factors, including hypertriglyceridemia, elevated low-density lipoprotein cholesterol (LDL-C), insulin resistance, hypertension and obesity. Coronary heart disease (CHD) is the most common manifestation of cardiovascular disease (CVD), comprising approximately 50% of patients’ first CVD events. Risk factors include a family history of premature ASCVD (men < 55 years old, women < 65 years old), metabolic syndrome (increased body mass index, elevated triglycerides >150 mg/dL, elevated blood pressure), hypercholesterolemia and chronic kidney disease.

Risk of ASCVD is categorized as low (< 5%), borderline (5%-< 7.5%), intermediate (> 7.5%-< 20) or high (> 20%) over a 10-year period. These risk stratifications can help determine the most appropriate interventions for patients. Those with minimal or borderline ASCVD risk may be eligible for lifestyle modifications, including dietary improvements, physical activity, and smoking cessation if applicable. In addition to lifestyle changes, several therapies are used to lower LDL-C and/or triglyceride levels, but only select agents have demonstrated a significant effect in reducing cardiovascular mortality.

This article reviews the evolving therapeutic landscape for lowering LDL-C and cardiovascular risk, with an emphasis on the role of omega-3 fatty acids. and atherosclerotic events (e.g., stroke or myocardial infarction).

Meta analyses suggest that statins reduce major adverse cardiovascular events and all-cause mortality in patients at risk for ASCVD. Additionally, reductions in LDL-C levels associated with the use of statins are generally irrespective of comorbidities, such as diabetes, chronic kidney disease or previous vascular disease.

The American College of Cardiology (ACC)/American Heart Association (AHA) guidelines recommend moderate or high intensity statins in addition to lifestyle modifications for those at moderate and high risk for recurring cardiovascular events.

**THERAPEUTIC TARGETING OF HYPERTRIGLYCERIDEMIA**

Beyond LDL-cholesterol lowering, therapeutic targeting of triglyceride levels can reduce cardiovascular risk, as triglyceride levels of 150 mg/dL or more are considered a marker of persistent cardiovascular risk despite controlled LDL-C. In high-risk patients, such as those with established cardiovascular disease or diabetes, lowering triglyceride levels, along with decreasing LDL-C levels and raising HDL-C levels, produces trends suggesting reduced cardiovascular mortality. In addition to lifestyle changes, several therapies including ezetimibe, fibrates, and niacin; omega-3 fatty acids have been shown to lower triglyceride and non-HDL-C levels, but only select agents have demonstrated an effect in improving cardiovascular morbidity and mortality.

- When ezetimibe therapy is added to statin or fibrate therapy, decreases in total cholesterol, LDL-C, and triglycerides, as well as increases in HDL-C levels, have been observed; however, the risk of cardiovascular events is only minimally improved and no effect
on cardiovascular mortality has been observed.\(^6\) Fibrate therapy has been associated with a 10% relative risk reduction for major cardiovascular events.\(^{17}\) Although niacin, in combination with statin therapy, may increase in serum HDL-C levels, it does not reduce cardiovascular mortality or recurrent events in patients with/at high-risk for ASCVD.\(^{18}\) As a class, omega-3 fatty acids (eicosapentaenoic acid [EPA], docosahexaenoic acid [DHA]), have been shown to decrease triglyceride levels. Recent data on EPA/DHA combination regimens generally confer no evidence of a significant effect on cardiovascular disease composite end points or all-cause mortality.\(^{15,16}\)

### THE CARDIOVASCULAR BENEFITS OF OMEGA-3 FATTY ACIDS

Another intervention that has shown efficacy toward lowering triglyceride levels is omega-3 fatty acids, which can be used for patients with high (200-499 mg/dL) or very high (≥ 500 mg/dL) triglyceride levels.\(^{19}\) Omega-3 fatty acid products are available as prescription or as dietary supplements.\(^{18,19}\) DHA and EPA are the primary long-chain fatty acids components of omega-3 fatty acids.\(^{20}\) The effects of omega-3 fatty acids on LDL-C vary based on the specific long-chain fatty acid (i.e., DHA or EPA) component. Findings from a systematic review of head-to-head studies of omega-3 fatty acid products revealed that DHA increased LDL-C by 2.6%, whereas EPA decreased LDL-C by 0.7%.\(^{20}\)

Four FDA-approved omega-3 fatty acid therapies are currently available via prescription in the United States, and all are indicated to decrease triglyceride levels. They include omega-3 acid ethyl esters, omega-3 acid ethyl esters A, omega-carboxylic acids and icosapent ethyl (Table 1).\(^{21-24}\)

Early studies, such as the GISSI-Prevenzione study, demonstrated reductions in cardiovascular events with omega-3 fatty acid supplements\(^{25}\); however, in the era of statin therapy, these results have generally not been replicated.\(^{26}\) More recent studies have found that EPA/DHA combination products do not confer significant cardiovascular benefits.\(^{15,16}\) For example, the ASCEND trial evaluated the use of omega-3 fatty acids in 15,480 patients with Type 2 diabetes. Patients were randomized to either 840 mg of omega-3 fatty acids (EPA, 460 mg; DHA, 380 mg) once daily or placebo. Compared with placebo, those in the omega-3 fatty acid group had no significant difference in the risk of serious vascular events.\(^{15}\) Additionally, the VITAL trial evaluated the use of vitamin D\(_3\) plus omega-3 fatty acids for the primary prevention of cardiovascular disease and cancer. Overall 25,871 patients were randomized to either vitamin D\(_3\) 2000 IU plus omega-3 fatty acids (EPA, 460 mg; DHA, 380 mg) once daily or placebo. Use of omega-3 fatty acids did not result in a decreased incidence of either cardiovascular events or cancer.\(^{16}\)

Icosapent ethyl, the most recent product in the omega-3 landscape, 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 levels and established CV disease or diabetes mellitus and two or more additional risk factors.
for CV disease. It is also indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Unlike other omega-3 fatty acid formulations that contain DHA and EPA, icosapent ethyl is a purified ethyl ester of EPA.

The approval of icosapent ethyl was based on data from the multicenter, randomized, double-blind REDUCE-IT (Reduction of Cardiovascular Events with Icosapent Ethyl-Intervention) trial that demonstrated a reduction of risk of ischemic events, including cardiovascular mortality, in patients receiving icosapent ethyl. Investigators evaluated the use of icosapent ethyl in patients with either (1) established cardiovascular disease or (2) diabetes and other risk factors who had triglyceride levels of 135-499 mg/dL and were currently receiving statin therapy. Overall, 8,179 patients were randomized to statin plus icosapent ethyl 2 g twice daily (n = 4,089) or statin plus placebo (n = 4,090). The primary end point was a composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization or unstable angina, while the secondary end point was a composite of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke.

After a median of 4.9 years, patients randomized to statin plus icosapent had significantly fewer primary composite (17.2% versus 22%, respectively; P < .001) and secondary composite events (11.2% versus 14.8%, respectively; P < .001) versus those randomized to statin plus placebo. This represented a 25% relative risk reduction in primary composite end point of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or unstable angina. At a median follow-up of approximately 5 years, the number needed to treat to avoid one primary end point was 21.

Because some results from international trials have shown poorer outcomes in patients in the United States, a subgroup analysis of the U.S.-only population (REDUCE-IT USA) was conducted. Primary and secondary composite events were significantly reduced in patients randomized to statin plus icosapent ethyl versus those randomized to statin plus placebo (P = .000001 and P = .00008, respectively). In addition, the U.S. population demonstrated particularly robust risk reductions across a variety of individual and composite end points, including cardiovascular death (P = .007), myocardial infarction (P = .01), stroke (P = .02), and all-cause mortality (P = .004).

In the overall international population and in the U.S.-only cohort, overall rates of adverse events, and serious adverse events leading to discontinuation did not significantly differ between groups. Icosapent ethyl was generally well tolerated and presented with no poly-

**TABLE 2** Guideline Recommendations for the Use of Icosapent Ethyl for Cardiovascular Risk Reduction

<table>
<thead>
<tr>
<th>Guideline Name</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Diabetes Association Standards of Medical Care in Diabetes for 2020</td>
<td>In diabetic patients with ASCVD or other cardiac risk factors that are currently on a statin with controlled LDL-C, but have elevated triglycerides, the guidelines recommend considering icosapent ethyl to reduce cardiovascular risk (level of evidence, A).</td>
</tr>
<tr>
<td>American Association of Clinical Endocrinologists and American College of Endocrinology 2020 Comprehensive Type 2 Diabetes</td>
<td>Within the ASVCD risk factor modification algorithm for dyslipidemia, guidelines recommend icosapent ethyl 4 g per day if triglycerides are elevated (135-499 mg/dL) and the patient maximally tolerates statins.</td>
</tr>
<tr>
<td>American Heart Association 2020 Science Advisory on the Management of Stable Coronary Artery Disease in Patients with Type 2 Diabetes Mellitus</td>
<td>Considered first-line therapy for patients with Type 2 diabetes and cardiovascular disease who have elevated triglycerides (&gt;135 mg/dL) despite maximally tolerated statin therapy and lifestyle changes.</td>
</tr>
<tr>
<td>National Lipid Association Scientific Statement on the Use of Icosapent Ethyl</td>
<td>Icosapent ethyl is recommended for ASCVD risk reduction in patients ≥ 45 years with clinical ASCVD (or ≥ 50 years with diabetes mellitus requiring medication plus ≥ 1 additional risk factor) who have fasting triglycerides of 135-499 mg/dL and are receiving high-intensity or maximally tolerated statin therapy (± ezetimibe) (evidence rating, class I; evidence level, B-R).</td>
</tr>
</tbody>
</table>

ASCVD, atherosclerotic cardiovascular disease; LDL-C, low-density lipoprotein cholesterol.
harmacy issues when combined with statins.

Following the REDUCE-IT findings, numerous guidelines were updated to include recommendations for the use of icosapent ethyl to reduce cardiovascular risks (Table 2).

**CONCLUSIONS**

With the approval of icosapent ethyl, the role of omega-3 fatty acids in the evolving spectrum of ASCVD management and prevention is expanding. Moreover, the continued research and integration of icosapent ethyl in combination with other approaches could potentially reduce risks of CV events.

**References**


Overcome your bias blind spots to better help patients

by Rebekah Bernard, M.D.

The last thing I wanted to do was to write an article on racism. Not being an expert on the topic, any time I even contemplated writing something, I was crippled by self-doubt. But even more, I was paralyzed by fear. All I could think of were the buzzwords floating around social media. If I wrote against racism, would I be accused of “virtue signaling”? If I didn’t go far enough in condemning racism, would my words be perceived as insufficient, a mere “dog whistle”? What if I unintentionally wrote something that smacked of “white fragility”? Worse yet, I found myself avoiding the topic because of my own discomfort. What if in researching the issues of systemic racism I found myself unintentionally complicit in hurting people I cared about? How would I face this guilt and shame?

But the universe has a way of forcing us to face the unpleasantness that we dread, and when my editor specifically asked me to write an article for doctors on facing implicit bias in medicine, I knew that I had to answer the call. I’m glad I did. Because after speaking with multiple physician experts, I now have the tools to begin to identify and overcome my own implicit biases, and so can you.

Acknowledging blind spots

Every one of us has a certain degree of implicit bias, or subconscious automatic thoughts about others that stem from our upbringing and social framing. Having these thoughts does not mean we are inherently bad or evil. But if we fail to identify areas of implicit bias — blind spots in our knowledge and understanding of other groups of people — we risk inadvertently providing them with lower-quality care. Because this is the antithesis of what most doctors strive for, realizing that we have blind spots may be hard for us to admit.

Christina Girgis, M.D., a consultation-liaison psychiatrist in Chicago, Illinois, and founder of the Psychiatry Network, an educational group and advocacy resource for psychiatrists, says that one of the biggest challenges of acknowledging implicit bias is the cognitive dissonance that it creates. “We all want to think that we are good. Recognizing that we have automatic negative thoughts about certain groups of people does not fit with that belief. That’s why it can be so hard to recognize and accept this within ourselves.”

But everyone struggles with bias, including doctors of color. Brian Dixon, M.D., is a Fort Worth, Texas, psychiatrist, author and founder of Together Forward, a nonprofit think-tank focused on improving health and alleviating cultural disparities. Dixon discovered during a test of implicit bias that he, a black person, was biased against black people and in favor of white people. “I already knew it,” says Dixon, who grew up in a predominantly white area and attended medical school and residency with few other black people. “My biases, like those of anyone, are a result of my environment and the societal messaging I have received in my lifetime.”

Wamda Ahmed, M.D., a neurologist in Houston, Texas, with a special interest in racial disparities, agrees. “Even African American physicians face similar bias, because we receive the same messages and social framing that our white colleagues experience.” Ahmed notes that she sometimes even struggles to overcome automatic negative thoughts about herself that stem from her social
conditioning. “I have to challenge my ‘imposter syndrome,’ and consciously transform the negative thoughts of ‘I am not good enough’ into ‘I can do better.’”

“Having bias doesn’t make you a bad person,” says Nicole Christian-Brathwaite, M.D., child adolescent and adult psychiatrist and CEO and founder of Well Minds Psychiatry & Consulting in Boston, Massachusetts. “Identifying bias is an opportunity to become aware and act.” To help recognize our inherent bias, psychiatrists like Christian-Brathwaite and Dixon suggest taking the Harvard University’s Implicit Associations test, which, although imperfect, can at least begin to raise our self-awareness. Another good way to avoid blind spots is to focus on patients as individuals. “Ask your patients about their cultural backgrounds. Listen to your patients’ stories. The more you individuate, the less likely you are to stereotype,” says Christian-Brathwaite.

Maiysha Clairborne, M.D., an integrative family physician, physician coach, neurolinguistic programming expert and founder of Stress Free Mom MD, says that one of the keys is to not only listen to patients but to watch their responses carefully when you talk with them. “Don’t dismiss patients’ reactions as sensitivity,” advises Clairborne. “If you see your patient react, ask them about it.” Clairborne uses the technique of emotional mirroring and validation, labeling the response that she sees the patient exhibit and asking for clarification. “Check in with your patient. If I see a patient flinch, I might say, ‘I just observed your face change, what happened there?’” She recommends asking specifically, “Was that a racially insensitive thing I just said? I’m sorry, I’m still learning.” This takes the pressure off and gives the patient space to respond.

Get help with processing your emotions

One of the reasons that we fail to examine our biases is because of the emotions they can produce. These emotions can be immensely powerful, and without help in processing them, we may develop maladaptive coping mechanisms, including denial or anger. “Trauma begets trauma,” Dixon says. “If we are not careful in dealing with our emotions, we can risk traumatizing others. It becomes a vicious cycle unless we learn to break it.” Dixon believes that this trauma is one of the reasons it has been difficult to have a reasoned discussion about racial issues. “We cannot even begin to have a public debate or discourse about racism when tensions are high, because traumatized people can’t act in an even-keeled manner. When you feel afraid, you have a biological imperative to run away or lash out.”

To help examine your emotions, Dixon recommends finding a guide, usually a psychiatrist or psychologist. Another option is a physician coach, which may be ideal in states where the medical licensing board takes a punitive approach to mental health counseling. “It’s important to find someone to help you interpret areas of implicit bias and to remind you that having automatic thoughts doesn’t make you a racist. You may need help in overcoming the trauma of realizing that you’ve hurt someone. You have to learn to forgive yourself, and that takes work,” Dixon says.

Girgis says that physicians must work to change our thinking from “I’m a bad person” to “How can I change this type of thinking?” We can also transform our feelings from being about us to being about other people. “Reframing is one of the best tools that we can use. We need to see the realization that we are biased as a positive; now we can begin to deal with it,” Girgis says.

“The best way to deal with anxiety or fear is exposure therapy,” says Christian-Brathwaite. She compares the process to what physicians experience to M&M (morbidity and mortality) rounds during training. “We don’t go into medicine to hurt people, so when we do, it’s humiliating. We should discuss racism in medicine in the same way that we do medical errors, as both lead to negative patient outcomes. Although it’s difficult and uncomfortable, this is how we grow,” she says.

Do your homework

Once we have acknowledged that we have hidden bias, the next step is to develop a better understanding of the systemic issues that our patients face. We can do this by reading about social policies that have negatively affected black populations, such as redlining (the denial of mortgage loans in certain areas for people of color), wage inequality and unjust criminal justice policies. We must also research the effects of racism on medical outcomes. For example, Christian-Brathwaite notes that black patients are more likely to be improperly diagnosed with psychosis and schizophrenia.
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Continued from Page 40

and more likely to be restrained in an inpatient psychiatric unit than white patients. Ahmed points out that African American and female patients are less likely to be treated with tissue plasminogen activator for a stroke and more likely to have a stroke misdiagnosed as a psychiatric disorder or drug abuse reaction. African American patients are also less likely to undergo cardiac catheterization or receive a kidney transplant compared with white patients. African American and Latino patients have been found to receive less pain control in the emergency room than white patients.

Resources for learning about racial disparities include the Office of Minority Health’s Knowledge Center and the American Medical Society’s Health Disparities Toolkit. Dixon suggests checking to see if your hospital or university has a diversity officer. “Many organizations are hiring diversity officers who are trained in addressing racial disparities.”

Applying new knowledge

“Physicians have a unique obligation to address racial disparities because our patients are vulnerable and trust us with their lives,” Ahmed says. However, she notes that this is not always easy, and she often must work at maintaining her objectivity. “Sometimes my first impression may be that a patient’s symptoms are psychiatric. But I remind myself to stop and follow my usual protocols for every patient until I have excluded the most serious neurologic causes,” she says.

Once she has confirmed that a patient is not suffering from a neurological condition, she takes the next step to try to determine the root of their problems. “I ask myself: ‘If this is not a stroke, what is it?’ Often, I discover that patients have had a recent traumatic life experience or an underlying socioeconomic cause for their symptoms,” Ahmed says.

Although many physicians worry they won’t have time to address racial disparities or socioeconomic pressures, Ahmed says that even taking a moment to connect with your patients on a human level can make an impact. “Take a few minutes to be kind, give encouragement or a hug, just to show that you care.” She notes that developing emotional connections with patients also has been found to decrease physician burnout.

Christian-Brathwaite, who specializes in helping physicians fight racial disparities, suggests that doctors take time to reflect on the care that we provide. “Consider doing a chart audit to look at your plan and your goals for different patients,” she says. “Ask yourself: ‘Are my treatments consistent?’”

She notes that implicit bias increases when we are tired, rushed or stressed. “Medicine is often not conducive to being unbiased because when we are under stress, we often find ourselves resorting to shortcuts, including stereotyping our patient,” Christian-Brathwaite says.

Developing anti-racist thoughts and behaviors

I hesitated to write this article because I was afraid of saying the wrong thing. I’ve also avoided discussing racial issues on social media for the same reason. Girgis told me that this is a common concern. “Discomfort can be the worst feeling, and most of us try our best to avoid it. Sometimes you just have to acknowledge your fear and just jump in,” she says.

Girgis notes that if we stay silent, our colleagues won’t know about our support. “Most of the time, our efforts are appreciated, even if they are clunky or imperfect.” She recommends using an accountability partner such as a friend or colleague to help us evaluate our objectivity.

One of the things we can all do, Girgis says, is to analyze what advantages and resources we have as physicians to help mitigate racial disparities.

“Take a few minutes to be kind, give encouragement or a hug, just to show that you care.”

“I may not be able to go out and protest, but I can take steps to make my patients feel more comfortable, to talk with my colleagues and to mentor trainees,” Girgis says. The public pays attention to doctors, and our words and actions carry weight. “We can educate the public by writing and speaking out, or we can just be a good example in our interactions with others outside of work,” she says.

“We have to keep trying,” Ahmed says. “I see the process of developing as a physician to like that of a parent. I’m not going to be perfect every day, but I’m going to keep trying, because the stakes are too high.”

Rebekah Bernard, M.D., is a family physician and author of “Physician Wellness: The Rock Star Doctor’s Guide” and “Change Your Thinking, Improve Your Life.” She can be reached at rebekahbernard.com.
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How to restore physician autonomy
by Chris Mazzolini, M.S. Editorial Director

The sad truth is that many physicians are dissatisfied with their careers. They still enjoy helping their patients, but often feel beaten down by many challenges that overwhelm the reason they went into medicine in the first place. Survey results show that a lack of autonomy often is to blame for their frustration. But what does physician autonomy mean in today’s health care world?

Medical Economics® recently interviewed Wendy Dean, M.D., a psychiatrist and president and co-founder of Moral Injury of Healthcare, to discuss what physicians can do to take back control of their careers. This interview was edited for length and clarity.

Medical Economics®: One of the things we hear about often from our audience is that they lack an autonomy they feel they should have as physicians. Can you talk a little bit about physician autonomy and what that means to you?

Dean: Physicians are trained from the time they go into medical school, and sometimes even before that, to be independent thinkers, to be critically analytical about the problems that they’re looking at that, that they’re investigating for their patients. And they’re also taught not to blindly follow algorithms because that may get them into trouble. And so, after a decade of that sort of training, to go out to practice and have to follow strict algorithms based on reimbursement policies, rather than on clinical best evidence, really goes against the grain of what we believe is good patient care.

ME: In a previous episode, we talked about moral injury. And I’m just wondering how much you feel there’s a relationship between moral injury and a lack of autonomy?

Dean: From my perspective, there’s quite a lot when we are not allowed, for reasons other than good patient care, to get patients what they need. That really goes against some deeply ingrained beliefs on our part and the promises that we made to our patients when we left medical school and went out into training. And the more we are constrained in what we can do for patients, the more frustrated, the more demoralized we become. So I think the two are linked.

ME: What systemic changes do you think need to happen with health care in our country to allow physicians to have more autonomy to spend more time with their patients?

Dean: The biggest change that needs to happen is for the health
Those things on our patients. When we don’t want to have to inflict pain on our patients, it’s going to cost them a copay. And all these things are going to cost the patient time, it’s not going to yield us as much as we’d like. It’s another type of imaging isn’t going to give us what we need. We’re pretty clear that maybe it’s going to take 15 years to know what our patient needs. We’ve trained for 10 years or more in medicine, and our patients need. We’re actually responsible to report to a lot of different people. And really what would be great is if the administrative side of medicine would instead ask how they can support the physician and the physician-patient relationship and change the dynamic so that the physician is facilitated, and how they can get their patients what they need.

**ME:** The No. 1 reason physicians tell us they are losing autonomy is prior authorization, the insurance companies telling them how to practice medicine. And I’m just wondering, from your experience, what’s the link between the growth of prior authorization and how physicians feel about their careers?

**Dean:** I think the growth of prior authorization goes along with a lot of the other regulations that have come in and a lot of the other cost-saving measures that have been implemented in health care. So it’s one of a number and it is the most abrasive. The challenge for physicians is we’ve trained for 10 years or 15 years to know what our patient needs. We’re pretty clear that maybe another type of imaging isn’t going to yield us as much as we’d like. It’s going to cost the patient time, it’s going to cost them a copay. And all of that is a challenge, it’s a struggle. We don’t want to have to inflict those things on our patients. When we’re clear we could go right to a particular test, a particular medication, and to be asked to do that based on reimbursement rather than good care, it goes against the grain of our training. And it also doesn’t feel at times as though we’re talking to an equivalent specialist. We’re talking to a nurse who’s trying their best to do what’s right by their company, but not by the patient. We may be talking to a neurosurgeon, may be talking to an OB/GYN to get authorization. And so it just goes against what we believe is good care.

**ME:** I’m wondering what changes you think need to happen in medical school in the way physicians are trained, to prepare them for the realities of health care and to participate in changing health care?

**Dean:** Medical students are so fantastic because they are energetic, they’re idealist, which is great. It’s also a double-edged sword. Because if we don’t prepare them for what they’re coming out into as residents or as attendings, then they may become very disillusioned very quickly. So I would love to see us train medical students in what the economic realities are of medicine, how the money flows, how reimbursement works, how policy gets made, how legislation happens. Really train them to be activists in their own interest and in the interest of their patients, because that’s what’s going to be critical in the next 20 years.

**ME:** What recommendations do you have for physicians to reclaim autonomy in their own careers? Obviously, there are a lot of systemic issues, but I’m wondering what can physicians do for themselves to carve out a space where they feel they’re practicing medicine the best way?

**Dean:** The best thing that they can do is learn how the incentives are aligned in their own institution. Understand how reimbursement happens, what the incentives are at their entity. And whether they can negotiate to build bridges with the administration, build bridges with other licensees, so that everyone can work together to start fixing things at the local level.

**ME:** Even for individuals, what this sounds like is they need to talk to their fellow physicians and their fellow health care providers about how to really put the patients front and center and make this better for everybody.

**Dean:** Correct. In talking to all their fellow clinicians and other physicians, they’ll start to notice what the patterns are, where the stumbling blocks are. Each separate specialty may have its unique challenges, but there will be commonalities that happen. And as you start to look into that more and more, you can quickly become an expert and can have the tools available to you to change what that problem is.

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**Check out Medical Economics® Pulse**

This interview was transcribed from a video interview that was recorded as part of Medical Economics® Pulse video program. Check out more video interviews with experts at bit.ly/MedEcVideo.
Coding case study

Type 2 diabetes

by Renee Dowling, CPC Contributing author

Getting paid requires accurate documentation and selecting the correct codes. In our Coding Case Studies, we will explore the correct coding for a specific condition based on a hypothetical clinical scenario. Check out the following scenario involving a patient presenting with a headache and see if you can choose the correct codes.

Clinical Scenario

Chief complaint
Patient presents with issues with palpitations and “not feeling right.”
- Palpitations
- Diabetes
- Hyperlipidemia
- Nicotine dependence

Review of Systems
Head/Ear/Nose/Throat (HENT): negative.
Eyes: negative.
Respiratory: positive for shortness of breath.
Cardiovascular: positive for palpitations.
Gastrointestinal: negative.
Endocrine: negative.
Genitourinary: negative.
Musculoskeletal: negative.
Skin: negative.
Allergic/Immunologic: negative.
Neurological: positive for weakness.
Hematological: negative.
Psychiatric/Behavioral: negative.
All other systems reviewed and are negative.

Social History
Smoking status: Current everyday smoker
Types: Cigarettes

Physical Exam
Constitutional: She is oriented to person, place and time. She appears well-developed and well-nourished.
Eyes: conjunctiva and extraocular movement are normal. Pupils are equal, round and reactive to light.
Cardiovascular: normal rate, regular rhythm, normal heart sounds and intact distal pulses.
Pulmonary/Chest: effort normal and breath sounds normal.
Abdominal: soft. Bowel sounds are normal.
Neurological: She is alert and oriented to person, place, and time. She has normal reflexes.
Skin: Skin is warm and dry.
Psychiatric: She has a normal mood and affect. Her behavior is normal. Judgment and thought content normal.

Assessment and Plan
- Palpitations: ECG 12 lead
- DM (diabetes mellitus) POCT hemoglobin A1c 5.7. Continue metformin (Glucophage) 500 mg
- Hyperlipidemia associated with type 2 diabetes mellitus (DM)
- Tobacco abuse: Discussed quitting with patient

Has four of five risk factors for coronary artery disease: DM, lipids, family history, tobacco.
Check calcium score; if positive, will need cardiology evaluation.
Documentation Coding Requirements

When documenting diabetes, include the following:

**Type:**
- Type 1
- Type 2
- Due to underlying condition
- Drug or chemical-induced diabetes mellitus
- Diabetes mellitus in pregnancy, childbirth and puerperium

**With or without complication**

**With or without coma**

**Eye:**
- Left
- Right
- Bilateral

ICD-10 Codes for Type 2 Diabetes Mellitus

**Type 2 diabetes mellitus**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E11.10</td>
<td>with ketoacidosis without coma</td>
</tr>
<tr>
<td>E11.11</td>
<td>with ketoacidosis with coma</td>
</tr>
<tr>
<td>E11.21</td>
<td>with diabetic nephropathy</td>
</tr>
<tr>
<td>E11.22</td>
<td>with diabetic chronic kidney disease</td>
</tr>
<tr>
<td>E11.311</td>
<td>Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema</td>
</tr>
<tr>
<td>E11.319</td>
<td>without macular edema</td>
</tr>
<tr>
<td>E11.3211</td>
<td>Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye</td>
</tr>
<tr>
<td>E11.3212</td>
<td>left eye</td>
</tr>
<tr>
<td>E11.3213</td>
<td>bilateral</td>
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<td>E11.3219</td>
<td>unspecified eye</td>
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<td>Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye</td>
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<tr>
<td>E11.3292</td>
<td>left eye</td>
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<tr>
<td>E11.3293</td>
<td>bilateral</td>
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</tr>
<tr>
<td>E11.3493</td>
<td>bilateral</td>
</tr>
</tbody>
</table>

For all codes, use additional code to identify control using:

- insulin (Z79.4)
- oral antidiabetic drugs (Z79.84)
- oral hypoglycemic drugs (Z79.84)

**FOR CLINICAL INFORMATION VISIT**

Renee Dowling is a billing and coding consultant with VEI Consulting in Indianapolis, Indianapolis. Send your diagnosis coding questions to medec@mjhlifesciences.com
Why we need to rethink treating obesity with physical activity

More Americans than ever are obese. The number of adults with obesity has skyrocketed 200% over the past 40 years, according to the Centers for Disease Control and Prevention. Obesity’s associated comorbidities and health care costs contribute to legitimate public health concerns in the face of novel health threats such as COVID-19.

However, as the number of Americans struggling to manage their weight continues to grow — 72% of Americans 20 or older are overweight or obese — our clinical understanding of this complex but treatable condition has increased. We know there are hormonal and metabolic differences between people who are obese and those who are not. We know that there is a range of effective treatment options for obesity, and, while it includes behavior modification and cognitive therapies, we also can explore pharmacological and surgical interventions. There are limitations to the effectiveness of physical activity on weight loss and obesity management.

Given all that we know about obesity, it is vital that clinicians and other health care professionals make it a priority to educate themselves on best practices for effectively integrating physical activity into obesity treatment plans.

We need to reexamine the role of physical activity in obesity management. Here’s why.

The notion that people can “win” the fight against obesity simply through dieting and exercise was taken to a new level with the introduction of television’s “The Biggest Loser.” Contestants experienced dramatic weight loss while appearing on the show — just as we might expect to happen when patients with obesity are prescribed high levels of physical activity along with around-the-clock monitoring — but maintaining highly intense exercise regimes is unsustainable for most people who are overweight or obese. Additionally, a key insight from a long-term study of “Biggest Loser” contestants tells us that physical activity plays a larger role in maintaining weight loss than it does in catalyzing it.

Certainly, that doesn’t mean physical activity plays no role in the weight loss journey. But it does mean that we should exercise caution in thinking about physical activity in terms of isolated exercise. Not only is it an ineffective weight loss treatment for patients with obesity, but it reflects an outdated understanding of the metabolic mechanisms behind weight loss.

We know that sitting for long periods of time can negatively affect insulin resistance, but breaking up those periods with short walks can reduce insulin and...
glucose responses. With that in mind, a more effective and sustainable approach would dispense with “eat less, move more” and instead encourage patients to “sit less, walk more.”

What health care professionals need to know about incorporating physical activity into obesity treatment.

Here’s what we do know about physical activity: It can power a number of positive health outcomes. Exercise can improve lipoprotein levels, blood pressure, insulin resistance, cardiovascular health and mood and brain function in patients with obesity.

Health care professionals should keep the following best practices in mind when collaborating with patients on obesity treatment plans:

Keep patients grounded:
Create realistic expectations of weight loss results, if any, based on individual patient activity programs. Help patients start to take a longer-term view of the weight loss journey to stave off feelings of burnout or frustration with the process.

Be supportive:
 Patients often begin the treatment process with a great deal of enthusiasm, which can inspire positive behavior changes, but it can also create the risk of exercise-related injury from doing too much, too fast. Help patients learn their individual exercise level and collaborate on finding ways to support and gradually increase the intensity. Discuss the risk of sore muscles after starting a new exercise program.

Get things going:
Starting a new exercise program can be a major hurdle to overcome. Help patients make the first step by connecting them with an easy-to-follow, actionable regimen that incorporates physical activity into their everyday lives. An easy place to start is by advising patients to walk a certain number of steps each day and gradually increase that number over time.

Reframe it: Keep the myriad positive outcomes of physical activity top of mind for patients and help them to understand that exercise is just one part of a broader plan of care to improve their overall health. This insight can make it easier for patients to prioritize physical activity every day.

Grow your obesity medicine knowledge:
Health care professionals can better meet the needs of this rapidly growing segment of Americans by deepening their understanding of obesity medicine. The Obesity Medicine Association (OMA) provides a number of resources to encourage this endeavor, including The Obesity Algorithm, Obesity Treatment Proficiency Badges, American Board of Obesity Medicine certification preparation materials and more. OMA hosts a series of virtual courses on the fundamentals of obesity treatment. The courses offer an informative primer on evidence-based approaches for evaluating, diagnosing and treating obesity.

Healthcare professionals who bring this knowledge into their practices can play a more active role in guiding patients with obesity to better health outcomes.

Angela Fitch, M.D., FACP, FOMA, is the associate director of the Massachusetts General Hospital Weight Center and faculty at the Harvard Medical School. She is board certified in obesity medicine, internal medicine and pediatrics. Fitch serves as vice president of the Obesity Medicine Association and previously served as secretary-treasurer. For more obesity medicine resources, or to become an OMA member, visit www.obesitymedicine.org.

“Create realistic expectations of weight loss results, if any, based on individual patient activity programs. Help patients start to take a longer-term view of the weight loss journey to stave off feelings of burnout or frustration with the process.”
LEGAL

COVID-19 fallout: Preventing employee lawsuits

Q&A

New malpractice risks to watch for post-COVID-19

by Chris Mazzolini, M.S. Editorial Director

It remains to be seen how the COVID-19 pandemic will affect medical liability, as so many aspects of health care are changing rapidly as a result of this world-shaking event. But there are steps physicians can take to protect themselves from new risks. Medical Economics® sat down recently with Sean P. Byrne, J.D., a medical malpractice defense lawyer in Richmond, Virginia, to talk through these strategies and learn how physicians can protect themselves from being sued in this new normal.

This transcript of the interview was edited for length and clarity.

Medical Economics®: How has COVID-19, has affected medical malpractice liability?

Byrne: The diversion of health care resources into treating the pandemic has affected us in the medical liability world significantly. ... In medical liability cases, the test is always: Did you comply with the standard of care? Did you act like a reasonably prudent provider would act under the same or similar circumstances? But we’ve never faced the same or similar circumstances with a novel virus and a pandemic like this in the era of modern medicine. What the law will ultimately define as reasonable health care services that met the standard of care is going to be evolving.

We've seen a couple of responses across the country, state by state, to try to address it. A number of states, either by executive action or by legislative change, have put in place immunity provisions to protect health care professionals from liability claims that may arise in this era. A number of those state laws will say that you cannot be sued for simple negligence, which just means a mistake or careless error. You cannot be sued for simple negligence in this era for COVID-19-related claims. Those vary widely across the country in terms of how nimble and what the politics are and what people have done. A number of them are limited to: You can't be sued for COVID-19-related claims that are caused by a lack of resources. And resources can mean [personal protective equipment], it can mean staffing, it can mean [intensive care unit] beds.

A number of states have also stated, “We're going to give you some protection from lawsuits if you practice somewhat outside your scope of practice, but within your license.” So when we see resources being diverted from one area of a hospital to another to fight waves of pandemic patients, state laws have given some protection in those cases.

The big issue to think about is standard of care. Are you acting reasonably under the circumstances following directives? You should know you have some immunity protections, and it’s helpful to know what they are in your state as you make decisions at a health care professional level. And then another topic that's coming up is what do we say to our patients and how can we deal with the disclosure of risk.

ME: What about disclosure of risk? What does that mean, specifically? And what do doctors need to communicate to their patients and in what way?
Byrne: Start with just the fundamentals, that we’ve always got an obligation to give our patients advice about risks, benefits, alternatives. So now that we’re facing the pandemic, folks have wondered, “What do I have to disclose to the patient? And can I protect myself from a lawsuit?”

We deal with that in a couple ways. A lot of providers have drafted, with the assistance of their lawyer and their risk management teams, COVID-19-specific programs. And so that will include protocols you have in place in your office for infection control, patient monitoring, screening employees and patients. It will also include some COVID-19-specific screening that goes into the patient’s medical chart about international travel, about symptoms, about exposure. And then a disclaimer or at least a discussion in your informed consent paperwork, where the patient has acknowledged that they’re aware that by being present in the health care environment, they’re assuming some risk of contracting the virus despite the best efforts of the provider. So we’re dealing with those on a number of fronts, and I’ve seen practices pivot really quickly to manage that risk.

ME: We’ve received questions from physicians along the lines of, “If I get a patient to sign something saying that they’re assuming risk, does that essentially wipe away my liability?” Is that true?

Byrne: It’s typically not that simple. I mean, most states have a public policy principle that says, “We ought not let people waive negligence.” [For instance], the back of your ticket to a ballgame or the documents you sign before an operation will have some broad language in there acknowledging the risk you’re undergoing, but you typically can’t waive negligence claims. So those disclaimers and informed consent documents are helpful; they can be damaging if you don’t do them. They can help you prove that you did disclose and discuss the risks with the patient. Ultimately, though, the test is usually going to be: Did you act reasonably? I think it’s advisable to include some language about COVID-19 in your discussions with your patients and in your documentation, but it’s not a blanket protection against a lawsuit. Interestingly, we have those immunity provisions that have come into play in a number of states that do provide some protection. What’s not crystal clear is: What about the downstream issues of preventative care screening for, say, breast cancer, for colon cancer, for other significant conditions? What about the other health care that’s being delayed? And from both lack of resources and patient reductions in seeking care, how will our immunity protections and the standard of care address that in the future? So those are going to be evolving considerations that, unfortunately, are going to keep lawyers like me busy in the years to come.

ME: Many physicians are now using telehealth to treat their patients. Are there any unique malpractice risks as a result of telehealth or considerations that physicians need to take into account?

“The advice we give, oftentimes, as medical liability defense attorneys is that your documentation can be your best friend.”
Byrne: There are some really important considerations there. A lot of the medical malpractice insurance carriers who had very specific rules about telehealth have loosened those rules or adjusted them to accommodate the shift in delivery models and the prolific use of telehealth on such short notice during the pandemic. It’s a good idea for a provider or practice group to see what your insurance carrier is saying about that. And have they acknowledged that it’s within the scope of your malpractice policy?

Similarly, state regulations that impose some requirements on how you can do telehealth and when you can do telehealth, many of those have been broadened, and some of the regulatory hurdles have been set to the side so that providers have easier access to telehealth. This pandemic has fast forwarded the thinking both from a business perspective and also from a regulatory and insurance perspective.

ME: What should physicians be thinking about to proactively manage both pandemic risks and these downstream risks that you mentioned?

Byrne: The advice we give, oftentimes, as medical liability defense attorneys is that your documentation can be your best friend. If a claim or lawsuit develops a couple years from now, we have to prove what you were thinking, your analysis, your careful reaction and your adjustment to the limitations that were being imposed on you and your practice by COVID-19. Good documentation of that in the chart is helpful. If patients are receiving routine follow-up or screening appointments are being missed or discontinued or postponed, good documentation of your follow-up efforts will be really helpful. Some place I see people fall short is, you know, when they make phone calls to patients to follow up on abnormal lab results or abnormal imaging studies or missed appointments, but they don’t document those efforts, which makes it hard for me to prove you were doing it. Your documentation becomes really important to help you out in these uncertain times.

ME: Do we expect some policy situations to change going forward? Will there be new policy riders? Are there any ways that you should change your approach to coverage?

Byrne: Great question. There might be a couple things to think about, including when quarantine rules took effect. Everybody went into lockdown, businesses shut down, the courts shut down, too. And so the deadlines for filing lawsuits, which are usually matters of state law, where patient has a year or two years or five years to file a claim, and these are hard and fast deadlines, oftentimes insurance policies follow alongside those deadlines in terms of the scope and duration of your coverage. As a result of COVID-19, those deadlines have been extended in various states.

ME: What kinds of things are you hearing from your physician clients?

Byrne: It varies widely by practice area. We get calls for risk management and compliance advice in all these areas. And people are thoughtful about when can I reopen. When the state governments imposed restrictions on elective procedures, there’s debate about whether a particular procedure is elective or medically necessary now, and it probably depends on your perspective, whether it’s you or your loved one, and it’s your practice or someone else’s practice. So we’ve had some debate about that. We’ve seen a few board of medicine complaints with unsatisfied patients saying, hey, my procedure was postponed as elective and it shouldn’t have been, and I want to move forward. I think the boards of medicine won’t have a lot of sympathy with patients who make those complaints when they know the providers are doing the best they can. 

“I think what providers can continue to do is focus on good charting, good relationships, staying up to speed on the developments.”

Check out Medical Economics pulse. This interview was transcribed from a video interview that was recorded as part of Medical Economics® Pulse video program. Check out more video interviews with experts at bit.ly/MedEcVideo.
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*Dr. Walter is UroLift System faculty and a paid consultant for NeoTract|Teleflex

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COVID-19 has created a global public health disaster. As world leaders struggle to contain the spread of the virus, they are also trying to figure out how to balance public health needs with economic stability.

For practice owners, especially those who have been hard-hit by the economic impact of the virus, making decisions to keep their business viable may not be easy. This could mean cutting jobs or furloughing staff. The question becomes how to balance the needs of the practice and staff and avoid legal fallout.

A grim picture for business
In the U.S. alone, unemployment rates jumped by 10.3 percentage points in April to 14.7%, the highest monthly unemployment increase since the Bureau of Labor Statistics (BLS) started tracking the data in 1948. More than 23 million Americans were out of work in April, a one-month increase of 15.9 million people, with 1.4 million job losses in the health care industry.

Although some of these job losses may be temporary, others are not. Dentists, physicians and other health care practitioners have had their livelihoods hit hardest in the health care sector. About 243,000 jobs were lost in physician offices and another 205,000 in other health care provider offices. The number of unemployed people in the education and health care sectors increased by nearly fivefold in the last year, according to the BLS, from about 512,000 to more than 2.5 million.

The problem for practices
While the hope is that business will at some point return to normal, that still may be a long way off. In the meantime, the number of outpatient visits and elective procedures has dropped sharply, along with the revenue for these office-based services.

Richard G. Roberts, M.D., J.D., FAFP, FCLM, is a professor of family medicine at the University of Wisconsin School of Medicine & Public Health in Madison and a practicing family doctor in a small, rural area. He says the pandemic has cast a spotlight on inequalities in health care, among patients and even among different types of practices. He pointed out the irony of some states pleading for help and more health care workers even as other states were forced to furlough health care workers.

While virtual visits have surged as a way to meet outpatient care needs during the COVID-19 pandemic, primary care visit volume is down 50%, and some practices were forced to cut costs right away, he says. “Patients are afraid to come in, and we are telling them not to come in,” Roberts says.

Although the majority of physicians are employed in health systems, there are still many physicians in small practices or groups who own or have a stake in their practice and have to make tough financial decisions.

Large systems have been able to move employees around and repurpose them instead of furloughing them, but this also presents challenges.

“Say you have been working as a nursing assistant in primary
care, and now you are bedside with COVID-19 patients,” he says. “It’s sort of like asking someone to move into a position with great risk to them without adequate protection or preparation.”

Smaller practices don’t have that option, however. “In a lot of primary practices, there is not the financial reserve to just keep going full speed ahead, and there’s not the ability to repurpose all that much,” Roberts says. “There’s just not as much latitude and flexibility available to you. You may have no choice but to furlough or terminate people’s employment.”

In the early days of the crisis, practice owners initially were concerned with how to protect their businesses while balancing the safety of staff.

“At least at the beginning of the virus taking hold, we started to hear from a lot of our medical practices about what this all means. How do we balance financial viability and medical staff needs for the front line?” says Shelly Waggoner, M.S., CEBS, SHRM-SCP, senior vice president of human resources at COPIC. COPIC is a Colorado-based medical liability insurance provider. It has been offering support to its more than 12,000 physician members through its HR Helpline and other virtual support during the COVID-19 crisis.

As the pandemic continued, many practice owners were forced to look at furloughing or terminating staff. With smaller and independent practices often lacking internal human resources departments, Waggoner says she fielded a lot of calls about how to have difficult, and sometimes legally loaded, conversations. “A lot of it was just helping to coach practices through how to have these conversations with employees, how to file for labor and unemployment,” Waggoner says. “We had a number of questions about the [Coronavirus Aid, Relief and Economic Security Act], having to pay out sick time and the impact and burden on practices to do so. Some that were on the border of 50 employees were having to pay salaries without the means to do so.”

The contract is king, if there is one
Ericka L. Adler, J.D., LLM, an attorney at Roetzel & Andress in Chicago, Illinois, says the best advice she has to avoid wrongful termination claims is to honor the contract, if there is one. “No matter what, if you don’t follow the contract you are opening yourself up to the risk of liability. Most contracts don’t give you the ability to just cut off someone’s salary or furlough them just because of [COVID-19] or any other reason,” Adler says. “Look first to see what the contract allows. Not every doctor out there will run and sue, but we are talking about risk aversion. Nobody’s ever gone through this, so most contracts weren’t written with a pandemic in mind, and we must work with the contract we have in place.”

Some employers are trying to get ahead of changes that have to be made by sending memos to update existing contracts. “Technically, most contracts have a provision that says the agreement can only be amended in writing,” Adler says. “If you send a memo and it’s not signed by the employee, it’s not an effective amendment.”

The only way to avoid risk altogether is to honor the contract that was signed, she says. For employees without specific contracts, such as nurses or support staff, it’s safest to stick to following any existing policies in place for the practice and otherwise make sure you comply with employment laws. However, if a business tries to terminate an employee who is refusing to come to work because the practice doesn’t have appropriate safety provisions in place, the employee could have grounds to make a wrongful termination claim. Practices must comply with state and federal requirements to protect employees.

Employment laws vary by state, and an employee’s rights when it comes to termination will depend largely on location and contract language. In at-will states, legal rights over wrongful termination are limited, Roberts adds. To win a wrongful termination claim, he says the employer usually has to do something outrageous, such as...
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terminate an employee for racial or ethnic reasons. When these claims are made, it also falls to the employee to prove it.

If you are terminating for a valid cause, be sure to track and document the reason, he adds. In the COVID crisis, some of these reasons will be financial. In these cases, Roberts says he thinks it’s highly unlikely courts will side with employees in a wrongful termination claim.

“It’s going to be hard for a court to say to an employer, ‘Yes, you have to pay that even if you’re going to run out of money in 28 days,’” he says. “Wrongful termination claims by employees are unlikely to be awarded because the courts at the end of the day will be pragmatic. You lost your job along with a quarter of the rest of America.”

Setting the stage for the next wave

If the virus continues to circulate, resulting in a second wave that is worse than the first, Adler says the problems from the early days of the pandemic will continue. That’s why she is working now to set up protections for her client for the next wave of infections.

“Clients will be best protected by having written policies in place that comply with available [COVID-19] guidance, and sticking to a standard of care to protect workers,” Adler says, adding she expects some liabilities problems from employers who open too soon. “There’s going to be more spikes in [COVID-19]. This will be cyclical, so we need to be prepared.”

Adler says in recent weeks she has been making amendments to employment contracts for employees she represents. These amendments will allow for easier termination in similar circumstances or unilateral changes to compensation in preparation for another round of practice closings.

“Anyone preparing a new contract or amendment is already preparing,” Adler says. “It will be easier for employers to terminate and not negotiate the next time around.”

She has seen disputes over furloughs, repurposing, safety, relocations and fears over COVID-19. The pandemic has forced changes and created business problems, but it hasn’t given employers free rein to change contracts, she says.

“If you are claiming a termination cause, you have to be able to defend it. But you don’t get to just walk away from a contract because it’s convenient,” Adler says. “At the end of the day, [COVID-19] did not change contract law.”

When it’s all over

During discussions about furloughs and layoffs, another concern Waggoner is hearing from practice owners is the fear they won’t have the ability to return to business as usual — whenever and whatever that is.

“One of the biggest concerns for them is what the new normal will be, and I want to make sure they have the talent there and ready to work again,” Waggoner says.

Staff members are being furloughed, and some may look for new work. Others are afraid.

“For clinicians, this is part of what they do, and they accept a level of risk knowing they are on the front line of health care,” Waggoner says. “But there’s a whole host of people who work in the health care community who are also being exposed. It’s some of those individuals that have a heightened level of concern.”

Adler says furloughs and layoffs are slowing down now, as many states consider some form of reopening from quarantines. Most of the attorneys at her firm who specialize in corporate business law are focusing now on how to handle employees who don’t want to come back to work because they are making more in unemployment. They also are drafting policies about how to come back to work.

Many employers have negotiated reductions in pay or work hours to manage staffing and budgets, but many of those agreements were made without an end date. In negotiating contracts for her employee clients, Adler says she has tried to get any compensation that was lost during the worst of the pandemic back in some form, even as an end-of-the-year bonus.

Employees also will have to decide what changes they are willing to tolerate to stay in their position.

“A lot of people assume hospitals and employers got all kinds of money, and they may have gotten money. But they also have a lot of expenses, so that does not mean funds are available to just pay out lost wages. Another issue related to reopening is that some employees just refuse to come back to work,” Adler says, adding that the Occupational Safety and Health Administration (OSHA) requires employers to establish a workplace “free from recognized hazards that are causing or likely to cause death or serious physical harm.”

“Refusing to go to work just because you’re afraid, that’s not okay. If a safety complaint is raised, OSHA requires the employer to address a legitimate concern,” Adler says.

Roberts says it’s important to evaluate long-term needs and make sacrifices accordingly. While an employer may be struggling to keep staff on during the crisis, finding and training new workers when business returns to a normal pace will cost time and money.

“Losing good employees can hurt practice for months and years to come, in terms of quality of care,” he says.

In talking with employees about
furloughs, work reductions and an eventual return to work, Waggoner suggests being open to their fears and concerns.

“What we thought was once not a high-risk position is different now. Things have changed,” Waggoner says. “Some practices are instituting a consent form for staff to acknowledge that working at the practice increases their risk of [COVID-19] exposure, that they [won’t] hold the practice liable and that they are employed at will.”

Waggoner says a number of practices she works with have shared that some employees have taken advantage of federal family leave programs during the COVID crisis, and some are looking for ways to come back to work safely or part ways altogether.

“The key is to follow the CDC’s guidelines, as well as any state-specific guidelines,” Waggoner says. This includes how to clean, how many people to allow in buildings at a time, temperature checks and personal protective gear guidelines. “[It helps] them limit some of the contact that happens in places like waiting rooms and [shows] them some of the protocols.”

For workers who don’t feel safe coming back to a practice, Waggoner says employers ideally should try to work with them on federal leave arrangements, find alternate work arrangements or consider a mutual decision to part ways. In some cases, employers have been surprised by employees refusing to work and then claiming wrongful termination or trying to claim unemployment benefits.

“I talked to a practice yesterday that had an employee who wasn’t comfortable coming back and asked for leave without pay, then filed for unemployment,” Waggoner says. “I think some practices are caught off-guard by that.”

Under normal circumstances, an employer would not be liable for unemployment when the employee initiated it, she explains. There is a bit of nuance in this situation because of the risks COVID-19 presents to both employees and employers.

If a worker is fired for wrong-doing or not performing well, the employer will not have to pay unemployment. When an employee is fired because there is some other reason they cannot do their job — a global pandemic, for example — Waggoner says it’s a “gray area.”

In this situation, the government is providing help in the form of small-business loans and payroll protection. Typically, employers are charged for unemployment and could have a higher tax liability, but unemployment claims related to COVID-19 won’t be counted against employers in this case, Waggoner says.

“It really is a silver lining in this, that when there’s so much out of their control, they don’t have to worry about that, as well,” she says. Employers should always be mitigating risk when it comes to unemployment claims and lawsuits over termination, but Waggoner says it’s helpful to know there’s some relief when things are out of employers’ control.

Small group practices and rural hospitals without their own human resources support seem to have the most trouble with navigating termination claims, Waggoner says. She says that even in at-will states it’s important to protect the practice and have consistent employment policies. Always document problems with an employee, shared conversations and actions taken, she says.

The best bet, Adler says, is to talk to employees about the needs of the practice and a solution that will meet the needs of both the employer and the employee.

“Most employees will be willing to work something out if you go talk to them,” Adler says. “If you don’t follow the contract you are opening yourself up to the risk of liability. Most contracts don’t give you the ability to just cut off someone’s salary or furlough them just because of [COVID-19] or any other reason. Look first to see what the contract allows.”

—Ericka L. Adler, J.D., LLM, attorney, Roetzel & Andress, Chicago, Illinois
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