June 12, 2023 | Volume 37, Issue 23

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In this issue

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Compliance

Doing telehealth from home? If you're zoned out, take steps to fix it

Because of an expected new enrollment requirement, providers doing "telehealth from home" (TFH) may want to check their local zoning ordinances before setting up shop.

As mentioned in a recent CMS call, the agency "expect[s] practitioners to update their enrollment information to reflect where they are performing their services" if they continue to provide telehealth services under the originating/distant site flexibilities instituted for the COVID emergency and extended until the end of 2023 (*PBN 6/5/23*).

This would include the TFH mode of work to which many providers became accustomed during the public health emergency (PHE). "I have physician friends who have opted to essentially practice 90% out of their home," says Khoren Bandazian, a partner in the real estate, zoning and land use practice and health services groups at the Rivkin Radler law firm in Hackensack, N.J.

But enrollment of one's home with a federal agency as a place of business is essentially a declaration that you're running a business there — not just working as a 1099 employee out of your home — and it's not impossible that your local zoning laws will prohibit that if you're in a residential rather than an industrial, commercial, mixed-use or other such zone.

The requirements vary from jurisdiction to jurisdiction. "We have 566 municipalities in New Jersey," Bandazian says, "and every one's got its own zoning code."

Winn Jackson, a partner at Shackelford, Bowen, McKinley & Norton LLP in Dallas, notes that in his area "a person can use their home as a place of business so long as they comply with a list of 'do-nots,'" which include:

- Do not post a business sign on the house or in the yard.
- Do not use the street address of the home on an advertisement.
- Do not employ more than one non-resident at the home who works more than four hours a week.
- Do not conduct activities on the exterior of the home that indicate a business is being run out of the home.
- Do not make loud noises or generate unreasonably disruptive traffic or parking congestion.

All of this is pretty much a cinch for a telehealth provider — and very similar to other residential-district requirements. (Others Bandazian mentions include that you have to be an actual resident of the home, and that you can't sell physical goods out of the home to customers.)

Note, though, that in Dallas your business "can only take up the lesser of 25% or 400 square feet of space" in your home, Jackson says. Be sure to check your local zoning ordinances.

4 more tips to avoid trouble

- **See if you need a permit**. In Washington, D.C., the Department of Consumer and Regulatory Affairs (DCRA) "requires residents to apply for a Home Occupation Permit for any full or part-time business, professional or economic activity occurring at a residence." Other jurisdictions may have similar requirements.
- **Cover yourself**. It can be as important to be able to show you're within your rights and it is to be within them. "It may be worthwhile to talk to the local building department and see if there's any type of zoning certificate of use," Bandazian says, just so you can head off a challenge.
- **See about a workaround**. If the address you're enrolling is in a residential zone and you're definitely not supposed to have a home business there, apply to the zoning or building authorities for a use variance, Bandazian suggests.
- **Check with your insurers**. Is your malpractice policy still good from your new workplace? Don't forget to double check to make sure you're covered. — *Roy Edroso* (redroso@decisionhealth.com) ■

Coding

Capture correct level of risk for Rx management, parenteral controlled substances

Help your team assign the risk of complications and/or morbidity or mortality of patient management based on prescription (Rx) drug management or parenteral controlled substances when you report E/M services.

You will find key insights into the risk category of the medical decision-making (MDM) table via three scenarios presented by Peter Hollman, M.D.,

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***PART B NEWS* TEAM**

Maria Tsigas, x6023
Product Director
mtsigas@decisionhealth.com

Marci Geipe, x6022
Senior Manager, Product and Content
mgeipe@simplifycompliance.com

Richard Scott, 267-758-2404
Content Manager
rscott@decisionhealth.com

Roy Edroso, x6031
Editor
redroso@decisionhealth.com

Julia Kyles, CPC, x6015
Editor
jkyles@decisionhealth.com

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and Barbara Levy, M.D., co-chairs of the CPT/RUC Workgroup on E/M, during the May 25 webinar "Reporting E/M Services in 2023: A Check-In to Stay Informed."

Coders, physicians and qualified health care professionals (QHP) should absorb three key lessons:

1. Reviewing a list of prescriptions does not meet the level for moderate risk based on Rx drug management.
2. Prescribing or managing a parenteral controlled substance does not automatically qualify as high risk.
3. Risk is calculated and assigned based on the treating physician's or QHP's clinical judgment. "One of the reasons we did not give a lot of examples in the MDM table of risk was because these things are patient-specific," Levy said.

Share the following scenarios, questions and answers to clear up confusion about the third column of the MDM chart.

Inpatient Rx drug management

Scenario: A 60-year-old patient is admitted with complaints of shortness of breath and chest pain. He has hypertension, diabetes and hyperlipidemia. In addition, he has a history of coronary artery disease and coronary artery bypass grafting. He is diagnosed with unstable angina. The treating physician takes the following steps related to the patient's medication regimen:

- **Day 1**: Review current medications. Prescribe aspirin and clopidogrel to reduce the risk of thrombosis.
- **Day 2**: Review current medications.
- **Day 3**: Review current medications.
- **Day 4**: The patient's blood pressure and blood glucose remain high. The treating physician adjusts the patient's hypertension and diabetes medications.
- **Day 5**: Increase the statin dosage to manage the patient's hyperlipidemia.

Question: When can the provider count (Rx) drug management toward risk for his or her MDM?

Answer: The treating physician could count Rx drug management on days one, four and five, but not on days two and three.

The guidelines that apply to (Rx) drug management in the outpatient setting apply to the inpatient setting. Reviewing prescriptions alone does not count, Hollman explained.

"Our feeling is … that simply reviewing the medications in the sense that you acknowledge that they're being taken — you're basically doing medication reconciliation," Hollman said. "[That] isn't sufficient."

To count prescription drug management toward risk, the documentation should show that the provider did something more than review the patient's medications. "For example, if you do address risk levels, if you do address the relevance to the plan … that would be pretty clear," Hollman said. "It doesn't necessarily have to be that you've changed the medication … but it does have to be addressed more than simply clicking a box that you're noting that the meds are being taken or reviewed."

Parenteral controlled substances – high risk

Scenario: A 65-year-old patient with a history of diabetes, hypertension and chronic obstructive pulmonary disease (COPD) is admitted for major abdominal surgery. After surgery he experiences an exacerbation of his COPD and has difficulty breathing.

The treating physician prescribes IV hydromorphone for the patient's post-operative pain on the second day of the patient's stay. The physician observes the first dose and then returns 30 minutes later to check the patient's pulse oxygen and respiration.

"The patient … is at very high risk with the use of IV narcotics and in this scenario considering this medical decision-making as high risk makes sense," Levy said.

Question: Can the treating physician assign a high level of risk based on the IV narcotics for each day of the patient's admission, or only the day when he prescribed the IV narcotic?

Answer: Like the answer for Rx drug management, the treating provider can count the parenteral controlled substance toward risk when it is a factor in the provider's MDM. "The patient has to be seen and accessed daily with some documentation in the record of that [MDM] related to the continuation, discontinuation or adjustment of the parenteral controlled substance for this risk to be counted on subsequent days. And in this case clearly that makes sense," Levy said.

Parenteral controlled substances – moderate risk

Scenario: A healthy 41-year-old patient delivers a baby by cesarian section. She has no complications and her physician expects that she will be up and around within 24 hours. The physician prescribes hydromorphone through a patient-controlled analgesia (PCA) pump to manage her post-procedure pain.

Question: Should the treating physician assign a high level of risk to the E/M visit based on the prescription of a parenteral controlled substance?

Answer: No. The patient's underlying condition doesn't support a high level of risk. A moderate level of risk based on Rx drug management could be appropriate.

"The level of risk varies by the underlying condition of the patient and the scenario in which a physician or qualified health care professional is making these decisions," Levy said. "And that's a really important point for all this. That these are decisions and clinical judgements that are made in very disparate kinds of circumstances and so there isn't a black and white answer that IV parenteral narcotics are always high risk, because it's really not the case."

"If it's the type of thing that it is PCA or [*pro re nata*] and even if you renew it on the second day that's really not a significant consideration because there's not much risk. That would be prescription drug management potentially but not necessarily high risk," Hollman added. — *Julia Kyles, CPC* (*jkyles@decisionhealth.com*) ■

RESOURCE

- Reporting E/M Services in 2023: A Check-In to Stay Informed: www.ama-assn.org/about/events/cpt-webinar-reporting-em-services-2023-check-stay-informed

Health IT

New health app rule would better protect users – and so can you

Now is a good time to inform your patients that the health apps they use, which you may have prescribed or recommended, have different privacy protections than those afforded by HIPAA. However, take note of a new rule proposed by the Federal Trade Commission (FTC); if finalized, your patients will have a better chance of finding out when their data has been compromised, and malefactors will have specific penalties to worry about.

Announced on May 19, the proposed FTC rule aims to update the standards and enforcement of its Health Breach Notification (HBN) Rule that applies to many consumer health tech solutions.

While protected health information (PHI) falls under the purview of HIPAA, the HBN rule is about personal health records (PHR), mainly distinguished by the fact that the "unsecured" data is volunteered by users rather than entrusted by providers.

Heidi Raines, founder and CEO of the health technology company Performance Health Partners in New Orleans, explains that while HIPAA applies to health plans, health care clearinghouses and health care providers, "third-party apps — like calorie-counting apps and period tracking apps, for example — aren't owned by these health care providers, and therefore aren't bound by HIPAA regulations. Consequently, these apps can utilize all the data they gather without any restrictions related to a user's medical privacy rights. Users, while willingly agreeing to the app's terms and conditions, consent to their data being collected and shared."

However, the FTC recognized that PHRs required protection, too, and at the behest of Congress set up breach and notification standards for that data in 2009. The standards currently require handlers of that data and related vendors to notify users within 60 days if the breach affects more than 500 users.

In its refresh, FTC notes that "since the Rule's issuance, apps and other direct-to-consumer health technologies, such as fitness trackers and wearable blood pressure monitors, have become commonplace." Along with language specifically adding "mobile applications" to its coverage, the FTC proposes changes to make breaches more obvious to users of such apps.

Pop-up breach notice?

For example, the rule currently only requires that a regular mail message be sent to affected users. In the proposed rule, along with email notification, the FTC proposes notice by "text message, within-application messaging, or electronic banner," to make it "unavoidable and consistent with the consumer's relationship with the product."

Danie Strachan, senior privacy counsel of global cybersecurity company VeraSafe, notes that under the new rule "the circumstances triggering a breach notification would also be refined to include unauthorized disclosures of identifiable health information to third

(continued on p. 6)

Benchmark of the week

After changes, FNA with ultrasound, tangential biopsy dominated

The codes for fine needle aspiration (FNA) and biopsy of skin lesions received a major update in the 2019 CPT manual. The update revised FNA code **10021** to become a primary code for a new add-on code and replaced three outgoing codes with 16 new codes.

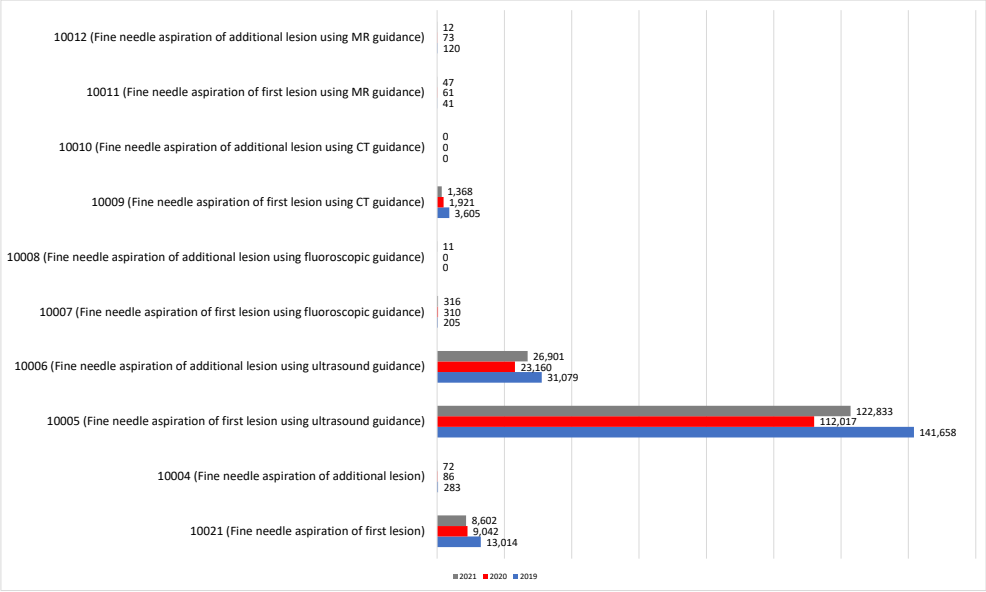
The update divided the FNA codes into four sets of primary and add-on codes based on the image guidance. The biopsy codes were divided by technique: tangential, punch or incisional.

The first chart shows total utilization for Medicare Part B in 2019, 2020 and 2021, the latest Medicare claims information available, and reveals that FNA with ultrasound (**10005**-**10006**) dominated the FNA code set. Claims for FNA with fluoroscopy and magnetic resonance (MR) have struggled to reach the triple digits. Note: A "0" in the chart indicates that providers reported the code less than 11 times during the entire year. Medicare doesn't release the utilization totals that fall below 11 claims to protect patient privacy.

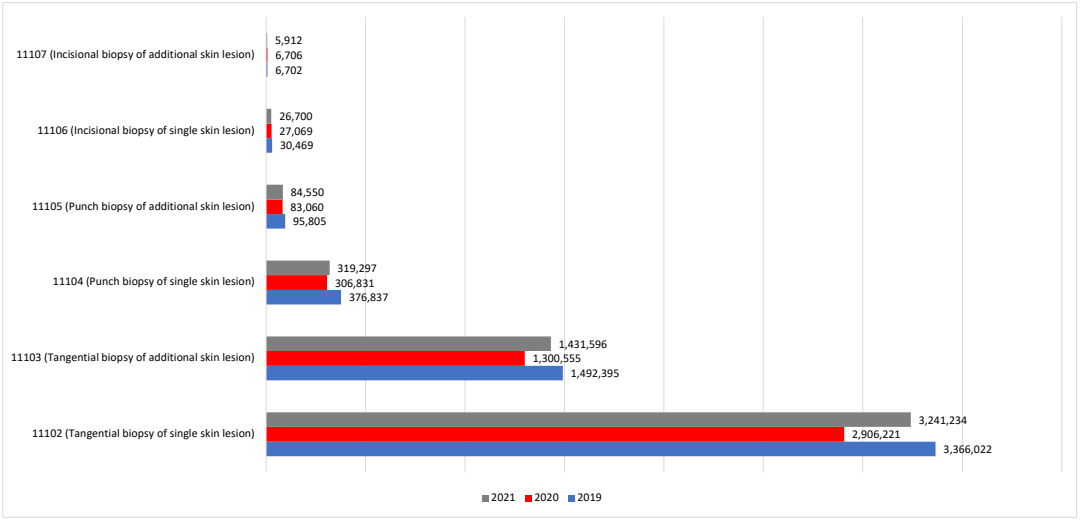
In addition to providing insight into how providers perform FNA, the data indicate another update to the code set could occur in the next few years. The AMA regularly deletes codes with chronically low utilization.

The four new biopsy codes also showed a considerable spread. Tangential biopsy was the technique of choice during the three years reviewed, with punch and incisional biopsies lagging far behind the more than 3 million primary services reported for tangential biopsy. – *Julia Kyles, CPC* (*jkyles@decisionhealth.com*)

FNA of skin lesions, total utilization, 2019-2021



Biopsy of skin lesions, total utilization, 2019-2021



Source: Part B News *analysis of 2019-2021 Medicare claims data and CPT consumer descriptors, 2019*

(continued from p. 4)

parties without the users' consent." These disclosures are a common pitfall of consumer apps, as recent high-profile accusations of unauthorized data harvesting involving Google and TikTok show.

Strachan adds that, under the new rule, app companies would be required to disclose to users "information about potential harm," such as medical or other identity theft, "and the identity of any third parties that have obtained access to the data as a result of the breach." The FTC also stipulates that breaches are "not limited to cybersecurity intrusions or nefarious behavior" and also can involve inadvertent disclosures. They would be redefined as "an unfair or deceptive act or practice" and subject the offender to fines of at least $50,120 per violation per day.

The FTC has largely relied on selective enforcement actions, such as one brought in February against GoodRx, the discount prescription service, charging that the company had shared user PHR data with "third party advertising platforms like Facebook and Google, without the authorization of those consumers." The FTC settled with GoodRx for $1.5 million.

Notes for providers

Matthew Fisher, general counsel with virtual care platform company Carium in Westborough, Mass., believes that merely suggesting your patient use an app is unlikely to expose you to legal or regulatory consequences. However, "a bad recommendation could have reputational or other similar impacts," Fisher adds.

Strachan suggests that providers who recommend or prescribe apps to their patients should perform some basic privacy and security diligence. "Before recommending an app, they should review the app's privacy statements to understand how user data is collected, used and shared," he says. "Ambiguous and overly broad statements or privacy policies that are hard to find should be a red flag."

Strachan adds that providers "should confirm that the app uses strong data encryption and authentication mechanisms, and that it requests the user's explicit informed consent before collecting health data."

Fisher notes that if you contract with the app company, that's a different story: "Then the practice will need to assess what services are being provided," he says. "In many cases, the services would likely involve the use or disclosure of protected health information. That means HIPAA applies and all of the requirements from HIPAA should be followed."

Alaap B. Shah with the Epstein Becker Green firm in Washington, D.C. adds that, in such a case, "if the health app vendor is a business associate [under HIPAA], given that the health app is being provided on behalf of the health care provider to patients, then any individually identifiable health information being collected by the health app — either directly from the patient or transmitted by the health care provider — would arguably be considered PHI and subject to HIPAA." Thus, in the event of a breach, the usual shared responsibility of covered entity and business associate would apply. — *Roy Edroso* (*redroso@decisionhealth.com*) ■

Practice management

As gun laws loosen, prepare for possibly armed patients

As gun laws grow more permissive across the country, consider the possibility that patients will show up to your office armed. Experts advise that you prepare with policies, intake procedures and a plan for untoward events.

Recent incidents of gun violence at medical facilities, such as the May 3 shooting at Northside Hospital Medical Midtown in Atlanta that killed one and injured four, are a reminder that doctors' offices are not immune to firearms danger. But even armed persons who enter the practice without the intention to shoot can still present a danger, as with the county detention center employee Sgt. Steven Parker, whose service weapon accidentally discharged at a medical facility in Lexington, Ky., on March 10.

The push in some jurisdictions for more permissive gun laws, such as the permitless concealed carry law recently authorized by Florida and Nebraska, and now legal in most states, makes the prospect of someone having a gun when they enter a doctor's office more likely.

"Many states are relaxing laws now and people, because they have a tendency to carry their guns everywhere, will undoubtedly also take guns to their physician's offices — especially if they're not the one being examined," says Jagdish Khubchandani, a professor of public health at New Mexico State University in Las Cruces.

"For example, [they might show up] at the pediatrician's office, where they can assume their child will be examined instead of themselves."

Fair warning

But that doesn't mean you have to let them in. Legal experts generally agree that private businesses have the right to ban guns from their premises.

"It's like 'no shoes, no shirt, no service,'" says Casey Kane, a partner with the Steven T. Rodemer law firm in Colorado Springs, Colo., citing the familiar store signage. "It's like the First Amendment: If you go into a business lecturing on politics, they can kick you out."

Key to this is clear signage expressing your policy "on entry doors and waiting rooms, as well as on intake forms," says Gene Petrino, a security consultant and co-founder of Survival Response LLC in Coral Springs, Fla.

You should make it part of the patient intake process, advises Richard F. Cahill, Esq., vice-president and associate general counsel of The Doctors Company in Napa, Calif. "Patients should be notified at the outset of the clinician-patient relationship in the conditions of treatment signed by a prospective patient as to the expectations that the practice has," including weapons on premises, Cahill says.

The reason for this preparation is legal and state-specific: "In states like Massachusetts or California, if a patient comes into the practice with a gun, it may be considered a crime depending upon the attendant circumstances, and the providers should contact the appropriate authorities," Cahill says. "However, in states like Florida or Texas, if a patient enters the practice with a weapon, they aren't necessarily in violation of the law. In this scenario, it would be best for the providers to ensure there is contractual language in the patient-provider contract that states, [e.g] 'for the safety and well-being of our staff and patients, weapons of any kind are not permitted on the premises.' Patients will then have to consent to this to receive treatment in the same way they consent to have their insurance billed."

You can, if you wish, advertise a blanket prohibition: No firearms. (However, exceptions must be made for law enforcement officers who often are required to carry a firearm both on and off duty, Petrino says.) But "especially in regions where gun ownership is prevalent or where legal requirements differ," Petrino says, you may choose to instead "provide guidelines on how firearms should be handled if brought into the facility, such as requiring them to be properly secured or notifying the staff upon arrival." You might, for example, have a locked storage facility where patients have to leave guns when they arrive and collect them when they leave.

Staff should be trained in this policy. But "a firearm should only be handled by those who have a fundamental understanding of firearm safety," Petrino says.

If they won't disarm

Even if you want guns to stay out of your office, you may still have to deal with patients who are not mindful or respectful of your wishes.

Depending on your circumstances, you may want to implement "controlled access measures," Petrino says. This might mean security personnel at controlled entry points, who might query patients or check their bags. In extreme cases, you might consider metal detectors.

If a patient balks at surrendering their weapon, Petrino emphasizes a "de-escalation" of the situation. A staff script might go like this:

"Thank you for understanding our commitment to maintaining a safe environment for all patients and staff. Our policy prohibits firearms within the premises. While we value your autonomy and appreciate your perspective, we would like to suggest considering an alternative approach that respects your preferences. We can provide you with a list of other health care providers who may have different policies regarding firearms, allowing you to receive care while feeling more comfortable."

If this doesn't work, it may be time to revert to your crisis plan — which you should have in place right now, Cahill reminds you, and in which you should train your staff (*PBN 6/20/22)*. Confer on the plan with "professional societies, licensing boards and other resources available in the community" and make sure your plan is "periodically audited to maintain consistency and compliance and routinely reviewed to adopt evolving conditions and standards."

But if you've made your policy clear, chances are things won't get that far. "Most law-abiding citizens with either open carry or concealed carry permits don't want to do anything that might terminate or restrict their right," Kane says, "whether it's a crime or anything else that [might result in] contact with the police." — *Roy Edroso* (*redroso@decisionhealth.com*) ■

Ask Part B News

PCP notification, not permission, is required for extended ESI treatments

Question: *We were told that we need to contact the patient's primary care provider (PCP) before we perform epidural steroid injections (ESI) for Medicare patients. It's hard to get the PCPs' authorization for the injections. Where can we find proof that we need a PCP's permission?*

Answer: Good news. Pain management practices do need to inform the patient's PCP when ESI treatments last longer than 12 months, but they do not need the PCP's permission to perform the block.

Medicare administrative contractors (MAC) created a uniform local coverage determination (LCD) for epidural steroid injections that includes the following requirement: "The primary care provider must be notified regarding continuation of procedures and prolonged repeat steroid use." PCP notification is one of four requirements that apply to extended ESI treatments — that is, treatments that last longer than 12 months.

The MACs clarified that the PCP notification requirement "does not require permission from the primary care provider to continue treatments but rather a notification of continued use, so they are fully informed of the treatment plan and potential side effects." The MACs did not specify how pain management practices should document the notification, which gives practices the freedom to develop an internal policy. However, the notice should be documented and included in the patient's chart.

Members of your practice who are involved in scheduling, performing and coding epidurals for chronic pain management should read the LCD and the companion billing and coding article to prevent improper claims. — *Julia Kyles, CPC* (*jkyles@decisionhealth.com*) ■

RESOURCES

- Noridian LCD L39240 Epidural Steroid Injections for Pain Management: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=39240&ver=5
- Response to Comments: Epidural Steroid Procedures Injections for Pain Management: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59079&ver=3

Coding

CMS releases HCPCS Level II codes for new products, live July 1

CMS published its first quarter 2023 HCPCS Application Summaries and Coding Recommendations as part of its April 27 publication of MLN Connects.

The document summarizes CMS' final decisions regarding applications for products that were seeking HCPCS Level II code assignments. Of the 77 submitted products, CMS approved 58 and assigned codes to them. It deleted seven codes, beginning June 30, and revised one code.

These 77 new codes, except for **J1411** (Injection, etra-nacogene dezaparvovec-drlb, per therapeutic dose), and the single code revision will become effective July 1.

HCPCS Level II code J1411 became available for implementation April 1. This change was "due to unique programmatic needs within the hospital outpatient settings," according to the application summaries document.

The majority of approved HCPCS Level II codes are for injections of specific drugs and skin substitute products, as seen in the following examples:

- **J9347** (Injection, tremelimumab-actl, 1 mg).
- **J9350** (Injection, mosunetuzumab-axgb, 1 mg).

The deleted HCPCS Level II codes, which will be discontinued June 30, are:

- **C9148** (Injection, teclistamab-cqyv, 0.5 mg).
- **C9149** (Injection, teplizumab-mzwv, 5 mcg).
- **J2370** (Injection, phenylephrine hcl, up to 1 ml).
- **S0020** (Injection, bupivicaine hydrochloride, 30 ml).
- **S0030** (Injection, metronidazole, 500 mg).
- **S0073** (Injection, aztreonam, 500 mg).
- **S0077** (Injection, clindamycin phosphate, 300 mg).

The single HCPCS Level II code that received a revised description was:

- **J2426** (Injection, paliperidone palmitate extended release [Invega sustenna], 1 mg).

The revision included the addition of "(Invega sustenna)" to the J2426 code description. ■

RESOURCE

- Submissions and the product descriptions, CMS' 2023 HCPCS Application Summaries and Coding Recommendations document: www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-1-2023-drugs-and-biologicals-updated-04/28/2023.pdf