REPLACING DOCTORS
Competition for the future of primary care
NEXPLANON is indicated for use by women to prevent pregnancy.

SELECTED SAFETY INFORMATION

**Who is not appropriate for NEXPLANON**

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

**Complications of insertion and removal**

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

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

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

**NEXPLANON and pregnancy**

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

- **Rule out pregnancy before inserting NEXPLANON.**

**Educate her about the risk of serious vascular events**

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

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

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

  Counselling about changes in bleeding patterns

- Women are likely to have changes in their menstrual bleeding pattern with NEXPLANON, including changes in frequency, intensity, or duration. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy.

  In clinical studies of the non-radiopaque etonogestrel implant, changes in bleeding pattern were the most common reason reported for stopping treatment (11.1%). Counsel women regarding potential changes they may experience.

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

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

- Remove NEXPLANON if jaundice occurs.

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

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

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

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

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

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

- NEXPLANON does not protect against HIV or other STDs.

Please read the adjacent Brief Summary of the Prescribing Information.
Implant are shown in Table 1. In these studies, women had an average of 17.7 days of bleeding or spotting every 90 days (based on 3,315 intervals of 90 days recorded by 780 patients). The percentages of patients having 0, 1-7, 8-21, and 22-28 treatment days are shown in Table 1. The proportion of 90-day intervals with these bleeding patterns, are summarized in Table 2.

### Complications of Insertion and Removal

NEXPLANON should not be used in women who have:

- Known or suspected pregnancy
- Known or suspected breast cancer
- Known or suspected prostate cancer
- Known or suspected endometriosis
- Known or suspected estrogen-dependent neoplasia or abnormalities of the genital tract
- Known or suspected estrogen-induced thromboembolic disease
- Known or suspected connective tissue disease
- Known or suspected porphyria
- Known or suspected allergy to any of the components of NEXPLANON

In clinical trials of the non-radiopaque etonogestrel implant (IMPLANON), bleeding patterns ranged from amenorrhea (1 in 5 women) to frequent and/or prolonged bleeding (1 in 5 women). The bleeding pattern experienced during the first three months of NEXPLANON use is broadly predictive of the future bleeding pattern for many women. Women should be counseled to expect minor bleeding or spotting. In clinical studies of the non-radiopaque etonogestrel implant, reports of bleeding changes in women who are using hormonal contraception. For women with well-controlled hypertension, use of NEXPLANON should be closely monitored. If sustained hypertension develops during the use of NEXPLANON, or if a significant increase in blood pressure does not respond adequately to antihypertensive therapy, NEXPLANON should be removed.

### Changes in Menstrual Bleeding Patterns

After starting NEXPLANON, women are likely to have a change from their normal menstrual bleeding pattern. These changes may include changes in bleeding frequency (absent, less, more frequent or continuous), intensity (reduced or increased) or duration. In clinical trials of the non-radiopaque etonogestrel implant (IMPLANON), bleeding patterns ranged from amenorrhea (1 in 5 women) to frequent and/or prolonged bleeding (1 in 5 women). The bleeding pattern experienced during the first three months of NEXPLANON use is broadly predictive of the future bleeding pattern for many women. Women should be counseled to expect minor bleeding or spotting. In clinical studies of the non-radiopaque etonogestrel implant, reports of bleeding changes in women who are using hormonal contraception. For women with well-controlled hypertension, use of NEXPLANON should be closely monitored. If sustained hypertension develops during the use of NEXPLANON, or if a significant increase in blood pressure does not respond adequately to antihypertensive therapy, NEXPLANON should be removed.

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Fluid Retention
Hormonal contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention. It is unknown if NEXPLANON causes fluid retention.

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

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

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

Drug-Laboratory Test Interactions
Sex hormone-binding globulin concentrations may be decreased for the first six months after NEXPLANON insertion followed by gradual recovery. Thryoxine concentrations may initially be slightly decreased followed by gradual recovery to baseline.

ADVERSE REACTIONS
In clinical trials involving 942 women who were evaluated for safety, change in menstrual bleeding patterns (irregular menses) was the most common adverse reaction causing discontinuation of use of the non-radiopaque etonogestrel implant (IMPLANON® [etonogestrel implant]) (11.1% of women). Adverse reactions that resulted in a rate of discontinuation of ≥1% are shown in Table 3.

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

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

†Includes “frequent”, “heavy”, “prolonged”, “spotting”, and other patterns of bleeding irregularity.

Potential contraceptive failure is associated with decreased pregnancy protection and increased risk of contraception failure up to 12 months after discontinuation of treatment with NEXPLANON. Women should be advised that the effectiveness of NEXPLANON may be diminished if used with medication that decreases the plasma concentrations of etonogestrel or that increases the plasma concentrations of progestins, including etonogestrol.

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

Human Immunodeficiency Virus (HIV)/Hepatitis C Virus (HCV) protease inhibitors and non-nucleoside reverse transcriptase inhibitors: Significant changes (increase or decrease) in the plasma concentrations of progestin have been noted in cases of co-administration with HCV protease inhibitors (decrease [e.g., neflifavir, ritonavir, darunavir/ritonavir, fosamprenavir/ritonavir, lopinavir/ ritonavir, and tipranavir/ritonavir]) or increase (e.g.), indinavir and atazanavir/ritonavir)/HCV protease inhibitors (increase [e.g., boceprevir, telaprevir]) or with non-nucleoside reverse transcriptase inhibitors (decrease [e.g., nevirapine, efavirenz] or increase [e.g., etravirine]). These changes may be clinically relevant in some cases. Consult the prescribing information of anti-viral and anti-retroviral concomitant medications to identify potential interactions.

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

USE IN SPECIFIC POPULATIONS

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

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

Pediatric Use

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

Geriatric Use

This product has not been studied in women over 65 years of age and is not indicated in this population.

Hepatic Impairment

No studies were conducted to evaluate the effect of hepatic disease on the disposition of NEXPLANON. The use of NEXPLANON in women with active liver disease is contraindicated [see Contraindications].

Overweight Women

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

OVERDOSAGE

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

NONCLINICAL TOXICOLOGY

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

PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling.

- Counsel women about the insertion and removal procedure of the NEXPLANON implant. Provide the PATIENT COUNSELING INFORMATION. Have the woman complete a consent form and retain it in your records. The USER CARD and consent form are included in the NEXPLANON packaging. Have the woman complete a consent form and retain it in your records. The USER CARD should be filled out and given to the woman after insertion of the NEXPLANON implant so that she will have a record of the location of the implant in the upper arm and when it should be removed.
- Counsel women to contact their healthcare provider immediately if, at any time, they are unable to palpate the implant.
- Counsel women that NEXPLANON does not protect against HIV infection (AIDS) or other STDs.
- Counsel women that the use of NEXPLANON may be associated with changes in their menstrual bleeding patterns such that they know what to expect.

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of MERCK & CO., INC., Whitehouse Station, NJ 08889, USA.

For more detailed information, please read the Prescribing Information.

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WOMN-1272021-0000 11/18
The best way to treat patients

I was at a conference recently, which always helps me reset professionally. One quote shared by a plenary speaker was from Patch Adams: “You treat a disease, you win, you lose. You treat a person, I guarantee you, you’ll win, no matter what the outcome.” As I saw patients in clinic today, I thought about things differently—what if I did treat Mary, Stuart, Lee, and Pamela rather than CHF, diabetes, asthma, and depression?

One of my patients has an emotional sickness that manifests all over her body. She has experienced one blow after another and now finds herself racked with pain. Another patient has intolerable back pain because of her job. If she wants to alleviate the back pain, she needs to find another job, but this is not easy.

One young patient who is essentially homeless and uninsured despite working full time needs a generic antibiotic but cannot afford the $12 co-pay. A patient with many chronic medical problems skipped an important diagnostic test because the copay was too high, and he cannot afford over the counter cough medication until he gets his next check.

The treatment these patients need cannot be packaged in a pill form. True treatment of the person involves so much more.

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The treatment these patients need cannot be packaged in a pill form. True treatment of the person involves so much more. However, those are the moments that make me feel incapable and impotent. I can be a sympathetic ear when I listen to patients describe the many trials they are facing, but I can’t solve them. The myriad complexities, inequity, instability, and inconsistencies in our current healthcare system seem to be unsolvable. Homelessness, joblessness, poverty, and broken relationships haunt my patients relentlessly and are the true health concerns they face. Yet these are the very problems I have few resources to address.

Caring, being empathic, and even being mindfully present can alleviate some of the suffering my patients experience. However, the human, rather than the distant professional, side of me wants to step into some of these spaces and help in a different way. I know that I can’t cover every copay a patient can’t afford, but I could’ve covered this one today. I’m not in the vocational rehab business, but I know of some job openings that may benefit my patient.

That instinct to help has been trained out of me, and I recognize that this is for some good reasons. Saving everyone would surely crush me under the weight of unmet social and societal needs. Maintaining objectivity does allow a physician to make certain decisions and do certain things that are necessary and hard.

So, I’m left wondering how to best treat my patients—how to balance the medical with the “other”—whether that is heartbreak or hopelessness. I may have found success at the end of my day with a lovely patient who is battling depression. At our last visit, he bowed under the weight of his life. I adjusted one medication, made some recommendations about his work environment, encouraged time in nature and in the sunshine. The medication change didn’t work—too many side effects. However, the changes to his work environment and spending time outside helped immensely. I need more treatment plans like this one.

Jennifer Frank, MD, is a family physician and physician leader in Northeastern Wisconsin and finds medicine still to be the best gig out there. Married with four kids, she is engaged in intensive study and pursuit of work-life balance.
Cover Story
Replacing doctors

Competition for the future of primary care  Page 16

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How technology can help solve the doctor shortage

The threat of a physician shortage is nothing new but seems to have picked up steam in the last few years. In fact, new figures from the Association of Medical Colleges (AAMC) anticipate a shortage of up to 120,000 physicians by the year 2030. This is a particular challenge in rural areas, where the ratio of patients to physicians is around 769 to 1.

As discouraging as these statistics may seem, there is still hope. The fact is that, despite a widening ratio of patients to doctors, there remains a severe lack of optimization in healthcare organizations across the country. Far too many appointments currently go unfilled or are missed by patients on a daily basis.

When physicians operate at full capacity, with fewer no-shows and cancellations, there’s a much better balance between healthcare demand and physician supply. Addressing this imbalance would be the equivalent of adding thousands of physicians into the healthcare system overnight.

To begin, we must build a system that benefits all involved in healthcare delivery—from physicians to patients to staff. The good news is this solution is already available. Several strategies facilitated by technology are helping provide access to hidden capacity in our current health system.

Digital care coordination, or technology with the ability to intuitively guide patients to and immediately schedule them with the right care, is key to filling any open or unused appointment slots and reducing no-show rates, both of which increase physician capacity. With direct access to physicians’ calendars, call center agents, patients, and referring agencies can see all available appointment slots in real time for any given day. This increases the chances that those open slots will be filled on an ongoing basis, ensuring that physicians’ daily schedules are full.

Physician practices note that no-shows are one of their biggest challenges. Across specialties, no-show rates hover between 5 percent and 10 percent on average although we have seen them as high as 30 percent or more. Implementing online self-scheduling with automated reminders can help physicians regain these lost appointment times and reduce no-show rates.

To read more, visit bit.ly/tech-doctor-shortage

MORE ONLINE

“Remember, the process of mirroring and validation is not telling the patient that they are right or do that you agree with them! It is simply a tool that allows you to demonstrate to the patient that you understand his or her emotional state and belief set at that moment.”
—Rebekah Bernard, MD, on using psychology to defuse emotionally charged situations

“Like the stethoscope, the EHR can become that indispensable tool that fulfills its promise to improve patient care and safety and reduce the time burden on clinicians. We have much more work to do together for this to be a reality.”
—Carrie Horwitch, MD, MPH, on what can be done to improve the EHR.

To view, visit bit.ly/docs-have-it-worse

For more, visit bit.ly/practice-RCM.
I appreciate the position and understand the rationale of physicians who charge monthly fees to their patients in the Direct Primary Care (DPC) model ("The value of the direct pay monthly fee," November 10, 2018 issue). I don’t begrudge those that charge a membership fee, but I would argue that the fee is not always necessary and can be justifiably seen as exclusionary by some.

I have operated a no insurance model of primary care for over 20 years. Like the DPC model, I have been able to offer markedly reduced fees compared to traditional practice models by avoiding the significant (and passed down) expenses of insurance billing, extra staff, EHRs and the various mandated acronyms that drive physician burnout.

While a bargain to many, some patients simply cannot afford the annual membership fee that is commonly charged. The vast majority of my patients would be able to have 5 to 10 visits per year with basic labs for less than the DPC fee.

Keith Dinklage, MD
NEW CASTLE, IND.

It will last 6 or 7 years not 11 years. Most of them will be trained in community health centers and not in hospitals, since all of the care they provide is office care and most of their time is spent treating uncomplicated illnesses and coordinating care with specialists.

There will always be exceptions of course for physicians who want further training because they want to take on supervisory or administrative positions in health networks overseeing nurse practitioners.

The point is that a national shortage of primary care physicians exists. Addressing the problem has been a long time in coming. Much work remains to be done.

Nurse practitioners practicing primary care within the limits of their training is the first step in addressing and correcting the problem.

Edward Volpintesta, MD
BETHEL, CONN.

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Nurse practitioners are the first step in correcting the primary care shortage

disagree that nurse practitioners providing primary care independently is ‘ruining medicine’; “Replacing primary care physicians with NPs/’PAs” (What’s Ruining Medicine, December 25, 2018 issue).

Many states have already licensed nurse practitioners to practice independently, a position also been endorsed by the National Academy of Medicine—and with only 18% of American medical students entering primary care residencies it is even more likely that nurse practitioners will be entering the primary care workforce.

The role of primary care doctors has changed. The current route of 4 years of pre-med, followed by 4 of med school, and 3 of residency no longer serves because primary care doctors do not need in-depth knowledge of subjects like organic chemistry and biochemistry and physics. The pre-med and medical school curriculums could be combined by customizing the science courses to include only what is necessary.

Primary care doctors of the future will be trained much differently than today. Their training will be more practical. It will consist of those skills that are needed in the health care system, skills that are different than those taught in traditional programs.

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Direct primary care can work without a monthly fee

I disagree that nurse practitioners providing primary care independently is ‘ruining medicine’; “Replacing primary care physicians with NPs/’PAs” (What’s Ruining Medicine, December 25, 2018 issue).

Many states have already licensed nurse practitioners to practice independently, a position also been endorsed by the National Academy of Medicine—and with only 18% of American medical students entering primary care residencies it is even more likely that nurse practitioners will be entering the primary care workforce.

The role of primary care doctors has changed. The current route of 4 years of pre-med, followed by 4 of med school, and 3 of residency no longer serves because primary care doctors do not need in-depth knowledge of subjects like organic chemistry and biochemistry and physics. The pre-med and medical school curriculums could be combined by customizing the science courses to include only what is necessary.

Primary care doctors of the future will be trained much differently than today. Their training will be more practical. It will consist of those skills that are needed in the health care system, skills that are different than those taught in traditional programs.

It will last 6 or 7 years not 11 years. Most of them will be trained in community health centers and not in hospitals, since all of the care they provide is office care and most of their time is spent treating uncomplicated illnesses and coordinating care with specialists.

There will always be exceptions of course for physicians who want further training because they want to take on supervisory or administrative positions in health networks overseeing nurse practitioners.

The point is that a national shortage of primary care physicians exists. Addressing the problem has been a long time in coming. Much work remains to be done.

Nurse practitioners practicing primary care within the limits of their training is the first step in addressing and correcting the problem.

Edward Volpintesta, MD
BETHEL, CONN.

Direct primary care can work without a monthly fee

I appreciate the position and understand the rationale of physicians who charge monthly fees to their patients in the Direct Primary Care (DPC) model ("The value of the direct pay monthly fee," November 10, 2018 issue). I don’t begrudge those that charge a membership fee, but I would argue that the fee is not always necessary and can be justifiably seen as exclusionary by some.

I have operated a no insurance model of primary care for over 20 years. Like the DPC model, I have been able to offer markedly reduced fees compared to traditional practice models by avoiding the significant (and passed down) expenses of insurance billing, extra staff, EHRs and the various mandated acronyms that drive physician burnout.

While a bargain to many, some patients simply cannot afford the annual membership fee that is commonly charged. The vast majority of my patients would be able to have 5 to 10 visits per year with basic labs for less than the DPC fee.

All I am saying is that the DPC model can work without charging a monthly fee and that may be an option for physicians who embrace all of the other features of that model.

Keith Dinklage, MD
NEW CASTLE, IND.
WHO REMAINS UNINSURED IN THE POST-OBAMACARE UNITED STATES?

Despite passage of the Affordable Care Act (ACA), or so-called “Obamacare,” millions of Americans still lack health insurance. The Kaiser Family Foundation, a non-profit organization that focuses on analysis of healthcare issues, recently compiled a report that broke down the who and why of the American uninsured population. This data is from 2017, the latest available.

The top five reasons are:

- Cost of insurance is too high (45%)
- Lost job or changed employers (22%)
- Lost Medicaid (11%)
- Status change (11%)
- Employer does not offer insurance or ineligible for coverage (9%)

A member of a working family
- Low income
- Non-elderly adult
- More likely to live in a state that did not expand Medicaid coverage, and in a Southern or Western state
- Been without coverage for long periods of time

“Ongoing efforts to alter the ACA or to make receipt of Medicaid contingent on work may further erode coverage gains seen under the ACA.”

—Kaiser Family Foundation, “Key facts about the uninsured population,” December 2018
When patients hit ‘record’ at the doctor’s office

I was recently at my physician’s office and observed a patient recording himself and a family member in the waiting room. He continued recording as he walked down the practice hallway and entered the examination room. It was clear that the patient had not only recorded himself, but had captured other patients in the room and patient names being called out. He even potentially captured conversation between patients and health care providers. Yet, no one from the practice told him to stop filming, questioned his activities, or otherwise reacted. Has this happened in your practice? If it did, how would you react?

The right to record

Finally, practices should be aware that patients have the right in most states to record interactions with third parties where the law only requires one party to consent to the recording. This means a patient does not need to inform the physician that he or she is recording at all.

Other states, such as Illinois, require that both parties are aware of the recording. This means that in these states, a patient who records a physician or staff interaction without permission has actually violated the law.

I recommend exploring these issues with legal counsel in order to assure that your practice is properly protected, and that any plan is tailored specifically to your practice’s needs. For example, the approach may be different for an internal medicine practice compared to one that focuses on cancer or communicable diseases.

Knowledgeable legal counsel can assist in understanding your practice’s legal risks and potential vulnerabilities.

Plan ahead

The above scenario is hardly surprising in the age of social media, although it was a first for me.

However, while most healthcare providers and medical practices are aware of the significant limitations HIPAA places on their activities, it is less clear how to react when it’s the patient who wants to record the physician and could potentially expose protected health information of other patients.

Practices should address the issue of patients recording themselves and others by planning ahead. A practice should develop a policy for handling such activity and prepare the necessary paperwork for patients to acknowledge the policy put in place.

If a practice chooses to allow such recordings, then the policy must set the appropriate parameters for recording at the practice, such as where filming can occur, whether permission must be requested, and other necessary requirements.

Sometimes patients ask their physicians directly to record an encounter for arguably legitimate reasons, such as to help remember medical information or instructions or share the details of the visit with caretakers or loved ones. A practice should have a separate approach for physician recordings and should tailor it to physician preferences.

Take precautions

What happens if a patient does not ask permission and records the physician without his or her knowledge? While this may violate the practice’s policies, such activity can also expose the practice to liability and impact its reputation. What information was in plain sight and recorded that presented a HIPAA issue? Could the practice be liable for anything else related to the recording? How did its staff behave?

Practices should be aware at all times that recordings may take place without their knowledge, so appropriate HIPAA precautions and patient interactions should be the norm through training and preparation.

Ericka L. Adler, JD, has practiced in the area of regulatory and transactional healthcare law for more than 20 years. Send your legal questions to medec@ubm.com.
Experts analyze a proposed Medicare change that could impact the way physicians prescribe pharmaceuticals

by KEITH LORIA  Contributing author

**HIGHLIGHTS**

- The plan would index drug prices for Medicare to make them comparable to 16 other nations that pay much less for the drugs than Medicare.

- Although the proposed index is likely to save money in the short term, some experts worry it will harm innovation in the long term.

President Donald Trump has proposed lowering drug prices by basing them on other countries’ costs, a monumental change that could save Medicare beneficiaries—as well as the government—millions of dollars.

But many Republicans oppose the plan because it promotes importing price controls from other countries, while Democrats feel it doesn’t go far enough. Numerous physician groups and provider advocacy organizations have already spoken out against the proposal.

Conservative groups are fighting it as well. Last month, FreedomWorks, a Washington-based advocacy group, and Americans for Tax Reform, an anti-tax organization, wrote a joint letter to HHS Secretary Alex Azar criticizing the proposal and demanding that it be withdrawn.

Trump released the outline of his plan shortly after the October publication of a government report showing that Medicare was paying as much as 80 percent more than other advanced industrial countries, such as France and Germany, for some of the most expensive physician-administered medicines.

Additionally, the report showed that the costs charged by drug manufacturers to U.S.-based wholesalers and distributors were 1.8 times greater than in other countries for the most prescribed drugs.

Under the administration’s proposal, CMS would reduce the Medicare payment amount for some Medicare Part B drugs to make them more comparable to international prices by benchmarking them against 16 other European and Asian nations.

Additionally, it would allow private-sector vendors to negotiate drug prices and compete for physician and pharmacy business, and would increase the 4.3 percent drug add-on payment to 6 percent of historical drug costs. The proposal also would pay physicians a flat fee for prescribing medicines, independent of pricing.

HHS estimates this new payment model would save $17 billion over five years.

Edward Halperin, MD, chancellor and CEO of New York Medical College, says the proposal only addresses about 5 percent of the drug market, focusing on drugs administered by physicians in their offices, adding that Trump’s action is a slow motion, minimalist attempt to deal with a small proportion of pharmaceutical companies’ price gouging.

“It has nothing to do with the vast majority of the purchases of drugs: people filling prescriptions at either their brick-and-mortar or online pharmacies,” he says. “For a self-proclaimed economic nationalist, President Trump seems perfectly happy to outsource negotiating lower drug prices to European national health systems rather than do the right thing for most Americans: empower Medicare to directly negotiate lower drug prices for Medicare Part D with pharmaceutical companies.”
THE POSSIBLE IMPACT ON PATIENT CARE

Lindsay Bealor Greenleaf, director at ADVI Health, which counsels healthcare companies on government affairs, says the Trump administration has enacted several promising reforms to align incentives across the supply chain and reward innovation, but the latest proposal to implement international reference pricing for Medicare Part B drugs is troubling.

She says the proposal poses significant access issues for seniors suffering from some of the most devastating and complex conditions, such as cancer, rheumatoid arthritis, and other autoimmune diseases.

“Compared to the rest of the world, the U.S. places a high value on access to therapies, which is why Americans currently enjoy access to cancer treatments about two years earlier than other developed countries,” she says. “If the government chooses to swap today’s payment design for a model that links to foreign countries’ socialist payment designs, then the speedy access to innovative therapies that we enjoy today is at risk.”

She argues that this IPI (International Pricing Index) model would hinder access to current and future drugs, and would restrict access to patients’ preferred physicians as many of today’s independent practices would be compelled to sell their practice to large hospital systems to absorb the uncertainty and financial risk associated with the proposal.

Independent practices already face pressure to sell themselves to hospital systems, she says, due to the significant reimbursement disparities between hospital outpatient departments (HOPDs) and physician offices, and due to the 340B drug discounts afforded to HOPDs and not physician offices. If finalized, this proposal would add to that pressure by creating significant reimbursement uncertainty for independent practices.

“The cures on the market today are the result of an environment that encourages and rewards innovation,” she says. “Going forward, if the U.S. reimbursement system is tied to socialist countries that do not reward innovation, manufacturers will lack the incentive to invest in the costly research and development that is required to produce these treatments.”

Although the proposed index is likely to save money in the short term, it will have an adverse effect on patient health in the long run, says Jason Shafrin, PhD, senior director of policy & economics for Precision Health Economics.

“Linking U.S. pharmaceutical prices to those in other countries to drive down cost means that the overall revenue for innovators will also fall,” he says. “Academic research clearly indicates lower revenues lead to pharmaceutical firms reducing their investments on research and development, leading to lower levels of future innovation.”

If only certain drug classes were affected, innovation could be expected to fall for just those specific therapeutic areas, he says. For instance, pharmaceutical firms could shift towards R&D for treatments that affect a larger number of working age adults.

“One item to note is that overall innovation may not be affected if the result of the plan is that pharmaceutical firms raise prices in Europe and Asia,” he says. “In that case, U.S. prices would fall, European and Asian prices would rise, and overall innovation may not change for these products.”

In the short run, however, it may be difficult to change prices abroad if these contracts are already negotiated.

Precision Health’s research shows that cancer mortality reductions were highest in countries that spent the most on cancer treatment. Therefore, Shafrin believes, while the Trump plan would produce short-term cost savings, it would risk worsening America’s long-term health prospects due to lower rates of innovation.

The logic chain is whether more innovation results in more novel treatments, which then results in better patient outcomes. The study Shafrin cites does not link reimbursement to levels of innovation, but rather that more innovation/quicker adoption of innovation leads to better outcomes.

“The Trump plan will benefit patients’ wallets as lower drug costs likely would mean either lower patient out-of-pocket costs or lower premiums,” he says. “However, patient health is likely to suffer as there will be fewer new and effective treatments available, unless pharmaceutical firms are able to raise their prices in Europe and Asia.”

While costs may not be cut only from R&D, additional belt-tightening not affecting the bottom line assumes that pharma is inefficiently run and includes a lot of waste to wring out. Shafrin says if that were
the case, pharma companies could already make more profits by cutting non-R&D costs.

"At a more basic level, pharma firms will consider whether to invest R&D dollars in a risky clinical area," he says. "If there is additional belt tightening, that likely means return from that investment will be lower. Lower returns likely will reduce the number of treatments pharma will try to pursue."

For instance, if a drug had a 5 percent chance of coming to market, with lower subsequent profits, perhaps pharma would only invest R&D funds in treatments that have a 10 percent chance of approval. The numbers are hypothetical, but they demonstrate how expected reimbursement and profits will affect the likelihood of individuals (or in this case companies) investing in the first place.

THE EFFECT ON PHYSICIAN PRESCRIBING

John Driscoll, CEO of home health coordination company CareCentrix, explains that physicians currently are paid a percentage of the price of the drug that they administer. They lose income when they prescribe a less expensive medication, even though they are saving Medicare money, and they gain when they prescribe something more expensive and when prices increase. Under Trump's plan, physicians would receive a flat fee, which is a more logical approach that aligns the interests of doctors and patients.

If office-based infusion becomes less financially attractive, he adds, in some cases physicians may refer their patients to far more expensive hospital outpatient facilities, driving system costs up. Ideally, Medicare would provide coverage for home-based infusion, which is more convenient, less expensive, and safe.

Shafrin says a drawback to flat rate reimbursement is that it could limit patient access to breakthrough treatments, as some physician-administered medications may cost tens or even hundreds of thousands of dollars per year and physician outlays on inventory for these treatments can be substantial.

"Flat physician payments do not take into account physicians cost of capital needed to hold these treatments in inventory over an extended period of time," he says. "Thus, physicians may begin refusing to stock highly effective, though expensive, treatments if the administration costs more than this new flat rate reimbursement level."

For example: Drug A is more expensive than drug B, but expected survival for patients on drug A is 10 years compared with only one year on drug B. Most people would want patients to get the more effective drug A. But under the proposed plan, physicians may not be able to afford the capital cost of holding drug A in inventory.

Halperin says that by creating a flat fee for physicians to buy and sell drugs administered in their offices, rather than paying them as a percentage of the price of the drug, there will be no financial incentive for physicians to choose high-cost drugs over equally effective and cheaper alternatives.

"Physicians try to justify reasons to select expensive and complex treatments when simpler and less expensive options are just as effective," he says. "To the extent that this proposal cuts the legs out from the profit motive that influences drug selection by physicians giving drugs in their offices, it will be to the benefit of patients."

In many European countries, there is a social contract that the government holds down the cost of treatment and assumes most of the cost, and patients are willing to wait longer for innovative treatment.

"Historically, in the United States, people do not want the government dictating prices centrally and do not want delayed access to potentially life-saving treatments," Shafrin says. "The key question is: Are Americans willing to reduce innovation in the future in order to gain more affordability in the short run?"
During each of the past three years, covered entities paid more than $20 million in HIPAA fines. While a handful of major breaches made headlines—most notably Anthem’s $16 million mistake—small practices can’t afford to be complacent about security.

The more negligent a healthcare organization is found to be at the time of a HIPAA violation, the higher the penalty. According to the U.S. Department of Health and Human Services, fines can range from $100 to $50,000 per violation or record, with a maximum penalty of $1.5 million per year for each violation.

For physician practices, even minor penalties can take a major financial toll. And that’s where the trouble just begins.

“More importantly for practices, a breach could impact their business continuity,” says Robert Tennant, director of health information technology (HIT) policy for the Medical Group Management Association. The loss of one month’s worth of claims data, for example, could cause significant disruption and potential loss of revenue, he notes.

Another significant risk to medical practices is damage to their reputations, says Matthew Fisher, JD, a partner with Mirick, O’Connell, DeMallie & Lougee LLP, in Massachusetts. Once you’ve had a HIPAA breach, the name of your practice is listed permanently on the Office for Civil Rights’ Wall of Shame—including the offense, date, and number of individuals affected. “It does have an impact in terms of patients wanting to continue with the provider,” Fisher says.

There’s also the ongoing cost of providing credit monitoring to affected patients for at least a year, as required by HIPAA, as well as the mental anguish of having to respond to a government investigation, whether a fine is issued or not, adds Fisher.

As a result, preventing breaches of protected health information should be viewed by practices as a business imperative, says Tennant, adding that security depends on continually asking the question, “What if?”

The list of scenarios to consider is nearly infinite: a phishing attack, sending a fax to the wrong number, losing an unencrypted thumb drive, as well as threats that have yet to evolve.

**CONDUCT A RIGOROUS A RISK ASSESSMENT**

The best way to identify a practice’s key vulnerabilities is by conducting a baseline risk assessment, which has been required of practices since the HIPAA Security Rule went into effect. HHS is vague as to when and how often covered entities must conduct risk assessments—they recommend it be done “regularly”—but experts suggest performing this assessment at least annually.

“The risk analysis is going to give you a pretty comprehensive overview of your weaknesses, and is really going to help frame out how you’re going to implement all...”
the different security policies,” says Fisher. Nonetheless, it’s a step practices often skip. “For incidents that result in a settlement of monetary fine, almost every time, there’s either a missing risk assessment or an inadequate risk analysis,” he says.

For practices that don’t have the necessary in-house technical expertise, it can be worth the cost to outsource at least part of the project, experts say. A third party may then there’s probably somebody who’s going to tell them.”

Yamamoto recommends that healthcare organizations of all sizes focus cybersecurity training around the basics of everyday work life. “Fundamentally, a lot of security comes down to people’s passwords,” he says. “If somebody gets that password, they’re in.”

To keep hackers at bay, he recommends using long passwords with at least 12 characters, and different passwords for every place a user logs in. To keep track of them all, he advises using a password manager, which is a software application that stores and manages a user’s passwords for all their various online accounts and security features. This tool stores the passwords in an encrypted format, which the user accesses with a master password.

Fisher also recommends that practices require multi-factor authentication, such as a password and a fingerprint, whenever possible.

Another best practice is to instruct individuals not to access medical records they don’t need to perform their job. “People probably don’t realize they’re perpetuating data breaches when they enter a record that they really have no clinical reason to be in. We tell people they can’t look in their own medical records or those of family members outside of the due course of their jobs,” Fisher says.

Finally, physicians must take cybersecurity training seriously and keep their knowledge up to date by really listening to the education their employers provide, says Rebecca Grochow Mishuris, MD, MPH, associate chief medical information officer for Boston Medical Center and an assistant professor of medicine at Boston University School of Medicine.

“There are new threats coming out all the time that we have to address,” she says. “It’s not enough to say you learned it three years ago. Three years ago, things were very different than they are now from a data security standpoint.”

For example, phishing attacks have become much more sophisticated in recent years. “It’s not like the email from the prince in Nigeria anymore. It’s an email that looks like it came from your institution,” says Mi-
shuris, a general internist at Boston Medical Center. So anyone using the practice’s email system needs to be aware that the practice will never ask for a password over email, or a link that requires the user to sign in, without verbal warning.

A strong spam filter will catch most emails falsely claiming to be from the practice or other trusted entities, but it’s critical that all users learn to recognize a potentially dangerous email and what to do about it.

REQUIRE REPORTING
Practices must make it clear to all clinicians and staff that if they click on a bad link, open a suspicious attachment, or make another security-related mistake that they will not be disciplined—and that reporting incidents is crucial, Mishuris says.

The sooner a potential breach is discovered, the sooner an organization can take steps to stop or minimize the damage, such as securing the employee’s password and sending a blast email to describe the threat to the rest of the staff and instruct them on what to do if they receive it. To that end, individuals must be trained in reporting procedures, which typically involve notifying IT via a dedicated email address of phone number, she explains.

“It’s important that the practice culture not penalize reporting, but promote behaviors that help find gaps and make improvements,” Mishuris says. Early detection that allows time to intervene in a breach is essential to limiting a practice’s liability when security incidents occur, she says.

COMMUNICATE CREATIVELY
Security and privacy officials at Beth Israel Deaconess employ several tactics to instill good security habits throughout the organization, but a common thread is an effort to make messaging memorable, says Yamamoto.

For example, the organization has distributed bags of Swedish Fish candy with accompanying information about phishing, he says. Yamamoto has also been filmed holding a fishing pole in an educational video about the same topic.

“We try to use a story-based approach, using funny or [silly] things that will help people stop for a moment and think about what they’re doing,” he says. “When you’re so busy pushing things out, it’s really easy to perpetuate a major problem.

GIVE HIT SOME TLC
Finally, HIT systems themselves need regular attention to operate securely, using outside help if necessary, says Yamamoto. It is especially important to install software updates when they are released and make sure antivirus software is adequate and up-to-date.

“Keep those things up with some tender loving care, and you’ll be in pretty good shape,” he says.

“Fundamentally, a lot of security comes down to people’s passwords. If somebody gets that password, they’re in.”

—MICHAEL YAMAMOTO, CHIEF INFORMATION SECURITY OFFICER FOR BETH ISRAEL DEACONESS MEDICAL CENTER

Get help on your security risk assessment
The Office of the National Coordinator for Health Information Technology (ONC) has an online tool designed to help physicians navigate the process of conducting a risk assessment.

Steve Maron, MD, read an article in his local newspaper about nurse practitioners (NPs) providing care independent of a physician’s supervision and worried the public might confuse the two professions. As a result, he penned an op-ed for his local newspaper, the Green Valley News in Green Valley Ariz., in January 2018 highlighting the differences in training between a doctor and a nurse practitioner.

Maron, a pediatrician who worked at a Federally Qualified Health Center in Green Valley, was informed a few days later by the facility’s leadership that they were terminating his employment because his opinion was counter to the organization’s principle of mutual respect.

Stunned by the decision, he offered to apologize for any offense he caused in what he saw as nothing more than a comparison of training levels to help educate the public about the different types of providers.

“They said it was too late for that,” says Maron, who adds that the whole incident was outrageous and traumatic, and something he still isn’t completely over. He had planned on working at the clinic for at least five more years, but the firing forced him into quasi-retirement. Maron now works as a locum tenens for the Indian Health Service while he searches for a permanent position.

“The nurse practitioners I’ve encountered are very intelligent, motivated, and for the most part, have good interpersonal skills and do very well with patients,” says Maron, adding that they are especially good

HIGHLIGHTS

Nurse practitioners now have independent practice rights in 22 states and the District of Columbia.

Advocates for nurse practitioners say studies show they provide care that is as good as or better than doctors, in many cases. Physicians say the studies are limited in scope and that the evidence doesn’t support that conclusion.

"REPLACING DOCTORS"

Competition for the future of primary care

by TODD SHRYOCK Managing Editor
at working with patients who have chronic conditions.

But he objects to the idea that NPs should be allowed to practice independently. “I think we are on a slippery slope where the nurse practitioner organizations are pushing the idea—and the public is accepting—that they are pretty good at what doctors do. Where nurse practitioners fall short isn’t because they aren’t smart enough, but because they haven’t had the training and background. They are dismissing the value of medical school residency and fellowship.”

**GROWING CONCERN**

Maron is not alone in his concern about the growing influence of nurse practitioners and other non-physician providers in primary care. Readers of Medical Economics ranked “replacing primary care physicians with NPs/PAs” fifth in the magazine’s “What’s ruining medicine?” poll. And a group advocating for patient care led by physicians, Physicians for Patient Protection, launched late last year in response to the growing movement favoring independent practice rights for non-physicians.

NPs now have independent practice rights in 22 states and the District of Columbia. While physician assistants (PAs) still require a formal agreement with a supervising physician, the American Academy of Physician Assistants is advocating that a collaborative agreement with a physician no longer be necessary to practice. And while the organization says it still expects its members to maintain such relationships, it wants to eliminate the legal formality of a the agreement.

The American Osteopathic Association (AOA) issued a news release in October voicing its objection to non-physician providers being granted independent practice rights (known legally as full practice authority) and the effect that will have on patient care. It also called for greater transparency to patients about the qualifications of who is providing their care.

“Ultimately, we want to make sure patients have the information to make informed decisions about their care,” says David Pugach, JD, senior vice president of public policy for the AOA. “There are highly trained, qualified providers across all professions, but the fact is, given the educational requirements and variations, you don’t know what level of training the provider has if the person you are seeing is not a physician.”

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**NP scope of practice laws, by state**

Scope of practice laws for nurse practitioners (NPs) vary between states. In **full autonomy** states, NPs can evaluate patients, diagnose, order and interpret diagnostic tests, initiate and manage treatments, including prescribing medication and controlled substances. In **reduced autonomy** states, NPs are restricted from at least one element listed above and usually require a collaborative agreement with a physician. In **no autonomy** states, NPs have career-long supervision by another provider, usually a physician.
While Pugach says that physicians value the skills NPs and PAs bring to patient care, the AOA believes they should be part of a physician-led team. “When part of a physician-led team, there is additional assurance that the physician plays a role in the diagnostic and treatment decision-making process, which is important for high-quality care,” says Pugach.

According to the AOA, physicians average more than 12,000 patient-care training hours, while NPs average more than 500 and PAs over 2,000.

“Even the best NP is not trained or prepared to function fully independently like a physician,” says Richard Thacker, DO, FA-COI, an internist and assistant professor of internal medicine at the Alabama College of Osteopathic Medicine.

In addition to the concerns over training hours are questions regarding how and where some NPs are being instructed. “Some of the programs for NPs are almost exclusively online,” says Thacker. “That’s just crazy.”

Joyce Knestrick, PhD, FAANP, president of the board of directors for the American Association of Nurse Practitioners (AANP), says that how a nurse practitioner receives his or her education is irrelevant. “There is no evidence that shows that nurse practitioners who complete their coursework online versus a standard brick-and-mortar school are less qualified,” says Nestrick. “We do have standards the schools have to pass regardless of modality as well as clinical requirements. Regardless of where a student takes their courses, they still have to pass a test.”

Thacker says that a test is only one measure of competency, and that NPs who don’t have any nursing experience but practice independently are a concern to him. “Nothing substitutes for actual experience and managing patients at a bedside,” he says. “I’m board certified and have taken several high-stakes tests. I don’t like it, but it’s only one small aspect of demonstrating to the public that I’m qualified.”

Rebekah Bernard, MD, a family physician in Fort Myers, Fla., thinks NPs should not be allowed to practice independently. “They are told constantly in training and by their political organizations that they are just as good as doctors and can do everything a doctor can do,” says Bernard. “It may not be what they want to hear, but they don’t realize what they don’t know.”

Roy Stoller, DO, an otolaryngologist in New York City and board member of Physicians for Patient Protection, says his recently launched organization already has 10,000 physician members. He attributes its rapid growth to concern over non-physician providers providing care once reserved for doctors, and doctors’ fears about voicing objections to it.

“I have a bunch of friends who can’t speak out because they’ll lose their jobs,” says Stoller. “They are seeing ridiculous workups from unsupervised NPs, and do not want to stay silent. I’m not sure how someone with a master’s degree, who has not had the benefit of eight years of schooling and three years minimum of residency, can see themselves as just as qualified as a doctor.”

FILLING IN THE GAPS?

One of the arguments for granting NPs more independent practice rights is that they help alleviate the primary care physician shortage.

“We are seeing a drastic decline in the number of physicians in primary care, particularly in rural and underserved areas. We are able to go in and close those gaps.”

— JOYCE KNESTRICK, PHD, BOARD PRESIDENT, AMERICAN ASSOCIATION OF NURSE PRACTITIONERS

“We are seeing a drastic decline in the number of physicians in primary care, particularly in rural and underserved areas.”

— JOYCE KNESTRICK, PHD, BOARD PRESIDENT, AMERICAN ASSOCIATION OF NURSE PRACTITIONERS
NEWLY EXPANDED AGE INDICATION

GARDASIL 9 has helped protect appropriate 9- to 26-year olds from certain HPV-related cancers and diseases and can now be used in appropriate adults up to age 45.

Abbreviation: HPV, human papillomavirus.

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INDICATION

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

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

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

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

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

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

INDICATION (continued)

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

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

SELECT SAFETY INFORMATION

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

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

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

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

• The duration of immunity of GARDASIL 9 has not been established.

DOSAGE AND ADMINISTRATION

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

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

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

Please read the adjacent Brief Summary of the Prescribing Information.

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VACC-1265905-0000 10/18
After a previous dose of GARDASIL 9 or GARDASIL®.

Hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or higher anterolateral area of the thigh.

Administer GARDASIL 9 intramuscularly in the deltoid region of the upper arm or in the thigh. Do not use the product if the vial is damaged, solution is cloudy or discolored, or if the propanol is precipitated.

To maintain suspension of the vaccine. GARDASIL 9 should not be diluted or mixed with other vaccines.

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

ADVERSE REACTIONS

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

The safety of GARDASIL 9 was evaluated in seven clinical studies that included 15,703 individuals who received at least one dose of GARDASIL 9 and had safety follow-up. Study 1 and Study 3 also included 7,378 individuals who received at least one dose of GARDASIL 16 as a control and had safety follow-up. The vaccines were administered on the day of vaccination enrollment and the subsequent doses administered approximately two and six months thereafter. Safety was evaluated using vaccination report card (VRC)-aided surveillance for 14 days after each injection of GARDASIL 9 or GARDASIL 16.

The individuals who were monitored using VRC-aided surveillance included 9,087 girls and women 16 through 26 years of age, 1,394 boys and men 16 through 26 years of age, and 5,212 girls and boys 9 through 15 years of age (3,438 girls and 1,778 boys) at enrollment who received GARDASIL 9; and 7,078 girls and women 16 through 26 years of age and 300 girls 9 through 15 years of age at enrollment who received GARDASIL 16. The race distribution was similar to that of GARDASIL 9 cohorts.

Safety of GARDASIL 9 in individuals 27 through 45 years of age is inferred from the safety data of GARDASIL in individuals 9 through 45 years of age and GARDASIL 9 in individuals 9 through 26 years of age.

The health care provider should inform the patient, parent, or guardian that vaccination does not protect against disease in those who have had a previous diagnosis of cervical cancer, cervical, vulvar, vaginal, and anal cancers; CIN, VIN, VaIN, or AIN.

Not all vaccinees develop syncope, sometimes resulting in falling or injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.

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

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

<table>
<thead>
<tr>
<th>Injection-Site Adverse Reactions</th>
<th>GARDASIL 9</th>
<th>Post-dose 1</th>
<th>Post-dose 2</th>
<th>Post-dose 3</th>
<th>Any dose</th>
<th>Post-dose 1</th>
<th>Post-dose 2</th>
<th>Post-dose 3</th>
<th>Any dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain, Any</td>
<td>N=7095</td>
<td>N=6999</td>
<td>N=6909</td>
<td>N=7071</td>
<td>66.2</td>
<td>68.2</td>
<td>69.9</td>
<td>67.0</td>
<td>67.0</td>
</tr>
<tr>
<td>Pain, Severe</td>
<td>N=105</td>
<td>N=107</td>
<td>N=106</td>
<td>N=108</td>
<td>0.8</td>
<td>0.9</td>
<td>0.9</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Swelling, Any</td>
<td>N=7050</td>
<td>N=6935</td>
<td>N=6843</td>
<td>N=7022</td>
<td>1.5</td>
<td>2.3</td>
<td>3.5</td>
<td>4.5</td>
<td>4.5</td>
</tr>
<tr>
<td>Temperature ≥100°F</td>
<td>N=7052</td>
<td>N=6934</td>
<td>N=6842</td>
<td>N=7021</td>
<td>0.4</td>
<td>0.5</td>
<td>0.5</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Systemic Adverse Reactions</td>
<td>N=6958</td>
<td>N=6832</td>
<td>N=6743</td>
<td>N=7002</td>
<td>1.1</td>
<td>1.2</td>
<td>1.0</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Pain, Any</td>
<td>N=300</td>
<td>N=257</td>
<td>N=296</td>
<td>N=299</td>
<td>0.7</td>
<td>0.7</td>
<td>0.8</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Pain, Severe</td>
<td>N=106</td>
<td>N=109</td>
<td>N=107</td>
<td>N=108</td>
<td>0.9</td>
<td>0.9</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Swelling, Any</td>
<td>N=140</td>
<td>N=140</td>
<td>N=141</td>
<td>N=142</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Temperature ≥100°F</td>
<td>N=300</td>
<td>N=257</td>
<td>N=296</td>
<td>N=299</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Injection-Site Adverse Reactions</th>
<th>GARDASIL 9</th>
<th>Post-dose 1</th>
<th>Post-dose 2</th>
<th>Post-dose 3</th>
<th>Any dose</th>
<th>Post-dose 1</th>
<th>Post-dose 2</th>
<th>Post-dose 3</th>
<th>Any dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain, Any</td>
<td>N=7095</td>
<td>N=6999</td>
<td>N=6909</td>
<td>N=7071</td>
<td>66.2</td>
<td>68.2</td>
<td>69.9</td>
<td>67.0</td>
<td>67.0</td>
</tr>
<tr>
<td>Pain, Severe</td>
<td>N=105</td>
<td>N=107</td>
<td>N=106</td>
<td>N=108</td>
<td>0.8</td>
<td>0.9</td>
<td>0.9</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Swelling, Any</td>
<td>N=7050</td>
<td>N=6935</td>
<td>N=6843</td>
<td>N=7022</td>
<td>1.5</td>
<td>2.3</td>
<td>3.5</td>
<td>4.5</td>
<td>4.5</td>
</tr>
<tr>
<td>Temperature ≥100°F</td>
<td>N=7052</td>
<td>N=6934</td>
<td>N=6842</td>
<td>N=7021</td>
<td>0.4</td>
<td>0.5</td>
<td>0.5</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Systemic Adverse Reactions</td>
<td>N=6958</td>
<td>N=6832</td>
<td>N=6743</td>
<td>N=7002</td>
<td>1.1</td>
<td>1.2</td>
<td>1.0</td>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Pain, Any</td>
<td>N=300</td>
<td>N=257</td>
<td>N=296</td>
<td>N=299</td>
<td>0.7</td>
<td>0.7</td>
<td>0.8</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Pain, Severe</td>
<td>N=106</td>
<td>N=109</td>
<td>N=107</td>
<td>N=108</td>
<td>0.9</td>
<td>0.9</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Swelling, Any</td>
<td>N=140</td>
<td>N=140</td>
<td>N=141</td>
<td>N=142</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Temperature ≥100°F</td>
<td>N=300</td>
<td>N=257</td>
<td>N=296</td>
<td>N=299</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
<td>0.7</td>
</tr>
</tbody>
</table>
Table 1 (continued)

<table>
<thead>
<tr>
<th>Systemic Adverse Reaction</th>
<th>GARDASIL 9=299</th>
<th>GARDASIL 9=300</th>
<th>GARDASIL 9=299</th>
<th>GARDASIL 9=300</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature ≥102°F</td>
<td>2.3</td>
<td>1.7</td>
<td>2.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Temperature ≥100°F</td>
<td>0.3</td>
<td>1.0</td>
<td>1.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

The data for girls and women 16 through 28 years of age are from Study 1 (NCT01304498), and the data for girls 9 through 15 years of age are from Study 3 (NCT01304498). n=number of subjects vaccinated with safety follow-up. The number of subjects with temperature data for boys 9 through 15 years of age is different among studies. Pain, Any=mild, moderate, severe or unknown intensity.

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

<table>
<thead>
<tr>
<th></th>
<th>Girls and Women 16 through 28 Years of Age</th>
<th>Girls 9 through 15 Years of Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection-Site Adverse Reactions (1 to 5 Days Post-Vaccination, Any Dose)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>5.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Bruising</td>
<td>1.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Hematoma</td>
<td>0.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Mass</td>
<td>1.3</td>
<td>0.6</td>
</tr>
<tr>
<td>Haemorrhage</td>
<td>1.0</td>
<td>0.7</td>
</tr>
<tr>
<td>Induration</td>
<td>0.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Warmth</td>
<td>0.8</td>
<td>0.5</td>
</tr>
<tr>
<td>Reaction</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Systemic Adverse Reactions (1 to 15 Days Post-Vaccination, Any Dose)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>14.6</td>
<td>13.7</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>5.0</td>
<td>4.3</td>
</tr>
<tr>
<td>Nausea</td>
<td>4.4</td>
<td>3.7</td>
</tr>
<tr>
<td>Dizziness</td>
<td>3.0</td>
<td>2.8</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2.3</td>
<td>2.1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1.2</td>
<td>1.0</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>1.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Myalgia</td>
<td>1.0</td>
<td>0.7</td>
</tr>
<tr>
<td>Nocodermal pain, upper</td>
<td>0.7</td>
<td>0.5</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>0.1</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Serious adverse events were collected throughout the entire study period (range one month to 48 months post-last dose) for the seven clinical studies for GARDASIL 9. Out of the 15,705 individuals who were administered GARDASIL 9 and had safety follow-up, 354 reported a serious adverse event; representing 2.3% of the population. As a comparison, of the 7,378 individuals who were administered GARDASIL and had safety follow-up, 185 reported a serious adverse event, representing 2.5% of the population. Four GARDASIL 9 recipients each reported at least one serious adverse event that was determined to be vaccine-related. The vaccine-related serious adverse reactions were pyrexia, allergy to vaccine, asthmatic crisis, and headache. Deaths in the Entire Study Population: Across the clinical studies, ten deaths occurred (five each in the GARDASIL 9 and GARDASIL groups); none were assessed as vaccine-related. Causes of death in the GARDASIL 9 group included one automobile accident, one suicide, one case of acute lymphocytic leukemia, one case of hypovolemic septic shock, and one unexplained sudden death 678 days following the last dose of GARDASIL 9. Causes of death in the GARDASIL control group included one automobile accident, one airplane crash, one cerebral hemorrhage, one gunshot wound, and one stomach adenocarcinoma.

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

Clinical Trials Experience for GARDASIL 9 in Individuals Who Have Been Previously Vaccinated with GARDASIL: A clinical study (Study 4) evaluated the safety of GARDASIL 9 in 12-18-year-old girls and women who had previously been vaccinated with three doses of GARDASIL. The time interval between the last injection of GARDASIL and the first injection of GARDASIL 9 ranged from approximately 12 to 36 months. Individuals were administered GARDASIL 9 or saline placebo and safety was evaluated using VRC-aided surveillance for 14 days after each injection of GARDASIL 9 or saline placebo in these individuals. The individuals who were monitored included 658 individuals who received GARDASIL 9 and 305 individuals who received saline placebo. Few (0.5%) individuals who received GARDASIL 9 discontinued due to adverse reactions. The vaccine-related adverse experiences that were observed among recipients of GARDASIL 9 at a frequency of at least 1.0% and also at a greater frequency than that observed among saline placebo recipients are shown in Table 4. Overall the safety profile was similar between individuals vaccinated with GARDASIL 9 and saline placebo.

AAHS=Amorphous Aluminum Hydroxide Phosphate Sulfate.
with GARDASIL 9 who were previously vaccinated with GARDASIL and those who were naïve to vaccination with the exception of numerically higher rates of injection-site swelling and erythema among individuals who were previously vaccinated with GARDASIL (Tables 1 and 4).

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

<table>
<thead>
<tr>
<th>Solicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)</th>
<th>GARDASIL 9 N=608</th>
<th>Saline Placebo N=305</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection-Site Pain</td>
<td>90.3</td>
<td>38.0</td>
</tr>
<tr>
<td>Injection-Site Erythema</td>
<td>42.3</td>
<td>8.5</td>
</tr>
<tr>
<td>Injection-Site Swelling</td>
<td>49.0</td>
<td>5.9</td>
</tr>
<tr>
<td>Oral Temperature ≥100.2°F†</td>
<td>6.5</td>
<td>3.0</td>
</tr>
</tbody>
</table>

**Unsolicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)**

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

The data for GARDASIL 9 and saline placebo are from Study 4 (NCT01047345).

*Unsolicited adverse reactions reported by ≥1% of individuals

†For oral temperature: number of subjects with temperature data GARDASIL 9 N=604; Saline Placebo N=304

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

Post-Marketing Experience:

The post-marketing experience following administration of GARDASIL 9 is limited post-marketing experience following administration of GARDASIL 9. However, the post-marketing safety experience with GARDASIL is relevant to GARDASIL 9 since the vaccines are manufactured similarly and contain the same antigens from HPV types 1-15. Despite this pregnancy screening regimen, some subjects were vaccinated very early in pregnancy before human chorionic gonadotropin (HCG) was detectable. An analysis was conducted to evaluate pregnancy outcomes for pregnancies with onset within 30 days before or after vaccination with GARDASIL 9 or GARDASIL. Among such pregnancies, there were 62 and 55 with known outcomes (excluding ectopic pregnancies and elective terminations) for GARDASIL 9 and GARDASIL, respectively, including 44 and 46 live births, respectively. The rates of pregnancies that resulted in a miscarriage were 27.4% (17/62) and 12.7% (7/55) in subjects who received GARDASIL 9 or GARDASIL, respectively. The rates of live births with major birth defects were 0% (0/44) and 2.4% (1/48) in subjects who received GARDASIL 9 or GARDASIL, respectively.

A five-year pregnancy registry enrolled 2,942 women who were inadvertently exposed to GARDASIL within one month prior to the last menstrual period (LMP) or at any time during pregnancy, 2,566 of whom were prospectively followed. After excluding elective terminations (n=107), ectopic pregnancies (n=5) and those lost to follow-up (n=814), there were 1,640 pregnancies with known outcomes. Rates of miscarriage and major birth defects were 6.8% of pregnancies (111/1,640) and 2.4% of live born infants (37/1,527), respectively. These rates of assessed outcomes in the prospective population were consistent with estimated background rates.

In two post-marketing studies of GARDASIL (one conducted in the U.S., and the other in Nordic countries), pregnancy outcomes among subjects who received GARDASIL during pregnancy were evaluated retrospectively. Among the 1,740 pregnancies included in the U.S. study database, outcomes were available to assess the rates of major birth defects and miscarriage. Among the 498 pregnancies included in the Nordic study database, outcomes were available to assess the rates of major birth defects. In both studies, rates of assessed outcomes did not suggest an increased risk with the administration of GARDASIL during pregnancy.

Developmental toxicity studies were conducted in female rats. In one study, animals were administered a single human dose (0.5 mL of GARDASIL 9) 5 and 2 weeks prior to mating, and on gestation day 6. In a second study, animals were administered a single human dose (0.5 mL of GARDASIL 9) 5 and 2 weeks prior to mating, on gestation day 6, and on lactation day 7. No adverse effects on pre- and post-weaning development were observed. There were no vaccine-related fetal malformations or variations.

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

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

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

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

For more detailed information, please read the Prescribing Information.
Replacing doctors

NPs focus on primary care. “We are able to go in and close those gaps.”

Not everyone agrees. Henry Travers, MD, a retired pathologist in Sioux Falls, S.D., who is now the historian for the state medical association and studies trends in medicine, says non-physician providers aren’t helping rural areas.

“The evidence of expanded practice for midlevels in areas with a physician shortage is that they are having no impact at all,” Travers says. “Data suggests that midlevels are distributed about the same way as physicians, at least in South Dakota.”

Thacker says the same trend is evident in rural Florida. “NPs don’t go to rural areas any more than anyone else,” he says. “If you look at where they practice, they are concentrated in the same metro areas. The places that are underserved are still underserved, and they have not filled any gaps.”

Pugach of the AOA says that even if NPs provide care in underserved areas, he questions whether that care meets the highest standards. “The goal shouldn’t be ‘some care’ instead of ‘no care,’” says Pugach. “The goal should be, how do we ensure every American has access to optimal care?” Instead of expecting NPs to fill areas devoid of physicians, he says a better solution is to create policies and programs that can solve the physician shortage, so that everyone has access to a physician-led team of providers.

“The best way is to increase education and training in those underserved areas and then incentivize physicians to make it financially feasible to practice in that area,” says Pugach.

But experts acknowledge that consumers are driving much of the decision-making in medicine. With fewer physicians, the only way to better serve a society that wants on-demand care is to get patients in front of a provider, even if that provider isn’t a physician. Even consumers who have had positive experiences with non-physicians providers may not readily understand the difference—all they know is that they received a convenient appointment and believe their needs were addressed.

Doctors who have studied the topic also say that physicians are partly to blame for the expansion of independent practice rights for non-physicians by not always being strict in their oversight.

Lax supervision has given credence to the idea that non-physician providers can work on their own, says Thacker. “There has to be a dedication and commitment on the doctor’s end to work with the midlevels,” he says. “Once you hire them, you have to give them the training and supervision they need.”

THE FUTURE OF PRIMARY CARE

NPs say studies show they provide care that is as good as or better than doctors, in many cases. Physicians say the studies are limited in scope and that the evidence doesn’t support that conclusion.

But Travers says fear is driving much of the opposition. Fear of revenue loss is one aspect, but a loss of identity is really the key motivation. “The concept of their professionalism is being challenged by a group of people that have less training, less experience, and perhaps less ability, and who are holding themselves out to the public to do all the things a physician can, and that’s scary,” says Travers.

Randy Wexler, MD, MPH, an associate professor of family medicine at Ohio State
University and a practicing physician in Columbus, Ohio, says that primary care physicians have several things working in their favor and thus shouldn’t worry about being replaced.

First, as medicine continues to move toward value-based care, primary care physicians have proven that they are most effective at containing costs through prevention and disease management, says Wexler. One study published in *Rural and Remote Health* in 2008 by RC Bowman, MD, of the AT Still School of Osteopathic Medicine in Mesa, Ariz., showed that over the course of a 30-year

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**The non-physician provider viewpoint**

While many physicians worry about expanding independence for nurse practitioners and, to a lesser extent, physician assistants, the organizations representing these professions see these changes as a path toward better patient care and more commonsense regulations.

Joyce Knestrick, PhD, board president of the American Association of Nurse Practitioners, says that even with 22 states allowing for independent NP practice, that does not mean eliminating collaboration with physicians. “I think the collaborative relationships will always be there,” says Knestrick. “I think it’s important to understand that nurse practitioners have been providing quality care for over five decades, and we are seeing demand for our services grow.”

She says that it takes a team to provide quality care, and that the patient, not a particular profession, should be at the center of the team. “Both nurse practitioners and physicians need to work together — and often do in high-pressure situations — to provide that care,” says Knestrick. “If you’re responsible for someone’s care anyway, why do you need to be supervised by someone else?”

For nurse practitioners, it’s not about having autonomy or putting one profession above another, but being able to practice to the fullest extent of licensure to address the needs of the patient population, says Knestrick. “This is about us moving our profession forward,” she says.

Physician assistants cannot practice independently in any state. Ann Davis, MS, PA-C, president of the American Academy of Physician Assistants (AAPA), says that while the academy is not seeking to change that, they are advocating that PAs not be tethered to a specific physician.

“But having to have an agreement with a specific physician is yesterday’s news and not what we need.”

She says PAs have the knowledge and experience to know when to refer patients, and eliminating collaboration agreements won’t change that. PAs will continue to work with physicians to care for patients. “There is plenty of work to go around,” says Davis. “It’s not like there are too many people providing care but have insufficient patients. We are focused on team practice.”

PAs are not a threat to become independent because it is just as difficult for them to open an independent practice as it is for physicians. “The way of the world is not moving toward independent practice for anyone,” says Davis, adding that eliminating the collaboration agreement would also help lessen physician liability. “These changes would take away the idea that the physician is on the hook for a PA failure.”

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career, it took 10 NPs or 4.8 PAs to provide the same amount of care as one family physician. “So even if a health system has more non-physician providers, they are providing less care,” he adds.

But the biggest protection for primary care doctors is simply demographics, says Wexler. The population continues to age, creating more patients in need of care. “If you took all the primary care physicians, and the NPs and PAs who practice in primary care, there are not enough of them combined to manage all the patients moving forward,” Wexler says. “Primary care is the most sought-after specialty by search firms, and I would submit that is a strong indicator of future value.”

Although some health systems or institutions may opt for non-physician providers in lieu of physicians depending on the market, Wexler says research shows they tend to order more diagnostic studies and labs than physicians, which can eliminate the savings gained from their lower salaries.

“In a value-based world, what you need are individuals who can manage large populations with comorbid diseases—and manage them in a beneficial manner without extra lab studies. The only provider group that has shown they can do that is the primary care doc,” he says.

Travers says the paradigm in medicine is shifting, and the old model, where physicians are the apex of the pyramid and all other healthcare workers fall under them, is not sustainable. Quality-of-care arguments can be made, but he says there is probably no reversing independent practice rights in the 22 states that already have them. If anything, he expects more states to permit them.

### Training requirements for NPs and PAs

<table>
<thead>
<tr>
<th>NP</th>
<th>PA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Length of graduate education</strong></td>
<td>2-4 years</td>
</tr>
<tr>
<td><strong>Residency training</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Minimum number of patient care training hours</strong></td>
<td>500-720</td>
</tr>
</tbody>
</table>

Source: American Osteopathic Association.

Instead of fighting the trend, physicians should look for opportunities to cooperate with non-physician providers to make a difference in caring for patients, such as fighting for affordable drugs or eliminating prior authorizations, Travers says.

“The health of patients is our only goal,” he says. “That is what is most important, and that is what the system should be designed to do. Anything that doesn’t place the patient first has to be changed, but we can’t do it alone.”

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“The concept of [physician] professionalism is being challenged by a group of people that have less training, less experience, and perhaps less ability, and who are holding themselves out to the public to do all the things a physician can, and that’s scary.”

— HENRY TRAVERS, MD, RETIRED PATHOLOGIST, SIOUX FALLS, S.D.
As physicians look for new ways to increase productivity, they might consider the benefits of employing physician assistants (PAs) and nurse practitioners (NPs). Trends indicate these types of advanced practice providers (APPs) are filling gaps in patient care and helping to extend the doctor’s reach.

NPs and PAs can:
- Work with varying degrees of autonomy, increasing access and freeing up the doctor’s schedule for more complex patients.
- Spend extra time with patients, improving satisfaction scores.
- Monitor wellness, improving the practice’s quality metrics.
- Provide billable services, boosting practice revenue.

There are some practical distinctions between PAs and NPs. Essentially, PAs follow a medical model of training and focus on pathology, diagnosis, and treatment, while NPs follow a nursing model and concentrate on wellness and the impact of the diagnosis and treatment on the patient.

Joseph E. Scherger, MD, MPH, vice president for primary care at Eisenhower Medicine Center in Rancho Mirage, Calif., and a Medical Economics editorial advisor, says in a busy primary care office, the typical model is one in which the doctor and APP “co-practice.”

Under this model, patients are stratified according to complexity, and the physician delegates care for the less complex cases to the APP. Additionally, the APP might provide follow-up care for a complex patient the physician has already seen.

“Think of the APP as an extension of the doctor—that’s why doctors hire them—to meet the added demand,” Scherger says.

By taking on a variety of care delivery tasks, APPs can help reduce physician burnout, he says. However, new NPs and PAs shouldn’t be expected to start seeing patients on day one, he says. Practices should allow at least a month’s time for integration, during which APPs should shadow the doctor and become familiar with the practice, the workflow, and the patient population.

SIGNIFICANT WORKFORCE
According to the American Association of Nurse Practitioners (AANP), there are more than 248,000 NPs licensed in the United States, and 86.6 percent are certified in primary care. There are 123,000 PAs, and about 25 percent are practicing in primary care, according to the National Commission on Certification of Physician Assistants.

Each state’s scope-of-practice regulations define how PAs or NPs may deliver care. The broadest scope allows NPs to see patients, diagnose, order tests, deliver treatment, and prescribe medications for routine patient visits without physician oversight. PAs require supervision established through “collaborative agreements” with physicians—written documents that define the practice’s model for care delivery and how or when the physician should be involved in the patient’s care. AANP offers a state-by-state online resource citing regulations for
NPs, and AAPA offers similar information for PAs in a guidebook for members.

Generally, a PA is subject to a state's board of medicine regulations, while an NP will be governed by a state's board of nursing regulations, says Kevin Ryan, JD, a member of the law firm Epstein Becker Green.

"Even though the professional acts of the physician assistant and the nurse practitioner may be very similar, the supervision and collaboration requirements, if any, may be very different between the two," Ryan says.

In 22 states and the District of Columbia, NPs have full practice authority, according to Joyce Knestrick, PhD, APRN, president of AANP. Among states that have restrictions, the degree of supervision varies widely. For example, nine states limit the number of NPs a physician can supervise—with Florida being the most restrictive, allowing just one NP per physician.

"We think removing these practice barriers would be helpful to all of us in healthcare," Knestrick says. She believes full practice authority for NPs increases access for patients while also helping practices improve quality metrics tied to value-based payment because NPs are able to spend extra time with patients.

Jonathan Sobel, DMSc, MBA, president of the American Academy of Physician Assistants (AAPA) says the organization is similarly advocating for more independent practice authority for its members. "We want to see that relationship maximized without the administrative oversight regulated or legislated," Sobel says. "We want physicians to be able to define what's right for their practice."

**PHYSICIAN RESPONSIBILITY**

Generally speaking, scope-of-practice regulations are leaning toward greater independence for APPs as a direct response to nationwide provider shortages, but the specific provisions are ever-evolving, says Kim Hoppe, clinical risk management and patient safety specialist for Coverys, a medical professional liability insurer.

"Sometimes the physicians themselves depend too much on the NPs and PAs without understanding the full scope of their ability to practice," says Hoppe. "I've also seen NPs and PAs get very comfortable with their good relationship with the patient, resulting in 'scope creep.' They may be practicing above their scope of practice, certification, or education, and the physician may not be astutely aware of that."

In states where NPs can practice independently, the physician wouldn't have liability for the NP's actions. However, a PA is almost always required to have a collaborative agreement with a physician, according to Ryan.

"In states that require oversight and collaboration agreements, the risk to the physician will depend on whether the physician met the statutory obligations for oversight as well as the requirements in the collaboration agreement," he says.

If the physician is required to audit 10 percent of the PAs charts on a regular basis, for example, liability would be related to whether the physician fulfilled the obligation. Ryan says risk for supervising physicians is minimal when they meet their contractual and state requirements.

Consequences for noncompliance on the part of the overseeing physician could

"In states that require oversight and collaboration agreements, the risk to the physician will depend on whether the physician met the statutory obligations for oversight..."

— KEVIN RYAN, JD, EPSTEIN BECKER GREEN
include licensure action by the state board of medicine. Additionally, he says, the physician could be named in a malpractice case if he or she failed to provide the required supervision and if the APP acted beyond the allowed scope of practice and caused harm to the patient.

Hoppe says it’s best for practices to create written agreements between the physician and the APP. The content of the agreements should include details such as prescribing authority when permitted by the state, how often the physician and APP will interact, and how the physician will be involved in patient care when needed. Providers also should outline a contingency plan for instances when the supervising physician isn’t available, she says.

Some medical boards require that the practice file the written agreement with the state, while others allow the agreement to be a living document, kept at the practice level and updated as needed.

But physicians must be realistic about how much time and attention is necessary when using APPs. For example, when a chronic condition is not under control, a PA would likely hand off the patient to the doctor, according to AAPA.

**REIMBURSEMENT REALITY**

Full-time PAs and NPs earned a median annual salary around $105,000 in 2017, according to both AAPA and AANP. Scherger says with APP compensation equaling about half that of a physician, “they usually more than pay for themselves.”

Billing guidelines (Section 4112.1 and 4112.2) from the Centers for Medicare and Medicaid Services detail how and when an APP can bill for services for Medicare patients. Commercial plans often follow the lead of Medicare, but practices should verify any additional requirements, Hoppe says.

She cautions that improper billing of services can result in rejected claims, lost reimbursement, or even fraud investigations. “It’s muddy water,” Hoppe says, “and it can be hard to understand those rules.”

Medicare reimburses PAs 15 percent less than a physician for the same services, according to AAPA’s Sobel. However, he believes, adding a PA to the practice who can work independently and bill independently—even at the lower rate—produces a net gain in reimbursement.

“That 15 percent is offset big time,” he says. “You just have to do the math to figure out how many patients the PAs can see, if they are seeing new patients, and how they are expanding access to care for the overall practice.”
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How to manage staff time off

To allow flexibility for staff members while also maintaining a business, plan to get creative and get organized about it all, says Kate Othus, MHA, of Aldrich CPAs and Advisors in Oregon. She recommends these strategies:

1/ Start a paid time off (PTO) bank.
The idea is to pool vacation days, sick time, and an employee’s personal time, so the employee can use what they need when they need it. Think about work-life balance. According to the Society for Human Resource Management, PTO excludes paid holidays, such as Labor Day, Memorial Day, and Thanksgiving.

“PTO allows the employee to say, ‘I need the day off,’ without explaining why, so it creates some privacy for them,” says Othus.

2/ Be consistent.
An employee handbook allows policy to be set in stone and avoid future conflict. “Maybe you think you’re creating a more flexible work environment,” says Othus. “But if you go case by case, instead of following what’s documented, and a couple of employees compare notes, you may have to deal with poor morale issues, or be accused of favoritism—and not by design.”

3/ Don’t mess with guessing.
Othus recommends a tracking system as part of your payroll software, to chronicle absenteeism.

Creating a record also means that when Employee A asks, and there is a record that they’ve been prompt and diligent, you can say, “You’re always here, and you can absolutely take the day off or leave early if you need to, because you always more than make up for that time.”

Conversely, if Employee B is almost always late, and may be having other “social” issues at work, and both are impacting their ability to perform to expectations, documentation is key.

Make sure from the get-go that policies are written, updated, and understood, Othus says.

4/ Get legal help.
Maybe you’re wondering, “Is this vacation time or PTO?” Federal and state guidelines come into play, and since you’re a healthcare professional and not a lawyer, it’s always best to seek the advice of a practice employment attorney to ensure you’re not violating any statutes.

Develop the policy, have it reviewed, and then explain it to your employees, maybe more than once.

5/ Understand all the options.
With a PTO program, you’ll need to make a few decisions. For example, is the time earned based on accrual and if so, can employees take time prior to full accrual? Your practice will need to develop guidelines for maternity, paternity, adoption, and surrogacy leave, along with bereavement leave. And, don’t forget jury duty. Have your handbook reviewed by your employment attorney, because issues related to leave can be complicated.

Having a grasp of these issues, or paying someone to have that grasp, means less disruption to your practice, says Othus.

6/ Have a Plan B.
It isn’t ideal when one employee has already gone to Mexico on a honeymoon, and another got called on to jury duty you thought would be one day, but could be long-term. “You may need to roll up your sleeves and call a temp service. And that person may not initially understand the organizational workflow, which is tough,” says Othus. “Still, it’s an option.”

Stephanie Stephens is a contributing author. Send your practice management questions to medec@ubm.com.
More Americans are choosing high-deductible health plans for their lower monthly premiums, though this results in steeper out-of-pocket costs for care. According to the Centers for Disease Control and Prevention (CDC), in 2017 42.3 percent of insured patients were enrolled in high-deductible health plans, up from 39.4 percent in 2016. This leaves some physicians scrambling to collect payments and manage shrinking cash flow.

What can physicians do to improve their cash flow in this new landscape? Experts suggest that successful practices will review and establish new financial policies, do a better job of educating patients, and consider cash-pay services.

**PUT POLICIES INTO PLACE**

Many physician practices erroneously assume their patients know and understand their financial obligations and insurance details, according to David Zetter, CHBC, a healthcare business consultant in Mechanicsburg, Pa.

“Most practices don’t have patients sign a financial policy, so most patients have no clue what the practice expects,” Zetter says.

Physicians need to set policies on getting money up front, he says. He usually recommends a practice rewrite their financial policies to include steps such as: charging a late or no-show fee; requiring all patients to have a credit or debit card on file; or always taking a flat deposit upon booking an appointment, that can later be credited back to the copay once the patient’s percentage is determined.

“If the business isn’t taken care of first, you’re not going to be able to take care of patients, because you won’t be able to afford it,” Zetter says. He also recommends that every patient be required to have a phone meeting with a patient financial counselor, which can be an office staff person, who reviews the practice’s financial policies and gets the patient to sign the practice’s agreement to the financial policies.

“I’ve got clients that won’t even accept patients if they don’t have a debit or credit card. They don’t have an accounts receivable problem,” Zetter explains. Other practices he’s consulted with have strict policies where patients can’t be seen until they catch up on outstanding payments.

**EDUCATE YOUR PATIENTS**

Tisha Rowe, MD, a primary care physician in private practice in Houston, Texas, says that it’s up to the practice to help patients understand their financial responsibility.

“Whether that’s highlighting that portion of their [explanation of benefits] in writing or maybe creating a short video that spells it out, you want to make sure patients know their deductible and what a visit costs them,” Rowe says.

She’s had many incidents where patients were upset with her for being charged around $100 for something as simple as a medication refill where they had to come in...
office. However, the cost of the visit is related to what percentage of the deductible the patient has to pay. “I can’t change the price because [the patient] hasn’t met their deductible,” she says. “So we have to educate our patients.”

Rowe creates simple videos she uploads to a YouTube channel on topics such as telemedicine and wellness tips, each no longer than a couple of minutes. “You’re going to repeat that same information twenty times per day. Just put it out there, and make it accessible, and you can have partners share it,” she says, adding that even if a physician is not tech savvy or doesn’t have the time, it’s not complicated to get help creating them.

CONSIDER AN INSURANCE/CONCIERGE HYBRID

With deductibles increasing to all-time highs, Rowe says people who are not managing a significant illness or expecting surgery are unlikely to ever meet their health plan’s deductibles. Her practice has a hybrid concierge plan for these patients.

If she sees a patient for a physical and labs, they may end up paying $1,000, she says. However, she says, if a patient signs up for her concierge plan for $100 per month, the patient knows exactly what services they’re getting, and get better access, as well.

She says that physicians shy away unnecessarily from concierge or self-pay plans because they believe that only wealthy people can afford them. In her practice, she says, most of her concierge patients are working-class people.

Rowe contends that people who use a high deductible health plan can afford a concierge doctor because they’re unlikely to ever meet their deductible anyway. “I guarantee you’re not going to see that much in medical care most years,” she says.

Paula Muto, MD, FACS, a vascular surgeon in Lawrence, Mass., and the founder of UberDoc, which helps patients find specialists, agrees that doctors should have some form of self-pay offering because it works in both the physician’s and the patient’s favor. “It is usually cheaper for a patient with a high deductible to pay cash for a procedure. You’re never going to reach your deductible anyway.”

Physicians get paid immediately without going through the hassles of billing, coding, or denials, she points out. Muto suggests cash pay also creates greater transparency. She says that bringing it back to cash leads the physician talk to the patient honestly not just about their care itself but about the cost of their care. “If deductibles are here to stay, we must be transparent,” she says.

TAKE A DEPOSIT AND/OR GET A CREDIT CARD ON FILE

Another way to increase the likelihood of getting paid is to request a flat rate deposit on all appointments. Destiny Biggs, RN, practice manager for MedNow Urgent Care in Augusta, Ga, says that her practice requires a $75 deposit and a credit card on file for all patients with a high-deductible plan.

Additionally, if a patient comes in and has an outstanding balance, the balance is due at the time of service. “They don’t get to say, ‘I’ll pay it next week,’” Biggs says.

Just having a credit card on file has made a tremendous difference in their collections. Whatever the patient owes beyond the $75 deposit is charged at the time of service, and the patient is alerted at the same time. “With credit cards on file, we collected [an additional] 15 percent of our patient balances last year or this current year,” Biggs says.

This puts a greater responsibility on front desk staff to be assertive in obtaining

“If the business isn’t taken care of first, you’re not going to be able to take care of patients, because you won’t be able to afford it.”

— DAVID ZETTER, CHBC, HEALTHCARE BUSINESS CONSULTANT, MECHANICSBURG, PA.
patient credit card information every time, so she says practices should be thoughtful when hiring for these positions or consider training them in this approach. At MedNow, the front desk staff sells the idea by reminding patients that putting a credit card on file means they won’t have to receive bills in the mail and/or make payments later.

**THINK TWICE BEFORE YOU DIAGNOSE**

For James Wilk, MD, an internist who works for the University of Colorado in Denver, high-deductible plans have changed the way he orders diagnostic tests.

He admits that he didn’t know the cost of some of the tests he orders until patients complained about financial hardship, or worse, refused to get the tests, leading to worsening or untreated conditions. “So this person is walking around with probable but undiagnosed asthma because the cost of the test is so high that they couldn’t get it,” Wilk explains.

“I think twice about how necessary some diagnostic workups are. Instead of doing a bunch of tests, sometimes I’ll just plan a three- or four-step kind of thing. That way, if we make the diagnosis, we don’t have to test for twelve things, which would cost a fortune.”

He makes sure to inform his patients that he is ordering tests in the most cost-effective way possible. “They usually thank me for being conscientious of that,” Wilk says.

While this is not his ideal way of practicing medicine, he understands that patients are facing increasing financial pressure and encourages patients to work with financial counselors so that they don’t put off necessary treatment or tests.

**USE BIG DATA AND AI TO DETERMINE PROPENSITY TO PAY**

High deductibles may not be the only reason that patients are struggling to pay their doctor bills, according to Florian Otto, MD, co-founder of Cedar, a healthcare technology consulting business based in New York City.

He says that simply ranking patients by their propensity to pay may not be very effective because there may be multiple reasons ranging from:

- They don’t have enough money
- They don’t check their mail often
- They don’t speak English
- The bill is incorrect/not what they expected
- and patients don’t know how to get a corrected bill

He recommends that practices use artificial intelligence-based programs that draw from basic demographic information and user data to assess more accurately why patients aren’t paying. For example, he says, if a patient received their bill digitally and clicked on it three times but never paid, it might warrant sending a text asking if they are having trouble understanding the bill, and then connects them to a live chat function.

Additionally, he says, physicians should automate the billing process to make it easier for patients to pay. “We strongly believe that it shouldn’t take longer than 20 to 30 seconds to pay your bill, similar to the Amazon Prime experience,” Otto says.

Patients just want an easy, convenient and quick way to pay, he says, and it’s up to physicians to offer these.

“Reducing friction makes happier patients, and also increases cash flow,” Otto says. 

*“Instead of doing a bunch of tests, sometimes I’ll just plan a three- or four-step kind of thing. That way, if we make the diagnosis, we don’t have to test for twelve things, which would be a fortune.”*

—JAMES WILK, MD, INTERNIST, UNIVERSITY OF COLORADO

—James Wilk, MD, Internist, University of Colorado
3 ways to increase patient survey response rates

Think patients won’t respond to healthcare surveys? Think again.

You might be surprised to learn that 86 percent of Americans say they would likely take a survey from a healthcare provider, if asked. A West survey of 1,036 adults in the United States showed patients are more open to taking surveys than most providers realize. This is encouraging news for physicians who want to conduct patient satisfaction surveys, remote health monitoring surveys, health risk assessments, and other surveys.

There’s no question that healthcare surveys are valuable tools for improving healthcare and supporting health management. Providers believe it is useful to have patients complete satisfaction surveys (98 percent), health risk assessments (94 percent), remote monitoring surveys (91 percent), medication adherence surveys (94 percent), post-discharge surveys (91 percent), and gaps in care surveys (92 percent).

West’s research findings show patients value surveys nearly as much as providers. Patients are most interested in taking satisfaction surveys (86 percent), post-discharge surveys (85 percent), and health risk assessments (83 percent).

Despite their interest, patients don’t always participate in surveys, as healthcare teams know all too well. And nine in 10 healthcare providers say their organization does only a fair or poor job convincing patients to actually complete surveys.

Patient feedback suggests healthcare teams can influence survey response rates and that there are steps providers can take to increase patient participation. But in order to drive higher survey response rates, healthcare teams need to understand the factors that impact patients’ willingness to complete surveys.

According to West’s survey findings, patient participation may hinge on convenience, whether patients feel a survey will help them manage their health, and if a survey will serve as a springboard for follow-up communication.

The following recommendations, based on those findings, show three key ways healthcare teams can grow response rates by focusing on factors patients say influence their decision to participate in surveys.

1. Make it convenient and easy for patients to respond.

Convenience is a must when trying to convince patients to complete surveys. More than four in ten Americans (43 percent) say they would be more likely to take a survey from a healthcare provider if they could do it on their own time. This makes online surveys an attractive option for patients.

Online surveys give patients the flexibility to respond when it is convenient for them, rather than receiving an unexpected call from a live person and being expected to stop what they are doing to answer survey questions.

In addition, 33 percent of patients say having the ability to take surveys from any device makes them more likely to participate. Patients prefer the convenience of being able to respond to surveys on a mobile device, tablet, or desktop.

The takeaway is fairly obvious: if surveys are easy to take, patients are more likely to participate.

For most healthcare teams, inviting patients to complete online surveys means leveraging technology you might already be using. Teams can configure the same technology for sending reminders prior to appointments to deliver a satisfaction survey invitation to patients a few hours after their appointments.

2. Connect surveys to health management support.

Interest in surveys rises among patients when they understand how surveys will benefit them. More than four in ten patients (42 percent) report they would be more likely to take a survey if they knew how it would help with their treatment. Also, 39 percent of patients with chronic health conditions say they would be more apt to participate in a survey if they felt doing so would enable them and their healthcare team to better monitor their conditions.

Taking time to explain to patients why they are being asked to respond to surveys and how their
can show patients they are engaged and committed to improving patients’ health. For instance, when patients complete a medication adherence survey and confess they are not taking their medication, providers can learn why—and maybe find solutions to previously unknown medication barriers.

Outreach following a medication adherence survey demonstrates providers’ commitment to keeping patients on track, and it can make patients even more responsive to future surveys.

Healthcare providers and patients agree that surveys can be valuable healthcare tools. But surveys are only useful if patients take them. It’s frustrating when patients don’t respond to survey invitations, and it hinders providers’ ability to deliver the between visit support patients say they want.

Rather than accepting low survey response rates, healthcare teams can take action to achieve the changes they wish to see. They can drive more patient participation by taking patients’ requests to heart and ensuring that surveys are convenient, have clear health benefits, and are followed with additional communication.

3. Follow through on follow-up.

Actions speak louder than words. Rather than just telling patients about the benefits or how surveys can help them, healthcare teams can go a step further and show patients with follow-up communication. Patients who spend time completing a survey want to hear from their healthcare team. Thirty-four percent of patients say they would be more likely to take a survey if they were contacted immediately afterward by a healthcare provider.

In addition, patients say providers who follow up over the phone (37 percent) or via a text message or online chat (32 percent) would entice them to take surveys. While immediate follow-up is not necessary or appropriate in every situation, healthcare teams can make sure patients understand that they will be contacted promptly if follow-up is warranted.

By acting on survey data, healthcare providers can show patients they are interested in health monitoring surveys.

Healthcare providers can give patients a nudge to complete surveys by presenting them as a necessary part of their chronic care plan. During office visits, patients should receive an explanation of the survey process. Letting patients know, for example, that they will be sent a weekly survey invitation and that staff will closely track their responses and any progress or changes is a good way to reinforce the connection between monitoring surveys and health management support.

Healthcare teams can also emphasize the connection between survey participation and support following hospitalizations. Providers can use post-discharge surveys to follow up with patients at key points in the 30 days after discharge. Communicating to patients how their healthcare team can use information they submit through surveys to detect issues and intervene to prevent readmissions is an effective way to increase survey participation.

Forty percent of patients with chronic conditions say they would be more willing to take surveys if doing so would lessen their chances of being admitted or readmitted to the hospital. Healthcare teams that sell patients on this potential benefit of post-discharge surveys may be able to persuade more patients to participate.

33%

Percentage of patients say having the ability to take surveys from any device makes them more likely to participate. Patients prefer the convenience of being able to respond to surveys on a mobile device, tablet, or desktop.

Allison Hart is vice president of marketing at West, where she leads thought leadership efforts for West’s TeleVox Solutions. Send your technology questions to medec@ubm.com.
HEALThCARE POLICY IN 2019:
An interview with Rep. Phil Roe, MD

by JEFFREY BENDIX Senior Editor

Rep. Phil Roe, MD, the chairman of the House’s GOP Doctors Caucus, spoke recently with Medical Economics about healthcare issues he thinks the new Congress needs to address, including price transparency and the shortage of primary care physicians.

A transcript of the interview, edited for length and clarity, follows.

Medical Economics: What are some of the healthcare-related issues you think the House of Representatives is going to tackle in 2019?

Roe: I can’t say for sure what they will tackle. I can tell you what the Doctors Caucus is looking at. What we have been doing with the Doctors Caucus and what I’ve heard traveling around the country from patients is very much a concern about prescription drug pricing. And so we set up a series of meetings with [HHS] Secretary Azar and CMS Director Seema Verma about this and I am pleased to say that our Senate colleagues are joining us. So this has been a bicameral approach.

We’ve met with pharma and we’d like to also bring in the PBMs [Pharmacy Benefit Managers] and then maybe host a roundtable a little later to see how we can begin to get our arms around this very complicated issue of drug pricing. Everybody has a hand in it and the people I think that are being the least served by this system we have now are our patients.

If you’ve got great health insurance and you don’t feel much of the cost it’s working fine for you, but if you’re a small business person and you have a $6,000 deductible or you’re a senior and you drop into the [Medicare Part D] donut hole, all of a sudden you realize those rebates that are going to the PBM sector are not going to you. That you don’t see any of the benefit. And something as simple as insulin, where a person who’s not in a prescription drug plan is actually paying for it, is terribly expensive now.

So we’re looking at that. Also, we may come up with some legislation that will involve one of the things we hear about all the time, price transparency.

Medical Economics: Does transparency matter if you can’t afford the drug?

Roe: Knowing what something costs matters. And knowing how you arrived at that price absolutely matters big-time. Sunshine is a great disinfectant.
**ME:** It sounds like you’re saying the really important thing is not the price itself but knowing how the drug companies arrived at that price?

**Roe:** No, the price is important too. But finding out how that’s arrived at and allowing market forces, and we know the more generic alternatives you have—now in Medicare Part D, as I understand it, about 90% of the drugs that are prescribed are generics—the more generic prescription drugs we have, the lower the cost. So that does matter a lot.

**ME:** It’s been nearly four years now since Congress passed MACRA and I’m wondering what you and the other members of Doctors Caucus are hearing from your physician constituents about it. Has it worked out the way you thought it would? Do you see any major modifications coming down the road?

**Roe:** I don’t see major ones. Let’s put it this way: I’ve heard a lot less with MACRA implementation than I did with SGR every year.

One of the concerns that I have—and this will be something we’ll be talking about in the Caucus—is the cost of medical education and the staffing shortages that we have. If you look at what the AAMC [American Association of Medical Colleges] says, by about 2030 we’ll be as many as 100,000 doctors short. And if you look at the demographics of physicians, in this country it’s like 25% of practicing doctors are over 65. That is a huge problem and these are very productive physicians who are at the tail ends of their careers.

Then there’s the cost of medical education. I’ve been a proponent of educating our doctors less expensively. Let me use myself as an example. My dad worked in a factory and never made $10,000 a year in his life. I stayed at home and went to college and medical school and I graduated with no debt. Now, admittedly I worked through college, and during medical school. That’s impossible now. And these young people are coming out with hundreds of thousands of dollars of debt and I’m afraid it’s discouraging bright young people from going into medicine.

So we’re going to need to work this term on how we pay for medical education. And think about this: If we’re a hundred thousand doctors short in 2030, that means we’re into the 2040’s before we educate enough young doctors even to begin to fill that deficit. So we need to get started right now and one of the things that I’m going to look at and will bring up with the Doctors Caucus is how Medicare funds residency slots.

I say this as a joke but when I talk to medical students I say, “Look, everybody can’t be a dermatologist or radiologist. Somebody actually has to see patients and has to put their hands on people.” And we’ve got a huge problem in rural America of getting anybody to go into these areas and practice medicine. And we need to see if we can address it by helping students pay off debt or give them some incentives to go into underserved areas.

**ME:** What about the paperwork and all the hoops that doctors have to jump through to care for their patients. Can Congress do anything about that?

**Roe:** I think so, and when we meet with Azar and Verma, we fuss about that all the time. I call it polyboxia. If you don’t check all the boxes you don’t get paid.

So we’re trying to get them to think about, and get more comments on, of all those things we have to check off on our [EHRs], what really matters about patient outcomes? Because what really matters at the end of the day is: Do we get better patient outcomes? So if we could lessen that load and make it easier for our doctors when they see their patients to click just two, three or four things that really actually matter that would make their jobs much more satisfying.

I can remember installing our practice’s electronic health record in 2007. We spent a million dollars putting it in. It made my job a lot less fulfilling because I’m sitting there at night entering data into a computer. That’s not what I signed up for. I said, “if I’m here at 8:00 at night in my office, I should be seeing patients.”

So the Secretary is very well aware of the need to lessen that load and so is the CMS director. And I think they’re both committed to try to make things simpler.

**ME:** There have been studies showing that the number of people with healthcare
“I think [Medicare for all] should be debated. I don’t know that the country is ready for it when they find out what the implications are.”

Roe: One of the things we’re seeing is more and more people employed. So I think you’re actually going to see the actual number of people without coverage go down, because to attract good employees you have to offer benefits.

I do think we need to sit down with our Democratic colleagues and take a hard look at the ACA [Affordable Care Act]. The idea of expanding coverage and lowering cost, I absolutely agree with that. I just think the ACA was the wrong formula for it. You see it with these Christian Sharing Ministries, you see it with a lot of different things, the larger pool of patients you can get the more you can spread the risk, the more you can lower the cost.

I’ll give you a perfect example of that. A company in my district that has about 15,000 employees. And the owner hired a preventive healthcare nurse and said, “I want you to set up systems that help lower my healthcare costs.” So they’ve done programs addressing cholesterol, blood pressure, diabetes, smoking cessation, weight management. With all those things he’s been able to hold their healthcare cost increases to 1% per year.

And this is in rural east Tennessee, which is not exactly Nashville or San Francisco. So why wouldn’t you want a system that allows you to group in large groups association health plans to provide those things we already know that work?

And then being able to buy insurance across state lines. Health insurance is the only insurance I know of you cannot buy across state lines. That makes no sense to me. So those are things we need to start thinking about. How can we make insurance less expensive for people and don’t let it be a political issue.

ME: Do you see any possibility of the public option coming back? Might that be a way to lower costs?

Roe: I didn’t support the public option, but I think you will see a debate on Medicare for all. And I think we need to have that debate. I think we need to see what the benefits of that would be, what the cost would be and what the downside of it would be.

The only problem with it is that, even to make Medicare come into balance, at an absolute minimum you have to double the rates that we’re charging now [for the Medicare payroll tax]. You’d have to go from 1.45% to about 3% that the individual would pay and 3% the employer would pay right now to even make that plan come into balance.

So I think we have to be honest with the American people and say, what is the cost, what are you willing to give up, is care going to be rationed, how is it going to look? And I think, for physicians, many of them are saying, “Give me anything, just make it simpler for my practice.” I hear it all the time.

ME: So it sounds like you’re at least open to discussing it?

Roe: I think it should be debated. I don’t know that the country is ready for it when they find out what the implications are. Look, you have to have some very serious discussions about where money is being spent in Medicare right now, what percent is being spent in the last six months of life, all of those things. But those are debates that the American people deserve to have, and not in a demagogic way, but in a very open and transparent way.

ME: What do you think the implications will be now that Democrats control the House of Representatives?

Roe: I’ve been in the minority before, in 2009-10, and basically what happens when you’re in the majority is you determine what the theme of the day is. For example, as chairman of the Veterans Affairs committee I brought the Democrats in because without their support I couldn’t get it passed in the Senate. And so if the entire Congress would work a little bit more like the Veterans Affairs Committee I think you’d have a lot better legislation but it is politics at the end of the day.
Over the past 20 years, the practice of healthcare has been overtaken by secondary entities. Time spent in physician-patient interactions, the core of any medical practice, is now being governed by insurance companies and complex billing and payment systems, federal and legal mandates, the pharmaceutical industry, and technology that was intended to improve the business of care.

As physicians, we have given up control and lost the ability to do the job we were trained to do. Our focus has turned instead to serving needs that have become more demanding than those of our patients.

It is estimated that doctors today spend just 27 percent of their time interacting with patients, according to a study in the Annals of Internal Medicine. The remaining time—far exceeding our billable hours—is whittled away on administrative duties, often providing documentation required by law.

The frustration it leaves is real, not just for patients who wind up receiving fragmented care, but for physicians as well. Numerous global studies show that doctors are overburdened and burned out. The catalysts for choosing to pursue a medical career—helping people and making a difference—are buried under the mundane paper shuffling required of the medical field today.

Climbing physician suicide rates are likely examples of the most extreme consequences of this problem.

We’re struggling to understand how we, as healthcare providers, can provide quality medical care when we are rapidly losing control of our profession.

In many respects, we gave it away. We relinquished authority to peripheral entities instead of taking it upon ourselves to determine how to best serve our nation’s healthcare needs.

We can continue to let others create obstacles and mandates that impede care and tell us how to do our jobs—because they most certainly will—or we can take the lead by developing and leveraging technologies that safeguard personal interaction and create better, more efficient options for patients to access care. The choice is ours.

**LEAVING CONTROL TO TECH**

One of the major factors that contributed to our loss of control is when health IT entered the exam room.

Congress passed the American Reinvestment and Recovery Act of 2009 that included a requirement to convert to electronic health records (EHRs) or face Medicare reimbursement penalties.

With the passage of this law, instead of a systematic conversion to electronic records, we scrambled to digitize massive files of patient records and train ourselves and our staff to change our workflow to accommodate new systems and accompanying challenges. It was then that we began to lose eye contact with our patients as our attention turned instead to entering government or insurance required data that often has little or nothing to do with the chief complaint of the patient in front of us.

While managing records digitally offers numerous benefits, it must be done in a more thoughtful way.

Technologies, like the use of EHRs, are often aimed at providing convenience, yet they have a way of creating roadblocks to care. They are often outdated, time-consuming, and too complex to weave into regular practice.

The rise in on-demand medical services, websites and retail clinics make it clear that patients are seeking more convenient care options to accommodate their increasingly demanding lives.

Better access to care is necessary, yet many of the new models miss the boat by sacrificing continuity and personal connection for convenience, with care being provided by physicians who are unfamiliar with the patients they’re seeing.

**THE LAST WORD**

By Samant Virk, MD

**Take back control of your exam room**

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With so little time allotted to face-to-face patient interaction, how can we build compassionate, therapeutic relationships that lead to better patient outcomes?”

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GOOD TECH IS PATIENT DRIVEN

A recent study that asked healthcare consumers what matters most shows that patients want to be known and understood by their provider in order to get the personalized care they desire. They want to feel connected and understood by providers who know their personal stories—the unique factors that contribute to their overall wellness and its breakdown.

Without knowing those stories, we can’t provide good healthcare. It boils down to a personal connection.

Yet, with so little time allotted to face-to-face patient interaction, how can we build compassionate, therapeutic relationships that lead to better patient outcomes? It doesn’t have to take tremendous amounts of time. It’s here that technology can be used to enhance and even accelerate the process.

Machine learning and artificial intelligence (AI), for instance, can be leveraged to track and analyze complex, valuable data and empower us to better know our patients. It can process information beyond human capability, such as massive sets of lab test results, family history, socio-economic factors and clinical trial data, to help us monitor our patients’ well-being and assess their risks based on their own history and others like them.

These powerful technologies can help to flag signs of preventable, chronic diseases—including diabetes, heart disease, and even cancer that contribute to 86 percent of our nation’s healthcare costs and are responsible for nearly 70 percent of deaths each year—and provide us with clinical insights to aid in our planning and providing care, leading to more accurate, personalized treatment.

There is also the not-yet-measurable data we get when we look at our patients, hear what they say and understand their personal situations, that technology can help us address.

For example, telemedicine, the use of video-conferencing to communicate eye-to-eye with patients and provide healthcare without barriers of distance, allows us to leverage technology to add value to the most important part of a medical practice—seeing patients. It improves care and enables practitioners to see more patients by offering virtual care for level 1-3 visits—for instance, helping a patient manage diabetes or back pain before it reaches crisis level.

Televisits—conducted with a few clicks on a personal computer—promote continuity of care by keeping patients connected with their own doctors, and maximize billable time through a built-in mechanism that monetizes after-hours care and communications like return calls and follow-ups, helping us operate more profitable practices.

TIME FOR DOCTORS TO LEAD

By leveraging technologies truly aimed at helping us serve our patients, we can free ourselves to do the jobs we were trained to do.

It’s time to take the lead—speaking out about the role we want technology to help us fill—or continue to be victimized by insurance companies and government mandates that want to take over our exam rooms and tell us how best to do our job.

Samant Virk, MD, is founder and CEO of MediSprout, a company focused on connecting doctors with their patients through innovative technology solutions. He is also a physician, having practiced clinical medicine for almost 15 years, with a specialization in Neurology and Interventional Spine.

“We’re struggling to understand how we, as healthcare providers, can provide quality medical care when we are rapidly losing control of our profession. In many ways, we gave it away.”
“NPs are told constantly in training and by the political organizations that they are just as good as doctors.”

REBEKAH BERNARD, MD, FAMILY PHYSICIAN AND PRACTICE OWNER, FORT MYERS, FLA.

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“If the business isn’t taken care of first, you’re not going to be able to take care of patients.”

DAVID ZETTER, CHBC, HEALTHCARE BUSINESS CONSULTANT

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$20 million

Total fine paid annually due to data breaches each of the last three years

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Advertising in Medical Economics has accelerated the growth of our program and business by putting me in contact with Health Care Professionals around the country who are the creators and innovators in their field. It has allowed me to help both my colleagues and their patients.
“My clinic had to cut costs, so they traded me for two PAs and a nurse practitioner to be named later.”

The hassle of prior authorizations

Few issues enrage physicians more than prior authorizations. They view it as an attack on their medical autonomy, their years of training and their ability to care for their patients as required, not to mention the time it takes and revenue lost to haggle with payers over approval for drugs and tests. How can physicians communicate effectively with patients regarding prior authorizations? What strategies can physicians implement to lessen the burden?