Report on. **VEDICARE COMPLIANCE**

Weekly News and Compliance Strategies on Federal Regulations, **Enforcement Actions and Audits**

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Commercial Payer, Medicare Telehealth Audits Are Underway, With Some Surprises

In an audit twist that shows the prevalence of telehealth services because of COVID-19, some reviews are underway of in-person home infusion, with auditors questioning why home infusion physician practices aren't delivering more follow-up services by telehealth, an attorney said.

"There's a lot of scrutiny of how complex home infusion services are provided," said attorney Stephen Bittinger, with K&L Gates in Washington, D.C. "I have seen a significant uptick." Pandemic lockdowns in geographic areas played a role in an auditor's skepticism about the number of in-person visits to infusion patients. From the auditor's perspective, the nurses could use telehealth for lower-cost follow-up visits in between infusions. "Reviewers are going to be examining the context of delivery of services and questioning why providers weren't choosing less expensive telehealth options," Bittinger said. In this case, the auditor works for a commercial payer.

That is one type of telehealth audit underway, less than a year after audio-only and audiovisual visits became a lifeline-literally for patients and financially for providers, as COVID-19 cast its shadow across the country. Providers have been in uncharted territory. Medicare rapidly expanded coverage and accepts claims for telehealth services delivered to patients by providers in other states during the public health emergency (PHE) as long as they're licensed in one state (although they're still subject to state laws). As a result, there's a lot of room for error.

"It's going to be the most incredible wave of auditing we have ever seen," Bittinger said. "It's going to be wild for the next couple of years. There were so many shifts in who delivers services and changes in services."

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No Surprises Act Limits Out-of-Network Charges; **Exception Requires Compliance Oversight**

Hospitals and health plans soon will be circling each other in another realmpayments and claim denials for services provided out of network-now that Congress has enacted a law on surprise billing. The No Surprises Act,¹ which is part of the 2021 Consolidated Appropriations Act signed by President Trump Dec. 27, protects patients from large or unexpected bills when they're treated by hospitals, physicians and other providers that don't participate in their health plans, depending on the circumstances. The law also establishes an arbitration process for providers and payers to settle payment disputes about out-of-network services when they're at an impasse.

There are exceptions to the prohibition on surprise billing, and exceptions to the exceptions, a "convoluted" area with potential for providers to run afoul of the law, said attorney John Barnes, with King & Spalding, at a webinar sponsored by the firm's Los Angeles office.² It will require oversight by compliance professionals.

"The no surprise law may be the most earth-shattering change to managed care," said attorney Glenn Solomon, with King & Spalding. "Nothing will reshape managed continued care as much as this bill for years." HHS regulations are due out July 1, and the law takes effect for plan or policy year 2022.

"The marquee headline of the rule is it limits patient liability, when applicable, to no more than the patient's in-network cost sharing and deductibles for out-of-network care," said attorney Amanda Hayes-Kibreab, with King & Spalding. "Those are maximums applicable under that patient's health benefit plan." In other words, providers and hospitals can't balance bill patients, which makes sense since they can't bill more than in-network cost-sharing amounts, she said. To ensure hospitals and physicians are protected as well, payers must reimburse them directly for out-of-network care. "Plans are not permitted to send reimbursement checks to patients," Hayes-Kibreab said.

The protections vary depending on whether patients are receiving emergency or nonemergency services, and whether the hospital also participates in the patient's health plan.

There's a shortcut for determining whether the health plan complies with the prohibition on surprise billing, when it takes effect, Solomon said. Only the copay amount should appear on the explanation of benefits (EOB) form for the out-of-network provider in the patient portion. "Then the hospital can worry about fighting the health plan" for an appropriate payment,

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Subscribers to this newsletter can receive 20 non-live Continuing Education Units (CEUs) per year toward certification by the Compliance Certification Board (CCB)[®]. Contact CCB at 888.580.8373. he said. "Regulators have to make sure health plans correctly state on the EOB what's owed by patients."

The law applies to virtually all payers, Hayes-Kibreab said. That includes small and large group health plans, individual plans, federal employee health benefit plans and employer self-funded plans under the Employee Retirement Income Security Act.

Providers May Seek a Waiver, With a Caveat

The protections from surprise billing apply to nonemergency services provided by nonparticipating providers (out of network) at participating hospitals (in network), and to emergency services provided at nonparticipating hospitals by nonparticipating providers (see box, p. 4).³ In other words, the law only applies to hospitals with respect to emergency services for the most part, Barnes said.

For example, when a patient seeks nonemergency treatment at an out-of-network hospital and is treated by an out-of-network physician, there's no insulation from surprise billing. But it's out of bounds if the hospital is in the health plan network and the patient is treated by an out-of-network physician.

There's an exception for nonemergency elective services. Physicians may ask patients to waive their protection from surprise bills, Barnes said. If the patient agrees, physicians may charge the patient more than their copays. Why would patients agree to the waiver? Physicians may say they're unable to perform a procedure unless the patient essentially agrees to pay more for out-of-network care. "It's a Hobson's choice," Barnes noted. "Either the patient waives or the patient refuses to waive and has to find another physician to complete the service."

There are exceptions to the exception, however. "The common denominator to the exceptions is that patients don't have a meaningful choice about who will treat them," he said. If an in-network provider is unavailable, forget the waiver. That would be the case, for example, when a patient in a rural area needs a stent, and both cardiologists practicing in the local hospital are out of network. However, if a hospital has three cardiologists on staff and one is in the network of the patient's health plan, the physician can ask for the waiver, Barnes said.

Although the ability to seek a waiver "is not absolute," many physicians will go for it as they start to receive disappointing out-of-network payments. But others will be satisfied with the money, and "from a pure economic standpoint, they need a volume of services and maybe they won't ask for waivers," he explained.

The second exception to the waiver is for unforeseen or urgent circumstances, which "is in the

EDITORIAL ADVISORY BOARD: JULIE E. CHICOINE, JD, RN, CPC, General Counsel, Texas Hospital Association; JEFFREY FITZGERALD, Polsinelli PC; EDWARD GAINES, Esq., Zotec-MMP; DEBI HINSON, Compliance Content Developer, Healthstream; RICHARD KUSSEROW, President, Strategic Management Systems; MARK PASTIN, PhD, Council of Ethical Organizations; ANDREW RUSKIN, Esq., K&L Gates; WENDY TROUT, CPA, CHC, CCS-P, Director, Corporate Compliance, WellSpan Health; LARRY VERNAGLIA, Foley & Lardner LLP; BOB WADE, Esq., Barnes & Thornburg same vein" as the Emergency Medical Treatment and Labor Act (EMTALA), Barnes said. "Physicians can't ask a patient who needs urgent care to waive the protections of the act."

The third exception is for providers who aren't typically selected by patients, including radiologists, anesthesiologists, pathologists and intensivists. "They are categorically prohibited from asking patients to waive the protections of the act," Barnes said.

Congress apparently didn't want to make it easy to ask patients to waive their surprise-billing protections, because there are strings attached. For example, providers must request a waiver 72 hours in advance of delivering the services and include a good-faith cost estimate of outof-network services. The provider also must inform the patient of an in-network option. "All of this has to be done in a way that allows the patient to give informed consent," subject to state law requirements, Barnes said.

Post-Stabilization Is Outside the Law, But Be Careful

The No Surprises Act also applies to poststabilization services in hospitals, subject to a very limited exception (i.e., the patient can travel, and can and does give informed consent). The same strings attach, except for the 72-hour notice requirement. There won't be time for providers to ask for the waiver that far in advance because the services are provided after an emergency.

Enforcement of the waiver and its exceptions mostly falls to the states, Barnes said. "If a state fails to substantially enforce the act's requirements, the federal government may step in. The federal backup enforcement allows the federal government to impose civil monetary penalties against providers of up to \$10,000 per violation."

The exceptions process will require a lot of compliance oversight, Barnes said. Whether patients are capable of giving informed consent to waive their protections from surprise billing is a question under state law. "Some state laws are very specific on the circumstance in which you ask patients to give informed consent," he explained. That includes juveniles, patients receiving mental health services in facilities and people with severe disabilities under conservatorships.

"Significant policy work will have to be done by providers between now and January 2022 to be ready for compliance," Barnes said. "We have to consider whether hospitals will have the administrative capacity to obtain informed consent."

The law also addresses how patient cost-sharing will be determined. It will be based on a "recognized amount," Solomon said. The recognized amount is either set by state law or a "qualifying payment amount," which is the median of the contracted in-network rates as determined by all plans of a particular plan sponsor, he said. Different rules apply to Maryland, the only state that has an all-payer system, which means all payers reimburse the same for hospital services.

Baseball-Style Arbitration: The Winner Takes it All

Although patients don't foot the bill, out-of-network providers obviously will still be paid. The law might open another chapter in the epic battles between payers and providers over appropriate payment for claims, and undermine the purpose and motivation of contracting with health plans, the lawyers said.

With out-of-network services, initially the outof-network provider (hospital, physician or other practitioner/entity) bills the health plan for the service. Within 30 days, the health plan must pay the bill or deny the claim, said attorney Daron Tooch, with King & Spalding. When payers deny the claim, the two parties have 30 days to privately negotiate a solution to the payment dispute. If that fails, the payer and provider have four days to tell HHS they will voluntarily pursue an independent dispute resolution (IDR) process, he said. It starts on Jan. 1, 2022, and will use contract data from 2019.

With IDR, the two sides jointly pick an IDR entity to serve as arbitrator, Tooch said. It's "baseball-style arbitration," Solomon said. After hearing from the plan and the provider, an arbitrator will pick a winner; there's no compromise dollar figure, he said.

In making its decision on the out-of-network payment, IDR entities will consider the qualifying amount as well as seven other factors, Solomon said. The factors include the patient's acuity and complexity of the services provided; the market share of the provider or facility in the geographic region; and the level, training, experience and quality of the provider or facility. "Good faith efforts are also very important," Solomon said. "Even if you're not in network, you may want to be making good faith efforts to get in network." The same goes for the plans; if they don't make reasonable offers, "it will be considered."

IDR entities aren't allowed to consider reimbursement rates paid by Medicare, Medicaid and other public payers.

Upsetting the Contracting Apple Cart

Providers and health plans will gather information on these factors and present them to the IDR entity, but they'll have to do it fast. "This is not a one- or two-year process," he noted. They have 30 days.

The No Surprises Act and its IDR process will have a ripple effect on contracting, the attorneys said. "Contracted rates are meant to be a discount off something," Solomon said. "If you make it no better to be in network than out

of network, then providers will have to raise their rates, or health plans will not have any networks."

The quid pro quo of managed care is payers steer patients to providers, and they accept discounts on services. But that goes out the window "if payers take advantage of deeply discounted rates for out-ofnetwork services" and give providers nothing in return.

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Endnotes

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- King & Spalding, "The New Frontier in Managed Care: An Overview of the Newly Passed Federal Surprise Billing Legislation," webinar, January 12, 2021, https://bit.ly/3ib8vGh.
- 3. Nina Youngstrom, "Snapshot of the No Surprises Act: Its Application and the Arbitration Process," *Report on Medicare Compliance* 30, no. 2 (January 18, 2021).

Snapshot of the No Surprises Act: Its Application and the Arbitration Process

Here's a quick look at key provisions of the No Surprises Act, which limits patient liability for services performed by providers that are not in the patient's health plan (see story, p. 1).¹ This was created by the law firm King & Spalding. Contact attorney John Barnes at jbarnes@kslaw.com.

Applicable Services

Emergency Services	Nonemergency Services	
Nonparticipating Facility	Participating Facility	Nonparticipating Facility
Nonparticipating Provider	Nonparticipating Provider	Nonparticipating Provider
Act Applies	Act Applies	Act does not apply



Endnotes

1. Nina Youngstrom, "No Surprises Act Limits Out-of-Network Charges; Exception Requires Compliance Oversight," *Report on Medicare Compliance* 30, no. 2 (January 18, 2021).

New Law Gives Entities a Break on HIPAA Fines if Compliance Improved

In July, the HHS Office for Civil Rights (OCR) reached a \$25,000 settlement with Agape Health Services, a federally qualified health center in rural Washington, North Carolina,¹ after initially proposing a \$400,000 fine,² Clifton Gray III, the chief compliance officer for Agape, told *Report on Patient Privacy, RMC*'s sister publication. Even at \$25,000, the payment accompanied by a two-year corrective action plan—was "devastating," Gray said.

What so irked Gray was that OCR's investigation was triggered by a small email breach that had happened 11 years earlier, and that the agency refused to base the settlement on Agape's current state of compliance. OCR said Agape had been noncompliant until 2016.

Such a look back might be a thing of the past because Congress has passed a bill that would require OCR to review an entity's compliance over the previous 12 months when calculating fines.³

H.R. 7898, sponsored by Rep. Michael Burgess, R-Texas, a physician, passed the House on Dec. 9 and the Senate on Dec. 19. It was signed into law by President Trump on Jan. 5. The law amends the Health Information Technology for Economic and Clinical Health Act.

Burgess said the purpose of the bill was two-fold: to give the HHS Office of Inspector General the authority to investigate incidents of data blocking that he said was missing from the 21st Century Cures Act and to support security activities.⁴

Speaking before the House vote, Burgess also stated that it is important to ensure "patient privacy is protected and information is secure," adding that the bill "builds on the sections of Cures and encourages health care entities to adopt strong cybersecurity practices, which are critical in protecting patient data from bad actors."

Under H.R. 7898, OCR "shall consider whether the covered entity or business associate has adequately demonstrated that it had, for not less than the previous 12 months, recognized security practices in place," in order to "mitigate fines" and "mitigate the remedies that would otherwise be agreed to in any agreement with respect to resolving potential violations of the HIPAA Security rule...between the covered entity or business associate" and the agency.

The Law Is Retroactive

The bill defined recognized security practices as "the standards, guidelines, best practices, methodologies, procedures, and processes developed under section

2(c)(15) of the National Institute of Standards and Technology Act, the approaches promulgated under section 405(d) of the Cybersecurity Act of 2015, and other programs and processes that address cybersecurity and that are developed, recognized, or promulgated through regulations under other statutory authorities. Such practices shall be determined by the covered entity or business associate, consistent with the HIPAA Security rule."

One key point for organizations: The bill is retroactive to Dec. 13, 2016, the effective date of the Cures Act. It is not clear whether organizations that have already settled with OCR would be able to renegotiate the terms.

Importantly, organizations can decide which practices to use, and those "electing not to engage in the recognized security practices defined by" the bill are not more liable for penalties.

A version of this story originally appeared in *Report on Patient Privacy*. For more information, visit http://bit.ly/32HQiYF. ◆

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Telehealth Audits Are Underway

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Don't Forget to Document Time

Hospitals also are doing chart reviews internally to identify noncompliance with coding and documentation requirements. "We have done billing and coding audits and are seeing areas for improvement," said Chris Anusbigian, a specialist leader with Deloitte & Touche in Detroit. For example, there have been Medicare claims billed with the telehealth modifier 95 even though the documentation within the encounter gives the impression the services were provided in person, she said. Sometimes the notes are agnostic about whether the services were delivered in person, by phone or by audiovisual technology, she said. Although Medicare pays the

Have feedback? Please contact Scott Moe at scott.moe@hcca-info.org with any questions or comments. Have a story idea? Please contact Nina Youngstrom at nina.youngstrom@hcca-info.org. same for evaluation and management (E/M) services whether they're delivered in person or via telehealth during the COVID-19 PHE, "the reportable CPT codes are different for audio vs. audiovisual. It's important to document how the service was provided (in person, audio or audiovisual)," said Leslie Slater, a specialist leader at Deloitte Advisory in New York City. "Additionally, how the E/M levels are assigned is different for telehealth vs. an in-person visit." For an audiovisual telehealth visit, the E/M codes are assigned based on time or medical decision-making. In contrast, before new E/M coding guidelines took effect Jan. 1, 2021, an in-person visit required documentation of the E/M components—history, physical exam and medical decision-making (or time).

Documentation of the setting may also be important for medical legal reasons, Slater said. A provider's documentation of the physical exam may be different based on how the visit was conducted because "components of a physical exam may not be able to be conducted during a telehealth visit, and there is more reliance on the patient's description of what is going on," she noted.

Some services are exclusively billed based on time, such as psychotherapy, physical, speech and occupational therapy, and audio-only telehealth, Anusbigian said. With these telehealth visits, providers

CMS to Take Back Money It Returned Under Site-Neutral Payment Policy

CMS is taking back money from hospitals for outpatient clinic visits provided in 2019 at excepted off-campus provider-based departments (PBDs) after returning the money when it lost a federal court decision on the site-neutral payment policy introduced in the 2019 Outpatient Prospective Payment System regulation.

Now that CMS won its appeal¹ of the decision at the U.S. Court of Appeals for the District of Columbia Circuit, which restored the site-neutral payment policy, CMS "will begin reprocessing the claims" by July 1, 2021, according to an *MLN Connects*² posted Jan. 14.

"It is a shame CMS is taking this action now, when hospitals are struggling with the increased costs of responding to community need around the COVID pandemic," said attorney Larry Vernaglia, with Foley & Lardner in Boston. "While CMS has done many great things to assist the hospital community in the past 10 months, this will sting. Many hospitals will not have reserved for this recoupment. Indeed, this is an area where hospitals would have reasonably relied on CMS *not* taking this action—from the perspective of fairness and equity. No other industry could be expected to be whipsawed by their largest business partner in this fashion."

Under the site-neutral payment policy, Medicare pays the same for certain evaluation and management (E/M) services (HCPCS code G0463) whether they're performed in freestanding clinics or off-campus PBDs. That holds true whether they're excepted or non-excepted PBDs. The American Hospital Association (AHA) and about 40 hospitals had sued CMS in the U.S. District Court for the District of Columbia, asking it to void the policy. They won in federal district court, and CMS started refunding the differential in 2019 payments stemming from the site-neutral payment policy. But CMS appealed and won, which means hospitals are subject to reduced payments for the E/M services in off-campus PBDs. And now CMS wants its money back for 2019 as well. CMS says the site-neutral policy is designed to reduce overutilization.

However, on Dec. 11, AHA filed a joint status report³ with the court, saying "the plaintiffs anticipate that they will file a petition for a writ of certiorari for review of the Court of Appeals decision" by the Supreme Court.

The recoupment is "premature," said attorney Andy Ruskin, with K&L Gates in Washington, D.C. CMS, he said, "should have waited until there is a final, unappealable, or unappealed, decision. This seems more like the agency trying to clean up loose ends before the change in administration, as if there were concerns that the new administration might choose not to take this step. If that really is what's going on, then this would be one of the only administrations not to take the time-honored approach of refraining from taking any major actions in the waning days of that administration."

Contact Vernaglia at lvernaglia@foley.com and Ruskin at andrew.ruskin@klgates.com.

Endnotes

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- 2. MLN Connects, January 14, 2021, https://go.cms.gov/3icHbat.
- 3. American Hospital Association v. Alex M. Azar II, case no. 1:20-cv-80 (D.D.C. 2020), https://bit.ly/3bIZ3IL.

should consider putting the start and stop times in the medical record, not just the total time. "It's a good internal control to support billing," she said. Also, patients notice if the explanation of benefits form has charges for more hours of psychotherapy than they know they received.

Medicare, Commercial Payers Look Under the Hood

Commercial payer audits seem to be moving faster than Medicare audits, although they are underway as well, Bittinger said. "A big issue is a lot of providers who had never been in the telehealth arena jumped into it and jumped into it pretty poorly," he remarked. "Unfortunately, a lot of providers were just expecting grace out of the payers, and it's not happening. It's pretty disheartening because payers have had record profits" during the pandemic.

Bittinger said he has already seen a wave of commercial audits of audio-only telehealth services. "They are really focused on the level of evaluation and management services," he said. "From the first series of clients I am looking at, they had a hard time documenting sufficiently for what they felt was appropriate."

He said he has seen a coordination of reviews across some Blue Cross plans, particularly in the mid-Atlantic states (e.g., Maryland, Virginia). The plans are sending almost identical requests for documentation, often to physician practices, although other entities have been targeted as well. "I anticipate that will continue and accelerate," he said.

Partial Hospitalization and Zoom Don't Mix

In the Medicare world, a telehealth area "that has gotten real interesting real fast" is hospice, Bittinger said. He has seen an "uptick" in reviews by unified program integrity contractors (UPICs), although they are predominantly probe samples. The UPICs are focusing on the clinical appropriateness of hospice certifications and recertifications and whether hospices have sufficient clinical documentation. "Hospices got some significant waivers on the elements of care that could be provided via telehealth," Bittinger said. However, there probably wasn't enough clarification for hospices to know whether their interdisciplinary team, which is responsible for developing the plan of care, could make decisions by telehealth, he said.

At least one Medicare administrative contractor, Novitas Solutions, is denying telehealth claims for partial hospitalization, Anusbigian said. Partial hospitalization requires 20 hours of therapy a week, and patients often are unable "to sit on Zoom calls that long for therapy," she said.

Slater and Anusbigian audited one chart that was a headscratcher. The claim attached to it had a telehealth modifier, and the documentation included all the vital signs-pulse, respirations, oxygen level and blood pressure—"but there was no notation as to whether the patient provided the vital sign information themselves and reported the data elements to the provider or whether the vital sign information was from a prior note," Anusbigian said. No date or time was documented, and there were no initials indicating the identity of the person who collected the information. Also, there was no documentation of the provider's assessment or medical decision-making, but the services were billed as an audiovisual E/M service. As a result, it was unclear whether the vital signs were obtained by remote patient monitoring devices or the vital signs were cut and pasted from an earlier encounter without being updated, which is inappropriate. Or it was possible the patient was seen by the provider in person, she said.

When the telehealth waivers were first rolled out early in the pandemic, health systems were more vulnerable to mistakes, and their coding and billing departments often did 100% pre-bill holds and reviews. But they have systems in place now, and spreadsheets or shared drives to document requirements and comply with various payer telehealth requirements, Slater and Anusbigian said. "A lot of compliance and internal audit teams are starting to do follow-up internal billing audits," Slater said. "They are including telehealth audits and reviews in their work plans. The pre-bill holds have been relaxed as telehealth services and billing become part of everyday life."

The 2021 Medicare Physician Fee Schedule rule permanently added seven groups of telehealth services (known as category one), which means

CMS Transmittals and *Federal Register* Regulations, Jan. 8-14, 2021

Transmittals

Pub. 100-04, Medicare Claims Processing Manual

 January 2021 Update of the Ambulatory Surgical Center (ASC) Payment System, Trans. 10557 (Jan. 8, 2021)

Pub. 100-06, Medicare Financial Management

 Notice of New Interest Rate for Medicare Overpayments and Underpayments -2nd Qtr Notification for FY 2021, Trans. 10561 (Jan. 12, 2021)

Federal Register

Final Rule

 Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary", 86 Fed. Reg. 2,987 (Jan. 14, 2021)

January 18, 2021

they will be covered when the PHE ends but will be limited to originating sites and rural areas (known as category one).¹ CMS also added to the long list of telehealth services that are temporarily covered until the end of the calendar year in which the PHE is over (category three).

Bittinger said the outstanding question with telehealth centers on "the glidepath." What services will Medicare and private payers make permanent after the PHE is over? "We don't quite know," he said. And providers won't have to worry for a while, because Jan. 7, Sec. Alex Azar extended the PHE, which was set to expire at the end of the month, for another 90 days. When the PHE ends, or at the end of the year when the PHE ends, the originating site and rural site requirements kick in, unless Congress makes a move to broaden telehealth coverage. Meanwhile, "a lot of commercial payer policies remain broad, or they slowly roll people over to their telehealth platforms," Bittinger said. For example, a lot of Blue Cross plans have their own virtual care systems and telehealth providers.

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 Nina Youngstrom, "Final Physician Rule Changes Supervision, Adds Telehealth Codes, Some Permanently," *Report on Medicare Compliance* 29, no. 43 (December 7, 2020), http://bit.ly/35jzF8w.

NEWS BRIEFS

♦ Recovery audit contractors (RACs) may soon be auditing positron emission tomography (PET) for initial treatment strategy in oncologic conditions for compliance with medical necessity and documentation requirements. It was added to the list of proposed RAC topics¹ Jan. 5 for outpatient hospital and professional service reviews. CMS also added the first 2021 audit targets to the approved list: Air Ambulance: Medical Necessity and Documentation Requirements,² Hospice Continuous Home Care: Medical Necessity and Documentation Requirements,³ and Ambulance Transport Subject to SNF Consolidated Billing.⁴

 Spinal Decompression Clinic of Texas (SDCT) agreed to pay \$330,898 to settle false claims allegations for allegedly billing Medicare improperly for electro-acupuncture device neurostimulators, the U.S. Attorney's Office for the Eastern District of Texas said Jan. 12.5 SDCT charged Medicare for implanting 41 neurostimulators, which is a surgical procedure that usually requires an operating room, from Aug. 21, 2018, to June 26, 2019. Medicare paid SDCT \$177,051 for these procedures. The U.S. attorney's office alleged SDCT didn't perform these surgeries, and instead applied P-Stim devices, a single-use, electric acupuncture device affixed behind a patient's ear using an adhesive, in an office setting, without surgery or anesthesia. "Needles are inserted into the patient's ear and affixed using another adhesive. Once activated, the device then provides intermittent stimulation by electrical pulses," the U.S. attorney's office said. "Medicare does not reimburse for acupuncture or for acupuncture devices such as P-Stim, nor does Medicare reimburse for P-Stim as a neurostimulator or as implantation of neurostimulator electrodes." SDCT didn't admit liability in the settlement.

◆ Banner Health, on behalf of the Banner Health affiliated covered entities (Banner Health ACE), has agreed to pay \$200,000 to settle potential violations of the HIPAA Privacy Rule's right of access standard, the HHS Office for Civil Rights (OCR) said Jan. 12.⁶ This is OCR's 14th settlement under its Right of Access Initiative. OCR said it received two complaints against Phoenix-based Banner Health ACE about alleged violations. First a person alleged that she requested medical records in December 2017 and didn't receive them until May 2018. In the second complaint, the person asked for an electronic copy of his records in September 2019, and they weren't sent until February 2020. Banner didn't admit liability in the settlement.

Endnotes

- CMS, "2A261-Positron Emission Tomography (PET) for Initial Treatment Strategy in Oncologic Conditions: Medical Necessity and Documentation Requirements," proposed RAC topic, January 5, 2021, http://go.cms.gov/3oMJeVb.
- CMS, "0200-Air Ambulance: Medical Necessity and Documentation Requirements," proposed RAC topic, January 5, 2021, http://go.cms.gov/35Jx1co.
- CMS, "0201-Hospice Continuous Home Care: Medical Necessity and Documentation Requirements," proposed RAC topic, January 5, 2021, http://go.cms.gov/3oRUyiY.
- CMS, "0202- Ambulance Transport Subject to SNF Consolidated Billing," proposed RAC topic, January 5, 2021, http://go.cms.gov/2LOMEbw.
- Department of Justice, U.S. Attorney's Office for the Eastern District of Texas, "Texas Company Agrees to Reimburse Medicare for Improper Billing Related to Neurostimulators," news release, January 12, 2021, http://bit.ly/38IShkt.
- HHS, "Banner Health Resolution Agreement and Corrective Action Plan," resolution agreement, January 6, 2021, https://bit.ly/3oDYSSS.