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In this issue

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Patient encounters

Monkeypox PHE declared; tighten intake protocols, prep for anxious patients

U.S. health agencies are now operating under a second public health emergency (PHE) due to the growing number of monkeypox infections in the country. While the declaration shouldn't change day-to-day life for most providers, you may take it as a cue to increase surveillance and make preparations in case the formerly-rare disease finds its way to your door.

The PHE declaration on August 4 most directly and immediately affects government health entities, from HHS and CMS to local departments of health, that have responsibility for testing, vaccination and other interventions against the virus, which at this writing has infected some 10,300 Americans.

"Fifty-one jurisdictions have already signed data use agreements that will provide the Centers for Disease Control and Prevention (CDC) with information related to vaccine administration," HHS Secretary Xavier Becerra's declaration states. "Declaring the outbreak an emergency may provide the justification that the remaining jurisdictions need to sign their agreements. Additionally, it provides authorities to the Centers for Medicare & Medicaid Services to collect testing and hospitalization data."

For a response to suspected infections, the CDC's monkeypox page for health care professionals is practice providers' primary guidance document (*see resources, below*).

Not the first time

This isn't the first U.S. incursion of monkeypox. Along with some isolated cases, 47 people in the Midwest caught the virus in 2003.

Stay in line with Medicare updates

CMS announced significant changes to physician payments, Medicare-covered coding and billing policies, and numerous other regulatory items in the proposed 2023 Medicare physician fee schedule released in July. Attend the Aug. 23 webinar **2023 Medicare Physician Fee Schedule: Unlock CMS' Proposed Changes** to get a head start on the coming changes that are scheduled to take effect Jan. 1, 2023. Learn more: https://codingbooks.com/ympda082322.

Coding

Use these new CPT codes for monkeypox tests, vaccines

Practices testing or providing vaccinations for monkeypox will find it easier to bill for those services. The AMA on July 26 issued one new clinical lab test code and two vaccine codes for the virus, effective for use immediately.

New orthopoxvirus test code

In the microbiology section of CPT lab codes, the AMA added:

- **87593** (Infectious agent detection by nucleic acid [DNA or RNA]; orthopoxvirus [eg, monkeypox virus, cowpox virus, vaccinia virus]. Amplified probe technique, each).

The code describes polymerase chain reaction (PCR) testing of a swab sample from a skin lesion obtained from a symptomatic patient.

Two vaccine codes are product-specific

Select the appropriate vaccine code based on the specific vaccine product administered:

- **90611** (Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous injection)

Use code 90611 for the JYNNEOS combined smallpox and monkeypox vaccine manufactured by Bavarian Nordic. The vaccine, also called Imvamune or Imnavex, has been FDA approved for use in patients aged 18 and older. It requires administration of two doses 28 days apart.

- **90622** (Vaccinia [smallpox] virus vaccine, live, lyophilized, 0.3 mL dosage, for percutaneous use).

Code 90622 describes the ACAM2000 smallpox vaccine manufactured by Sanofi Pasteur Biologics Co. for patients 12 months and older, requiring just one dose. The FDA has approved the vaccine for use against monkeypox under expanded access Investigational New Drug (IND) application.

Use one of the existing vaccine administration codes (**90460, 90461, 90471** or **90472**) in conjunction with the new vaccine product codes.

The AMA decided to release the new codes after the World Health Organization (WHO) declared monkeypox to be a global health emergency, according to AMA President Jack Resneck Jr., M.D., in an AMA release about the codes. With cases of monkeypox on the rise, the addition of the codes seemed timely, he stated.

"The daily increase in cases in the U.S. shows community spread occurring; however we are relieved to see access to testing has increased to 80,000 specimens per week with commercial labs now online and vaccine supply is increasing," Resneck stated. — *Laura Evans, CPC* (levans@decisionhealth.com)

Donald J. Alcendor, Ph.D., assistant professor of the Department of Microbiology, Immunology, and Physiology at Meharry Medical College in Nashville, explains that outbreak was "associated with transport of animals — in that case, rodents [that came to Texas] from Ghana, squirrels and rats and so forth. It turns out these animals were housed close to prairie dogs that were sold as pets, and that infection got into the prairie dogs, which were purchased by people in the Midwest who developed monkeypox."

The 2003 spread was limited, in part because of the low-density settings where the infection was found. But the current outbreak has centered on denser regions, such as New York City, leading to rapid spread.

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J. Acey Albert, M.D., director, clinical content at epocrates, a medical information company in Austin, Texas, says "at present a majority of cases we've seen in this outbreak have occurred among men who have sex with men and have occurred as a result of high-risk prac-tices." But experts say that monkeypox is not solely or even primarily transmitted by exchange of bodily fluids; it mainly spreads by "close, personal, often skin-to-skin contact" and contact with contaminated objects such as clothing, bedding or towels, according to the CDC.

Also, Alcendor warns, the immunity that child-hood smallpox immunizations offer to other orthopox diseases, including monkeypox, is at low ebb. "We are coming to the ending of a continuum of vaccination for smallpox, which leaves us susceptible to monkey-pox," Alcendor says. "The end of [general childhood] vaccination for smallpox was 1978. So if you are a younger person, you didn't get the smallpox vaccine. And with people who got the vaccine [in childhood], their immune protection is waning and they represent a vulnerable population as well."

Know the signs, triage

The spread of monkeypox suggests practices should renew attention on infection control protocols, particularly during patient intake.

"I think we need to recall a lot of the lessons from the early days of the COVID pandemic," Albert says. That includes phone and online triage: "I think patients very quickly figured out during COVID that it was important for them to call their doctor and talk to them ahead of time," Albert adds. You can make extra sure with appropriate triage questions.

Alcendor notes the primary signs of monkeypox infection include lymphadenopathy and a distinctive blistering rash. Providers "will have to proceed with differential diagnosis because chicken pox can look a lot like monkeypox," he says. Albert adds that provid-ers have also mistaken it for herpes and syphilis.

Albert stresses the importance of having adequate personal protective equipment (PPE) on hand. "Fortunately we're not in the [poor] state of PPE supply we saw at the beginning of COVID," he says. "The precautions are essentially the same for clinical staff [as with COVID]: gowns, goggle, N95 respirators, gloves. "

Unlike with COVID, the risk of airborne transmis-sion with monkeypox is low: "CDC says respiratory transmission really involves prolonged, intimate face-to-face contact for a relatively long periods of time, like hugging and cuddling," Albert says. But skin contact and fomite infection are of even greater importance than with COVID.

"Ensure that staff is really clear on how to handle materials and disinfect surfaces and the room if a patient who has suspected monkeypox comes into the office," Albert says. "These patients should be appro-priately isolated within the practice and perhaps other pathways might be engaged."

Also, review CDC's guidance on contact precau-tions for patients with suspected monkeypox as well as for the handling of anything in office with which patients have come in contact. And, Alcendor reminds you, encourage handwashing. "We know monkeypox can be transmitted and facilitated by hand-to-mouth, -eyes and -nose transmission, the so-called T-Zone," he says.

Keep staff, patients calm

Testing, vaccination and drug therapies are largely in the hands of departments of health, which CDC advises providers to direct patients who have suspected infections. This may leave providers with anxious patients, frightened at the prospect of leaving the doctor's office with directions to a testing facility rather than medicine.

Alcendor stresses the importance of education. "Advise them in terms of how they should self-isolate because these lesions [are very contagious] and can con-taminate clothing, linens and bedding, and so forth," he says. "It's very important to observe mitigation strate-gies at home according to the latest CDC guidelines," particularly in shared residences.

Also, make sure you're constantly reviewing and updating your knowledge of the CDC guidance and that you can articulate it to patients. "It certainly doesn't help [anxious patients] when the clinician's office seems to not know what to do," Albert says. "Pay extra close attention to communications from your public health departments, whether state or local, because those are in fact the key to testing, prevention and treatment at this point."

If monkeypox is suspected, it's "good form" to let patients know you're obliged to report it to your local health department, Albert says. "I think most of us, if

we inform the patient their gonorrhea test came back positive, do a decent job of letting the patient know that it is a reportable disease and that the health department will be in contact and it's for their own safety as well as of that of folks they've been in contact with," he says.

"You have to put this into context," Alcendor says. "There are [thousands of] cases among a national population of 330 million. Some states have less than five cases. And we have yet to see a fatality in the U.S. due to monkeypox." Also, let patients know that their efforts and yours are not only going to make them well and safe but will also help snuff the outbreak. "Your monkeypox education platform has to be a strong and it has to be truthful." — *Roy Edroso* (redroso@decisionhealth.com) ■

RESOURCES

- HHS, "Biden-Harris Administration Bolsters Monkeypox Response; HHS Secretary Becerra Declares Public Health Emergency," Aug. 4, 2022: www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html
- CDC, monkeypox, "Information for healthcare professionals": www.cdc.gov/poxvirus/monkeypox/clinicians/index.html
- CDC, monkeypox, "Past U.S. Cases and Outbreaks": www.cdc.gov/poxvirus/monkeypox/outbreak/us-outbreaks.html

Compliance

Telemedicine or telescam? Heed the warnings in the latest special fraud alert

Physicians and non-physician practitioners who are approached by recruiters from a telemedicine company should read the latest fraud alert from the HHS Office of Inspector General (OIG) before they opt to get involved.

OIG issued the Special Fraud Alert (SFA), "OIG Alerts Practitioners to Exercise Caution When Entering into Arrangements with Purported Telemedicine Companies," July 20. The SFA contains information about fake telemedicine companies that use kickbacks and deception to attract practitioners who will enable schemes to defraud Medicare by prescribing medically unnecessary items and services.

OIG sends a warning

The special fraud alert lists seven red flags that may indicate a telemedicine company is really a front for a criminal enterprise. For example, the company says it pays based on the volume of prescriptions a practitioner writes or it does not give practitioners enough information about the patient to make medically meaningful decisions (*see sidebar, p. 6*). The alert comes as the Department of Justice and OIG continue to root out and prosecute telemedicine fraud schemes and warn practitioners that they too could face penalties if they ignore the warning signs.

"Practitioners who enter into arrangements with telemedicine companies in which one or more of these suspect characteristics are present should exercise care and may face criminal, civil or administrative liability depending on the facts and circumstances," the OIG writes.

The latest SFA "highlights that OIG is carefully watching the industry and has identified some very specific types of risks, as well as that providers are on notice about the warning signs specifically identified in the [SFA] and similar behaviors," says Amy Lerman, member of the firm with Epstein Becker Green in Washington, D.C.

"The SFA also spreads compliance education and industry norms, making it potentially more difficult for a practitioner to assert that they were not aware of being engaged in a prohibited (kickback) arrangement," says Sara Shanti, partner with SheppardMullin in Chicago.

"There have been numerous publications that have raised these and similar concerns, including information on HHS-OIG's website, public statements by agency officials, and others," says Ty Howard, partner with Bradley Arant Boult Cummings LLP in Nashville, Tenn. "But the alert is one more official publication that puts practitioners on notice of these concerns."

Know the compliance rules

Practitioners can protect themselves by avoiding dodgy schemes at the outset. But they shouldn't expect a recruiter to offer large payments for their help with a scam. The recruiters may have sophisticated pitches that go beyond promising money. For example, the recruiter may present working with the telemedicine platform as a solution to

(continued on p. 6)

Benchmark of the week

NPs set to benefit from the domiciliary, home visit merger

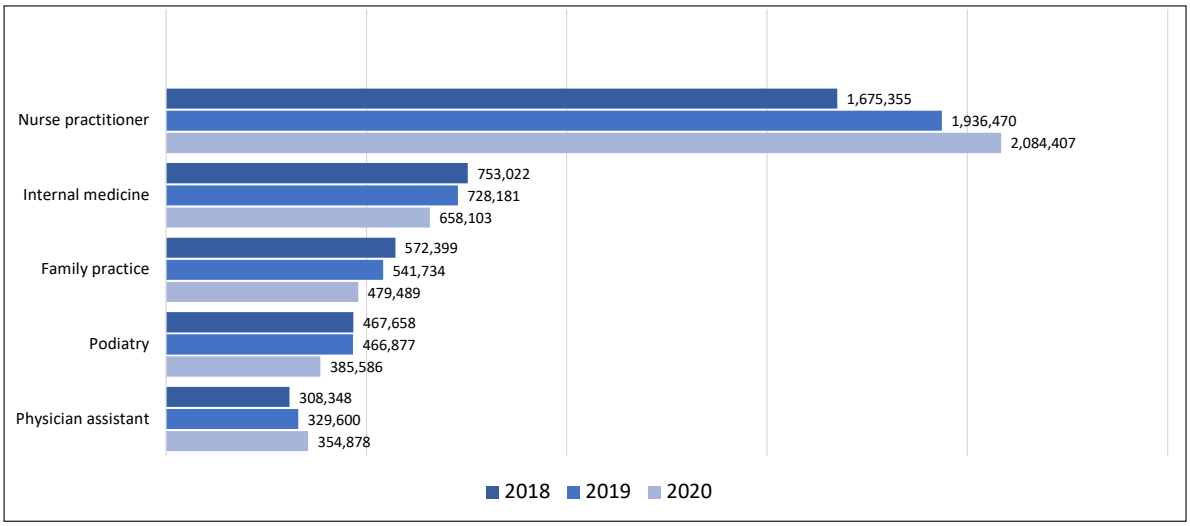
Nurse practitioners (NP) will find it easier to report visits in the domiciliary and home settings when the next E/M update goes into effect Jan. 1, 2023. The update will delete the code family for domiciliary, rest home and custodial care services (**99324-99337**) and fold the services into the home services family (**99341-99350**). That code family will be renamed "home or residence services."

The revision, which will reduce the number of patient residence codes from 18 to eight, is good news for NPs, who are the top reporters of both code families. A review of 2020 Medicare Part B utilization data, illustrated in the following charts, shows that four primary care provider (PCP) specialties and podiatry occupy the top five spots for visits that take practitioners out of the office and facility settings and into residences and temporary lodgings, such as hotels and campgrounds, according to the latest available Medicare claims data (*PBN 8/8/22*).

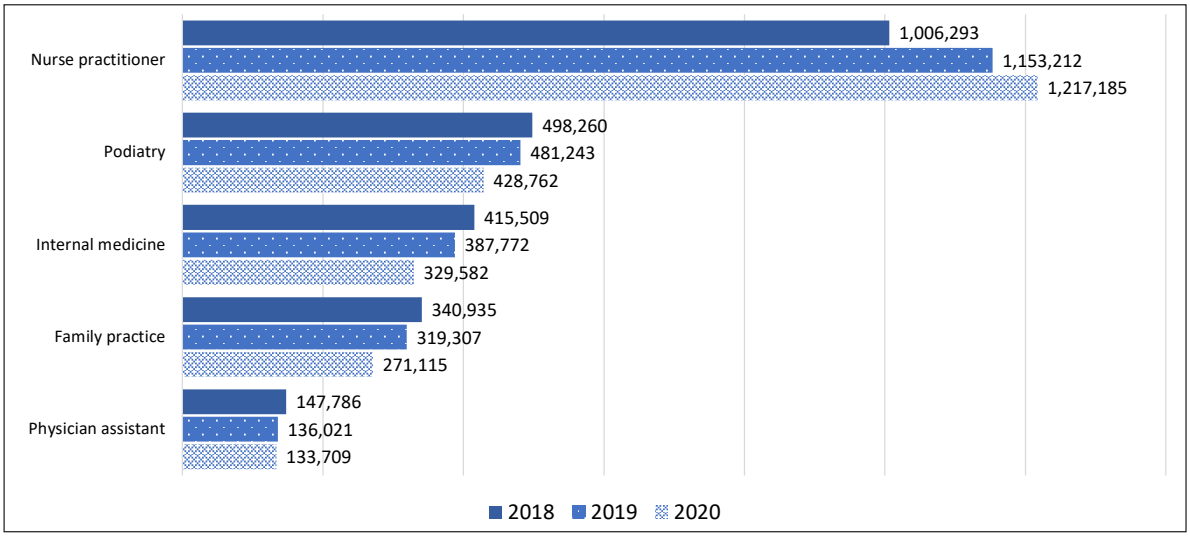
However, reporting isn't evenly distributed among the top specialties; NPs dominated both code families for all three years reviewed. In addition, NPs were the only specialists who performed more visits in both settings in 2020 compared to 2019. However, physician assistants saw a bump for domiciliary codes.

"Nurse practitioners have long recognized the value of home-based care and are committed to ensuring patients get the care when and where they need it," says April Kapu, DNP, APRN, ACNP-BC, FAANP, FCCM, FAAN, president, American Association of Nurse Practitioners. "During the pandemic, NPs expanded home-based care delivery to make sure their patients received the health care they desperately needed despite difficult circumstances." — *Julia Kyles, CPC* (*jkyles@decisionhealth.com*)

Total domicile E/M services (99324-99328, 99334-99337) 2018-2020



Total home E/M services (99341-99345 and 99347-99350) 2018-2020



Source: Part B News *analysis of 2018-2020 Medicare claims data*

Compliance

Provider beware: OIG issues 7 signs of a telemedicine scam

Physicians and other qualified health care professionals should check a recruiting telemedicine company's pitch against the seven signs of a problematic arrangement that the HHS Office of Inspector General (OIG) included in its special fraud alert "OIG Alerts Practitioners to Exercise Caution When Entering into Arrangements with Purported Telemedicine Companies" (*see story, p. 4*)

1. **Patient recruitment.** The telemedicine company recruited patients through a telemarketing company, sales agent, recruiter, call center, health fair, or through advertising online or on television and offered free or low out-of-pocket cost items or services.
2. **Limited patient contact.** The practitioner does not have enough contact with or get enough information from the purported patient to determine the medical necessity of the items or services the practitioner orders or prescribes.
3. **Volume-based pay.** The company pays the practitioner based on the number of items or services they prescribe. The telemedicine company may tell the practitioner that payment is based on the number of medical records they review.
4. **Federal programs only.** The telemedicine company only accepts patients who are covered by Medicare or other federal health care programs.
5. **Private payers only?** Conversely, the telemedicine company may say it doesn't accept patients who are covered by federal health care programs but actually bill those programs.
6. **Restricted treatment options.** The telemedicine company may only offer one product or type of product, such as genetic testing, diabetic supplies or durable medical equipment. These limits may limit the treating practitioner's treatment options.
7. **No follow-ups allowed.** The telemedicine company doesn't expect patient follow-ups and may not give practitioners information that would allow a follow up telemedicine visit.

— *Julia Kyles, CPC* (*jkyles@decisionhealth.com*)

Have a question? Ask *PBN*

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(continued from p. 4)

burnout or violence in the workplace and emphasize benefits such as "a nice work-life balance, with remote work, generous compensation, and less environmental stress for recruited professionals," Shanti observes.

Providers should also note how the recruiter describes the work. "Such payments are sometimes described as payment per review, audit, consult or assessment of medical charts," OIG writes in the SFA. There are legitimate arrangements that involve this type of work, but as with any arrangement the compensation must be for fair market value and not just an excuse to reward practitioners who generate claims.

Practitioners must remember that they are on the hook for claims submitted in their name, Howard warns.

"I think well-intended providers (and others) can be unwittingly drawn into these arrangements without realizing the risks or nature of them," he says. "Often providers are given an incomplete or inaccurate picture of the business and their role [or] they rely on others' advice as to compliance issues."

Practitioners who don't want to get caught up in a fraud investigation should make sure they have a complete understanding of the relevant laws, such as the anti-kickback statute and the business model of the telemedicine company or any other business venture they participate in, Howard adds. Be sure to do your own compliance homework rather than rely on the recruiter's assurances, he says.

Watch for warning signs of a scam

Telemedicine scams come in a variety of forms, but many restrict contact between the practitioner and the person they are supposed to be treating.

Some arrangements may interfere with legitimate patient-provider relationships required by various states' telemedicine laws, Lerman says. "If, as the [SFA] describes, there are scenarios occurring where telemedicine providers are practicing without having any or even limited interactions with the patients, where the providers are practicing without having access to basic and relevant information about the patients, and where the providers cannot have any opportunity or means to follow up with the patients, the telemedicine providers may be practicing in the absence of having valid practitioner-patient relationships established," she says. "This affects all telemedicine providers, including and most notably those who are performing services of a more consultative nature."

The SFA warns providers against telemedicine companies that only offer one type of service or treatment, such as "durable medical equipment, genetic testing, diabetic supplies, or various prescription creams." But providers who are approached by a telemedicine company should also examine the types of health conditions the telemedicine company wants them to treat. Be wary of arrangements that involve narrow patient demographics. That may include, for example, all patients are covered by Medicare, or are of a certain gender in a specific age group or have a specific condition.

"Certain patients may also be targeted, such as those without a health care advocate or with a private or stigmatized treatment, like seniors and patients seeking life-style treatments, as they are less likely to question a test or welcome scrutiny, respectively," Shanti says. She gives examples, such as hair restoration, reproductive treatments, therapy and other services "that may be less critical to survival but promote well-being and are matters patients may find more emotionally sensitive." — *Julia Kyles, CPC* (*jkyles@decisionhealth*) ■

RESOURCE

- Special fraud alert, OIG Alerts Practitioners to Exercise Caution When Entering into Arrangements with Purported Telemedicine Companies: *https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf*

Compliance

Know your rights for medical record access in post-Roe landscape

***Editor's note**: In the July 18, 2022, issue,* Part B News *discussed the implications of the* Dobbs *decision allowing state abortion bans on cross-border prescribing and treatment of abortion-related drugs and services (PBN 7/18/22). In the second segment below, you'll discover how much protection you have if you choose not to share medical records with prosecutors looking for evidence that your patient has sought or obtained such drugs and services, and what the recent HHS guidance on related emergency services and medication means for your practice.*

It is expected that prosecutors will seek medical records to support charges against patients they suspect of violating new statutes against abortion, either as evidence of illegal treatment or to determine from notes that the patient sought such services. HIPAA offers some limited protection to practices that don't want to give them up, and case law suggests the Privacy Law actually prohibits the surrender of protected health information (PHI) in some circumstances (*PBN 1/28/19*).

However, if you find yourself in this position, it is vital that you talk to your lawyer, because HIPAA is not a blanket get-out-of-providing-records card.

"When there's a qualifying court order, HIPAA falls away as a relevant law, because the Privacy Rule basically allows for the disclosure of protected health information where required by law," says David Quinn Gacioch, partner with McDermott Will & Emery LLP in Boston.

"There are a lot of misconceptions out there that HIPAA is going to protect [your patient data] 100%," says Bethany A. Corbin, Esq., senior counsel at Nixon Gwilt Law and expert on digital health and "femtech" issues. "HIPAA allows providers to disclose your data if the [request to do so] meets one of the 'permissible disclosure' exceptions" — that is, the provider is allowed to disclose PHI under HIPAA but is not required to do so, as with a request from law enforcement.

Gacioch notes a recipient of such a subpoena "could seek to quash or get a protective order against that subpoena based upon lack of jurisdiction over the recipient, undue burden" or other factors. And some state laws, such as one signed by Massachusetts governor Charlie Baker on July 29, may offer protection from a subpoena from another state regarding an abortion legally performed in yours.

Revisit policies and procedures

You will want to have policies and procedures (P&P) in place, as HIPAA compliance requires, that explain when and how disclosures should and should not be made, both in informing staff reactions to such requests and in defending your actions in the event of a challenge.

"Say you get a subpoena," Corbin says. "Your P&P might say, 'escalate it to the legal department,' to make sure [your decision] is not arbitrary and capricious. It should include a process that can be applied fairly across-the-board."

Corbin adds that it's acceptable to have different criteria for the types of data you're going to disclose. "For instance," she says, "if it involves reproductive health data, the company may have a policy that says it will not disclose that type of data. The companies should have policies and procedures that are consistent — meaning that if they say they won't disclose reproductive health data, they then don't disclose it for some individuals while withholding it for others."

Stacey L. Callaghan, a partner with McDermott Will & Emery LLP in Chicago, encourages practices to revisit their P&P now to "make sure that everyone

knows what's going on, do a quick training on it. And make sure they all know how to follow your organization's rules if a request comes in."

You might also want to warn patients who seek abortion care rendered illegal by new laws that not only their HIPAA-covered medical records, but their own digital records of health inquiries and activities — such as what may be contained in emails or pregnancy tracking app data on their phone — may be fair game, and these enjoy no HIPAA protection at all.

Corbin cites the 2017 Mississippi case of Latice Fisher, who was charged with second-degree murder for the death of her fetus. "As part of the case, prosecutors reviewed Ms. Fisher's cell phone data and found internet searches related to the purchase of abortion pills," Corbin says. "The data was used to help prove her intent to receive an abortion."

Also relevant is a recent Nebraska case in which prosecutors obtained private Facebook messages to bolster an abortion-related case. Facebook parent Meta claimed in an Aug. 9 statement they were responding to "valid legal warrants from local law enforcement" and that "the warrants did not mention abortion at all."

Fed action, small difference

The *Dobbs* decision led to a presidential press conference and several statements from the Biden administration. The most consequential of these for provider purposes are thought to be two HHS guidance documents on patients' Emergency Medical Treatment & Labor Act (EMTALA) rights as they relate to abortion services, issued July 11; and "Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services," issued July 14.

Caroline Reigney, partner with McDermott Will & Emery in Washington, D.C., notes that this guidance mainly interprets existing law and regulation and doesn't change either.

"I think that the federal government under the current administration is trying to do what they can do based on existing federal laws and regulations," Reigney says. "They're searching for any creative arguments they can put out there for providers to hold on to."

The former guidance asserts the primacy of EMTALA as a federal statute over state law when it comes to health care decisions under circumstances in which the "physician believes that a pregnant patient presenting at an emergency department, including certain labor and delivery departments, is experiencing an emergency medical condition as defined by EMTALA, and that abortion is the stabilizing treatment necessary to resolve that condition, the physician must provide that treatment." This, HHS says, takes precedence over contradictory state law.

On August 2, the U.S. Department of Justice brought suit against the state of Idaho on the grounds that its abortion law conflicts with that interpretation of EMTALA.

Given that EMTALA applies only to covered hospitals with emergency services, it has little relevance to physician practices. The pharmacy guidance, however, could impact your patients when it comes to drugs you may prescribe that are associated with abortion if pharmacies hesitate to dispense on those grounds, even if they are prescribed for something else. The guidance tells pharmacists that failing to dispense under those circumstances may be considered discriminatory under federal law.

For example, HHS specifically cites methotrexate as a drug that may be used to end an ectopic pregnancy, which may be interpreted by some pharmacists as illegal, notwithstanding its clinical necessity. "If a pharmacy refuses to fill the prescription because it will halt the growing of cells and end the pregnancy," the guidance says, "it may be discriminating on the basis of sex."

If the drug is prescribed for rheumatoid arthritis but the pharmacist withholds under the same reasoning, as Alice V. Harris of the Nexsen Pruet law firm in Columbia, S.C., says she's seen reported, HHS warns it may be discriminating on the basis of disability.

"The conundrum is that state law may ban certain drugs outright or as a means to induce an abortion, but the failure to fill the same prescription may violate federal law," Harris says. But note: "While some federal laws may provide a defense during prosecution, the HHS guidance isn't a bar to state prosecution," Harris adds. She expects the current conflicts to be worked out in court — and that could take years. — *Roy Edroso* (*redroso@decisionhealth.com*) ■

RESOURCES

- Executive Order 14076, "Protecting Access to Reproductive Healthcare Services," July 13, 2022: *www.federalregister.gov/documents/2022/07/13/2022-15138/protecting-access-to-reproductive-healthcare-services*
- HHS Secretary letter to health care provider re: EMTALA, July 11, 2022: *www.hhs.gov/sites/default/files/emergency-medical-care-letter-to-health-care-providers.pdf*
- HHS, "Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services," July 14, 2022: *www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html*