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

Contents

Five Hospitals Settle Case Over Exclusions; How Medicaid MCOs Overlooked an Excluded Provider

Five hospitals have agreed to pay $250,464 in the same settlement with the HHS Office of Inspector General (OIG) over people they employed who were excluded from federal health care programs and/or Medicaid. The hospitals are Monroe Hospital, North Vista Hospital, Paradise Valley Hospital, San Dimas Community Hospital and St. Mary's Regional Medical Center, according to the civil money penalty settlement. The settlements stem from the hospitals' self-disclosures to OIG and participation in its Self-Disclosure Protocol.

The case underscores the importance of screening employees for exclusions from Medicaid as well as federal health care programs. "States impose Medicaid exclusions that just apply to their states," and 42 states now have their own Medicaid exclusion databases, said Michael Rosen, founder of ProviderTrust. Medicaid managed care organizations (MCOs) also are obliged to check for exclusions from federal and state health care programs, said Robyn Hoffmann, senior manager of compliance and credentialing at BerryDunn in Connecticut. And some health care organizations run employees through the Medicare opt-out list and National Practitioner Data Bank. "You have to think more broadly and continually monitor these types of exclusion sites and registries because something can change in an instant," said Christa Bernacchia, senior manager and director of credentialing services for Berry Dunn.

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Multiple Auditors Hit Facet-Joint Injections; Some Apply Requirements 'That Don't Exist'

Some pain management providers feel they must resort to putting patients back on opioids because their Medicare claims for facet-joint interventions are being denied, even though they satisfy the requirements of their local coverage determination (LCD), according to an attorney. Auditors allegedly are holding providers to requirements for the procedures—which treat chronic neck and back pain—that aren't in the LCD and are applying the coverage criteria inconsistently. If that's the case, it doesn't bode well for providers, because facet-joint interventions are coming under scrutiny across the country.

"The providers are so frustrated," said Richelle Marting, an attorney and certified coder in Olathe, Kansas. "Pain doctors are wanting to get patients off opioids, and we have patients who could barely walk getting these injections and now can play golf, and Medicare doesn't want to pay for it."

Providers may want to pay attention to the possibility of audits coming their way because facet-joint interventions are being audited by Medicare's supplemental medical review contractor (SMRC)[1] and Medicare administrative contractors (MACs) in targeted probe and educate (TPE). Another shoe will drop soon because CMS proposed to add facet-joint interventions to the hospital outpatient prior authorization process in 2023, and they already have been the subject of several HHS Office of Inspector General (OIG) audits.[2]

continued

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Marting has had a front-row seat for MAC and SMRC audits, and they worry her. "This is the first topic I have seen in a while with such substantively different interpretations with substantively similar documentation," she remarked. The auditors for the MAC (WPS Government Health Administrators) and the SMRC have been "denying coverage based on wildly inconsistent policy interpretations and inferring language and imposing requirements that don't exist in the plain language of the coverage policy."

The audits come on the heels of a 2021 OIG audit of payment for facet-joint injections by Noridian Healthcare Solutions LLC, another MAC.[3] According to the OIG report, facet-joint injections involve an anesthetic to diagnose or treat neck and back pain. Medicare Part B covers facet-joint injections based on the narrative descriptions of Healthcare Common Procedure Coding System codes, including the number of levels in which the injections were administered. Additional requirements are spelled out in Noridian's LCD.

OIG audited Noridian's payments for a simple random sample of 100 beneficiary days of facet-joint injections with dates of service from Jan. 1, 2018, through May 31, 2019. The findings: 51 beneficiary days didn't comply with one or more of the requirements. As a result, Noridian overpaid physicians $12,546, which OIG extrapolated to about $4.2 million during the audit period.

Here are some of the causes of the overpayments:

- General requirements were not met for the procedures (e.g., the physician's procedure notes didn't have pre- and post-procedure pain assessments).
- Facet-joint injections didn't satisfy requirements for spinal levels (e.g., a physician performed unilateral injections but billed for bilateral injections).
- Facet-joint injections didn't comply with Noridian requirements for indications of beneficiary pain levels (e.g., moderate to severe pain for at least three months with functional impairment and insufficient response to conservative care, such as physical therapy).
- Injections didn't comply with the LCD for therapeutic injections (e.g., they can only be repeated if there is significant pain relief—more than 50%—for three months).

Notwithstanding OIG's findings, Marting is concerned about the way audits are playing out in Kansas and Missouri, and the potential for the same thing to happen elsewhere. The auditors aren't consistent from audit to audit. "The result is that Medicare beneficiaries even within the same state are not receiving consistent coverage of their Medicare benefits and providers are suffering the financial consequences," she said.

All Medicare auditors are operating from LCDs that have pretty much the same language in terms of pivotal coverage requirements, Marting said, referring to this section: "Facet Joint Interventions are considered medically reasonable and necessary for the diagnosis and treatment of chronic pain in patients who meet **ALL** the following criteria:

1. Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale*
2. Pain present for minimum of 3 months with documented failure to respond to noninvasive conservative management (as tolerated)
3. Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by facet joint synovial cyst)
4. There is no non-facet pathology per clinical assessment or radiology studies that could explain the source of the patient's pain, including but not limited to fracture, tumor, infection, or significant deformity.

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*Pain assessment must be done at baseline, after diagnostic procedure and at each follow-up using the **same** pain or disability scale for each assessment."[4]

Audit Findings for Two Providers Diverged

Some auditors have nitpicked the first two lines about the documented pain levels, Marting said. In many cases, it's clear the patient has had moderate to severe pain for a long time, including on the date of the injection, but "if you can't show for three consecutive months preceding an injection they were at least five out of 10, I am seeing denials," she said. And if the patients have any symptoms in their hip or leg, the claims are being denied because auditors are saying the pain is not axial, which refers to the back. That's bogus, she asserts, because the LCD requirement "is not exclusively axial. It is predominantly axial."

Auditors also have denied claims if providers haven't documented a disability scale at every procedure, which Marting said isn't required. Providers are very good at documenting the pain scale, which can be as simple as asking patients to rate their pain from one to 10, but a full-blown disability scale typically isn't documented every time. "I have reviewers telling me a full disability scale has to be performed at each procedure and follow-up" or they will deny the claim, but that's not what the LCD says. "The LCD says *pain assessment* must be done after each procedure, but the policy does not have language that extends that requirement to disability scales," she noted.

Here's an example of the divergent results: One provider had all claims approved after a SMRC review. The provider had documented moderate to severe pain scales and subsequent improvement but hadn't included disability scales for each injection in a series. In contrast, another provider's claims were all denied by the MAC during TPE even though they fully documented pain scales as well as disability scales at baseline. There's no rhyme or reason for the different findings, Marting said.

"The wildly different outcomes and interpretations are because there is so much ambiguity and reviewers are inserting their own interpretation into the language," she contended.

To prepare for potential facet-injection audits, Marting recommends providers review the coverage policy and compare it against their documentation to ensure they're meeting criteria to the letter. "Before responding to a record request, ensure you are supplying all documentation that would demonstrate each of the criteria have been met. I usually take the time to prepare a cover sheet with a checklist of those requirements and identify exactly where the record supports each one. If, despite that, you still receive denials, appeal," she said. "And if your appeals are successful, it can be helpful to share those results with the initial reviewer particularly if you are part of a TPE or similar ongoing medical review."

Also, it's important for providers to inform their medical societies and professional associations when reviewers may be stretching the language of a coverage policy.

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Endnotes

1. Noridian Healthcare Solutions, "01-304 Facet Joint Injections Notification of Medical Review," last updated February 16, 2022, https://bit.ly/3fovbFE.
2. U.S. Centers for Medicare & Medicaid Services, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating, 87 Fed. Reg. 44502 (July 26, 2022), https://bit.ly/3BPVPPn.
3. Amy J. Frontz, *Noridian Healthcare Solutions LLC, Made Improper Medicare Payments of $4 Million to Physicians in Jurisdiction E for Spinal Facet-Joint Injections*, A-09-20-03010, Office of Inspector General, U.S. Department of Health and Human Services, February 2021, https://bit.ly/3DZAghZ.
4. Centers for Medicare & Medicaid Services, "Facet Joint Interventions for Pain Management," Proposed LCD, DL38841, retired, updated on February 25, 2022, https://bit.ly/3CeOaeJ.

FCA Lawsuit Over Patient Gift Cards Survives Motion to Dismiss

A False Claims Act (FCA) lawsuit alleging that certain patient gift cards were kickbacks survived a motion to dismiss Sept. 26.

The lawsuit was filed by a whistleblower, 72-year-old retired Florida physician Niles Rosen, against Exact Sciences Corp. (ESC) and its subsidiary, Exact Sciences Laboratories LLC (ESL), which administers Cologuard, a colon cancer screening test.[1] Rosen alleges that a $75 Visa reward card offered to him and other Medicare beneficiaries as part of Exact Sciences' Patient Compliance Program was unlawful remuneration intended to induce their use of Cologuard. In 2018, "Medicare paid defendants more than $160 million for Cologuard tests while defendants were offering unlawful cash equivalent inducements directly to government beneficiaries," according to the complaint. The subsequent claims submitted to Medicare by Exact Sciences violated the FCA because they were "tainted," the complaint alleges.

"It was a straight-up kickback," contends attorney Marlan Wilbanks, who represents the whistleblower. "You can't offer cash or cash equivalents to anyone to induce them to use a government service."

In its motion to dismiss the complaint, Exact Sciences refuted the allegations and asserted, among other things, that the arrangement qualifies for the preventive care safe harbor to the Anti-Kickback Statute (AKS) and that the complaint fails for many reasons, including the whistleblower's inability to "adequately allege that Exact Sciences knowingly and willfully violated the law."[2] For now, though, the case is proceeding because a federal judge denied the motion to dismiss.[3]

The Department of Justice declined to intervene in the complaint.

Whistleblower: Visa Card Changed His Mind

The seeds of the complaint were planted in 2017 when a gastroenterologist prescribed Cologuard for Rosen, who is also the former medical director of the CMS National Correct Coding Initiative. Rosen, who was asymptomatic, received the test from Exact Sciences, but decided not to take it. About three months later, Exact Sciences allegedly sent Rosen a letter with the Visa reward card offer. According to the complaint, the letter stated that "Because your health is important, Exact Sciences Laboratories will send you a $75 Visa reward card for completing your Cologuard Test! In order to qualify for this special offer, your sample must be received at Exact Science Laboratories by Thursday, March 22, 2018." Rosen subsequently decided to take the Cologuard test because he wanted the reward card, the complaint alleged. After he submitted the specimen to the lab, Rosen got the reward card and used it to buy items unrelated to health care.

Rosen later visited the MyMedicare.gov website to confirm that ESL billed Medicare for his test and determined the defendants were paid $498.69. "Defendant ESL's claim to Medicare for Relator's Cologuard test is a representative sample of the thousands of such false claims submitted to government payers for the Cologuard lab test," the complaint alleged. Under the AKS, it's unlawful to knowingly pay remuneration to the beneficiary of a government program to induce them to complete Cologuard tests and the gift cards, which are cash equivalents, constitute unlawful remuneration, the complaint alleged. The whistleblower contends he wouldn't have picked Exact Sciences for the test or had the test without the $75 "inducement."

Do Gift Cards Qualify for a Safe Harbor?

Cologuard is indicated to screen adults over 50 years old at average risk for colon cancer. It's designed to detect occult hemoglobin in human stool and is used for the qualitative detection of colorectal neoplasia associated DNA markers, according to the complaint. Although a positive result should be followed by a colonoscopy, results in people over the age of 75 "should be interpreted with caution because the rate of false positives increase with age," according to the complaint. A false positive could lead to a medically unnecessary colonoscopy, the complaint contends, and "Medicare pays for those unnecessary colonoscopies and other medical expenses caused by the Cologuard false positive test results."

The complaint alleged that the reward cards don't quality for any safe harbors, which confer AKS immunity. That includes the patient engagement and support safe harbor recently added by the HHS Office of Inspector General (OIG). Labs are excluded from the safe harbor, and cash and cash equivalents, such as Visa reward cards, are not allowed, the complaint contends.

Exact Sciences Disputes the Allegations

In its motion to dismiss, Exact Sciences pushed back on the whistleblower's allegations. For one thing, it noted that encouraging a patient to have a medical service that was already ordered by a provider isn't an inducement under the AKS.

The defendants also argued that the whistleblower failed to "establish a predicate violation of the AKS," which would require showing Exact Sciences "(1) knowingly and willfully; (2) paid something of value; (3) to induce the purchase or ordering of services; (4) paid for by a Federal health care program." The complaint doesn't sufficiently allege inducement "because it contains no allegations about how the Patient Compliance Program influenced the actions of Relator's physician, who ordered the Cologuard test" or "clouded the independent judgment of the physician who determined the Relator should be screened for colorectal cancer, affected the physician's intent with regard to the selection of the Cologuard test, or influenced the physician to prescribe Cologuard to Relator," the motion argued.

The AKS allegations also fail because the whistleblower "does not and cannot allege that Exact Sciences ever knowingly or willfully violated the law by implementing its Patient Compliance Program," according to its motion. On the contrary, Exact Sciences said it had a good-faith belief that its Patient Compliance Program qualified for the preventive care

safe harbor, which permits the payment of incentives to federal health care beneficiaries for preventive care.

But the U.S. District Court for the Middle District of Florida denied the motion to dismiss. For one thing, at this stage, the whistleblower's allegations "are sufficient to plausibly allege Exact Sciences acted with scienter," although that determination will have to be made by a jury or at summary judgment because it's a factual one, the decision said. Scienter refers to knowledge that a false claim was submitted, which includes reckless disregard and deliberate ignorance.

Cash Equivalents Are Not Permissible Incentives

Also, "construing the allegations contained in the First Amended Complaint in the light most favorable to the Relator, the Court finds the First Amended Complaint adequately and sufficiently alleges Relator was induced to purchase, order, or arrange for the purchasing or ordering of Cologuard testing services," Judge Mary Scriven wrote. "A patient's submission of a stool sample, via the Cologuard test kit, to Exact Sciences could be found to fall within the ordinary meaning of 'order' because by returning a Cologuard test kit, a patient is making a request to Exact Sciences to supply lab testing services to the submitted specimen. Similarly, Relator seeks to prove that a patient purchases, via Medicare benefits, lab testing from Exact Sciences when the patient submits a Cologuard test kit for testing. In this regard, Relator alleges that Exact Sciences seeks reimbursement for Cologuard Tests only after the kits are returned to Exact Sciences. As such, the Court finds that at this early stage in the litigation, Relator has adequately pled the inducement element under 42 U.S.C. § 1320a-7b(b)(2)(A-B)."

The judge also noted that OIG excluded cash equivalents from permissible incentives under the preventive care safe harbor. Although Exact Sciences' letter to the whistleblower said the Visa reward card couldn't be used to get cash, it also states the card can be used anywhere a Visa debit card is accepted. "Therefore, the Court finds Relator's allegations are sufficient at this early stage in the litigation to plausibly plead that the $75 Visa reward card constitutes remuneration," according to the decision.

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Endnotes

1. Complaint, Rosen v. Exact Scis. Corp., 8:19-cv-1526-MSS-AAS (M.D. Fla. Mar. 7, 2022), https://bit.ly/3CmKiZe.
2. Motion to dismiss, Rosen v. Exact Scis. Corp., 8:19-cv-1526-MSS-AAS (M.D. Fla. Mar. 7, 2022), https://bit.ly/3ULQC3P.
3. Denial of motion to dismiss, Rosen v. Exact Scis. Corp., 8:19-cv-1526-MSS-AAS (M.D. Fla. Mar. 7, 2022), https://bit.ly/3RygRba.

Hospitals Win Another 340B Decision, but Dollars May Not Come Fast

In another win for hospitals on the 340B drug front, on Sept. 28 a federal court threw out CMS's 2022 payment rate in the wake of the Supreme Court's June 15 decision that massive cuts to 340B drug payments are "unlawful."[1]

"HHS should not be allowed to continue its unlawful 340B reimbursements for the remainder of the year just because it promises to fix the problem later," the U.S. District Court for the District of Columbia ruled.[2]

The 2022 payment rate was lower than average sales price (ASP) plus 6%, which is what CMS paid for 340B drugs before it slashed reimbursement to ASP minus 22.5% in the 2018 and 2019 Outpatient Prospective Payment System (OPPS) rules, setting in motion a four-year court battle. But the new decision only puts part of the 340B debate to rest. The court still must rule on how CMS will make hospitals whole for 340B payment cuts from 2018 through the date of the decision. Meanwhile, CMS in the 2023 proposed OPPS rule said it will pay ASP plus 6% moving forward consistent with the Supreme Court decision.

Before hospitals start celebrating, however, they should keep in mind that the dollars probably won't flow anytime soon. "An important note on [the Sept. 28] decision is it doesn't guarantee the government will immediately restore the payment," said attorney Emily Cook, with McDermott Will & Emery LLP in Los Angeles. "We have to see whether the government opts to appeal [the Sept. 28] decision or whether they move forward with restoring the payment cuts. When I was with HHS, they would note the Medicare payment system is held together with very old Scotch tape, and changing a payment provision is not something that can be done overnight."

Because the court decision is specific to the last few months of 2022, hospitals should think how their claims are affected by modifier JG, said attorney Andrew Ruskin, with K&L Gates in Washington, D.C. If hospitals have doubts about CMS restoring payments consistent with the court's direction, they may want to consider whether to stop reporting the JG modifier for drugs and biologicals acquired with the 340B drug discount, which triggers the payment cut, he said. Cook noted, however, that the proposed 2023 OPPS rule would both restore the payment amount and continue requiring the use of the modifier.

Hospitals went to court shortly after CMS implemented the 340B payment cuts. The American Hospital Association, the Association of American Medical Colleges, America's Essential Hospitals and several nonprofit hospitals challenged the cut in federal district court and won in 2018, but the victory was reversed by the

U.S. Court of Appeals for the District of Columbia in 2020. The hospitals then took their case to the Supreme Court.

'The Money has to Come from Somewhere'

In its opinion, written by Associate Justice Brett Kavanaugh, the Supreme Court explained that HHS has two choices for setting reimbursement rates under the statute: Either it bases reimbursement rates on hospitals' average drug acquisition costs after doing a survey and then may vary reimbursement for different groups of hospitals or, in the absence of a survey, HHS is required to base drug reimbursement on the ASP charged by manufacturers, without varying reimbursement for different groups of hospitals. "For 2018 and 2019, HHS did not conduct a survey of hospitals' acquisition costs for outpatient prescription drugs. But HHS nonetheless substantially reduced the reimbursement rates for one group of hospitals—Section 340B hospitals, which generally serve low-income or rural communities. For those 340B hospitals, this case has immense economic consequences, about $1.6 billion annually," the opinion stated. "The question is whether the statute affords HHS discretion to vary the reimbursement rates for that one group of hospitals when, as here, HHS has not conducted the required survey of hospitals' acquisition costs. The answer is no." Although the high court sided with hospitals, the decision sent the case back to the lower courts "for further proceedings."

That's what the district court has done for what's left of 2022. Its decision dismissed CMS's argument that budget neutrality is a reason to reimburse 340B drugs below ASP plus 6%. "The Court is troubled that HHS appears to rely on budget neutrality as a license 'to continue violating the law for the remainder of the year and make up for it later,'" the court said.

Notwithstanding the court suggesting that budget neutrality is not a requirement for restoring 340B payment cuts, "the government may take a different view that budget neutrality doesn't matter," Cook said. "That money has to come from somewhere. It may be that HHS is willing to restore payment cuts without an offset given the fact the year is almost over, but it is possible they will take a position otherwise." As for 2018 through 2021, the payments will "have to be handled" as retroactive adjustments.

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Endnotes

1. American Hospital Association et al. v. Becerra, Secretary of Health and Human Services, et. al, No. 20-1114, U.S. (2022), https://bit.ly/3E1VsE3.
2. AHA, et al. v. Becerra, et al. No. 18-2084 (D.C.D.C. Sept. 28, 2022), https://bit.ly/3riuMqU.

Five Hospitals Settle Exclusion Case

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Here's a summary of OIG's allegations in the civil monetary penalty settlement, which was obtained through the Freedom of Information Act:

- Monroe Hospital employed Danae Fleener for the provision of items or services from Aug. 20, 2020, to Nov. 5, 2020. Fleener is listed as nurse/nurse's aide in the OIG's List of Excluded Individuals and Entities (LEIE). "OIG contends that Monroe knew or should have known that Fleener was excluded from participation in all Federal health care programs and that no Federal health care program payments could be made for items or services furnished by Fleener," the settlement states.
- An excluded physician was a member of St. Mary's medical staff and ordered items or services from July 18, 2018, to June 9, 2021, that California Medicaid, known as Medi-Cal, may pay for. "The OIG contends that St. Mary's knew or should have known that [the physician] was excluded from participation in Medi-Cal and that no Medi-Cal payments could be made for items or services furnished, ordered, or prescribed by" the physician, who wasn't identified.
- OIG alleged that from Aug. 1, 2017, to Aug. 23, 2021, North Vista employed an excluded person for the provision of items or services for which Medi-Cal may have paid. OIG contends that North Vista knew or should have known the person was excluded from Medi-Cal and no payments could be made for items or services provided by them.
- OIG alleged Paradise Valley employed Nina Rivers from Oct. 8, 2019, to April 12, 2021, for the provision of items or services for which payment may be made under Medi-Cal. "The OIG contends that Paradise Valley knew or should have known that Rivers was excluded from participation in Medi-Cal and that no Medi-Cal payments could be made for items or services furnished by Rivers," the settlement said. She is not on the LEIE.
- From April 26, 2017, to Dec. 7, 2017, and from Feb. 4, 2018, to March 3, 2021, OIG alleged San Dimas employed an excluded person for furnishing items or services for which payment may be made by a federal health care program, and that the hospital knew or should have known this person was excluded and no federal health care payments could be made for items or services they provided.

The hospitals are part of the same settlement, but it's unclear how they're related to each other or exactly where they're located. Their attorney didn't respond to *RMC*'s requests for more information and OIG didn't elaborate by press time. The hospitals didn't admit liability in the settlement.

Settlements over excluded employees continue to appear regularly on OIG's website, an indication they still fall through the cracks for various reasons. Timing may be one of them. "There has been some question at times over whether the screening of the LEIE needs to be conducted on a monthly or quarterly basis," Hoffmann said. "I feel monthly is the most appropriate and rigorous approach." If organizations wait too long to run employees through the LEIE, they may be billing directly or indirectly for the services of an employee (clinical or administrative) who has been on the payroll for months.

Excluded Provider Got by Medicaid MCOs

The Medicaid piece is very important, with both fee-for-service and managed care in play. Hoffmann shared a cautionary tale about exclusion screening from her days working as a consultant to a state Medicaid agency on the MCO side of the house. States are required to ensure MCOs, prepaid inpatient health plans and prepaid ambulatory health plans don't employ or contract with excluded providers[1] and must periodically screen and revalidate all network providers.[2]

At some point, Hoffmann was notified by the Medicaid fee-for-service program that a health care provider who had been excluded from participation in federal and state health programs was now eligible to seek Medicaid enrollment because his federal exclusion period had ended. "I looked at the provider's name and enrollment panels for the Medicaid-participating managed care organizations and was shocked to see this provider listed as an active provider in their networks," she said. It turned out the provider had his license suspended in a far-away state, then moved and was granted a license in the new state. When he applied to the Medicaid MCOs in his home state, the provider was approved based on the state license. But that doesn't make the exclusion disappear. If it's an exclusion from federal health care programs (e.g., for a licensure suspension), OIG requires the excluded person or entity to apply for reinstatement, and the same is true in some states. Until then, the exclusion stands, and Hoffmann said the MCOs were supposed to check the LEIE monthly. "That was a contractual requirement," she noted. "We are thinking, if they're checking the LEIE monthly, how did this happen?"

Hoffmann said the clinician had an unusual first name, and one of the MCOs reversed the first and last names when checking the LEIE, which is why there was no match. "So this provider slipped through the cracks for them," she said. "They were quite shocked and very open to discussing it. For them it was a learning experience." The MCO screened providers when they enrolled and with every LEIE monthly exclusion update, but it was not running names through the full LEIE every month. That's a big gap "because the monthly supplement only shows the names of newly added individuals," Hoffmann explained.

To continue in the MCOs, the provider had to seek reinstatement to Medicaid. In this case, the provider thought that because his exclusion had expired and he got a license in another state, he was good to go.

"In a mobile society where providers cross jurisdictions and put out their shingle, make sure there's a lookback on the full LEIE" and on the state Medicaid exclusion list in all states and territories where they have worked, Hoffmann advised. On the MCOs' credentialing and privileging side, "identify any disciplinary actions

CMS Transmittals and *Federal Register* Regulations, September 23-29

Transmittals

Pub. 100-04, Medicare Claims Processing

- October Quarterly Update for 2022 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule, Trans. 11619 (September 29, 2022)
- Instructions for Downloading the Medicare ZIP Code File for January 2023, Trans. 11618 (September 29, 2022)
- Instructions for Retrieving the January 2023 Home Infusion Therapy (HIT) Services Payment Rates Through the CMS Mainframe Telecommunications System, Trans. 11617 (September 29, 2022)

Pub. 100-20, One-Time Notification

- Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter As Certain Colorectal Cancer Screening Tests, Trans. 11622 (September 29, 2022)

Pub. 100-09, Medicare Contractor Beneficiary and Provider Communications

- The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Years (FYs) 2019 and 2020 for Inpatient Prospective Payment System (IPPS) Hospitals with Updated Data for Hospitals in the 9th Circuit, Trans. 11616 (September 29, 2022)

Federal Register

Interim final rule; reopening of public comment period

- Medicaid Program; Temporary Increase in Federal Medical Assistance Percentage (FMAP) in Response to the COVID-19 Public Health Emergency (PHE); Reopening of Public Comment Period, 87 Fed. Reg. 58456 (September 27, 2022)

CFR correction

- Standards for the Electronic Health Record Technology Incentive Program, 87 Fed. Reg. 59027 (September 29, 2022)

taken by the relevant licensure agency in the states and territories where they have worked."

State Medicaid exclusion databases can be very helpful and may include excluded parties from other states, but they're all over the map, Rosen noted. Some states, like Texas, mimic OIG's in allowing users to run names through an automated database and require excluded people and entities to apply for reinstatement when the exclusion ends. Texas also indicates when the person or entity has been reinstated.

"Pennsylvania is the most complicated," Rosen said. The website states when an exclusion ends "but won't tell you when the person applied for reinstatement so you can't rely on the end date having passed. You have to call." The states vary on the mechanics and the fact is, "sometimes we see that a person is excluded but still enrolled in Medicaid," Rosen said.

Some Organizations Check Opt-Out Website

Exclusion screening, which is the purview of compliance professionals, overlaps with "what's tracked and maintained through a medical staff office," Bernacchia said. Exclusion screening tends to focus on the LEIE and the System for Award Management (SAM.gov), a federal government debarment and sanctioning database, while the medical staff office oversees the provider credentialing and privileging space. "There is much more integration now than there has been in the past," she said. "It's up to every organization to examine their compliance program and their medical staff privileging and enrollment systems. It's about quality patient care and minimizing risk."

To that end, more organizations are running providers through the Medicare opt-out website.[3] When physicians opt out of Medicare, they can still treat beneficiaries, but Medicare won't pay a dime for the services. Opting out means physicians choose not to be enrolled for a two-year period, with automatic renewals unless the physician wants to enroll. Beneficiaries pay out of pocket, and physicians are free to charge as much as they want under a private agreement. There's no picking and choosing once physicians opt out. "Under the statute, the physician/practitioner cannot choose to opt-out of Medicare for some Medicare beneficiaries but not others; or for some services but not others," section 40.5 of the *Medicare Benefit Policy Manual* states.[4]

"If providers opt out of Medicare you wouldn't know that unless you run providers through the Medicare opt-out website," Bernacchia said. "You can query directly for any provider." It's a particular challenge when organizations hire part-time or moonlighting employees and find out after the fact their services can't be billed to Medicare.

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Endnotes

1. 42 C.F.R. § 438.214(d), https://bit.ly/3SKg47Z.
2. 42 C.F.R. § 438.602, https://bit.ly/3UPWAQY.
3. Medicare.gov, "Opt out search results," search engine, last accessed September 29, 2022, https://bit.ly/3y1HrT7.
4. Centers for Medicare & Medicaid Services, "Chapter 15 – Covered Medical and Other Health Services," § 40.5, Medicare Benefit Policy Manual, Pub. 100-02, revised July 12, 2019, https://go.cms.gov/2VSe3Mn.

NEWS BRIEFS

◆ **In a Medicare dialysis services provider audit, the HHS Office of Inspector General (OIG) said Nashville, Tennessee-based Dialysis Clinic Inc., the largest nonprofit provider of dialysis in the country, received at least $14 million in unallowable Medicare payments during 2018.**[1] OIG reviewed a random sample of 100 claims and concluded that "DCI claimed reimbursement for dialysis services that did not comply with Medicare requirements for 70" of them. Among the problems, comprehensive assessments or plans of care failed to meet Medicare requirements, dialysis wasn't completed and dialysis treatments weren't documented, OIG contended. The net overpayment on the sampled claims was $21,669, which was extrapolated. In a written response, Bradley, a law firm representing DCI, said that the OIG's report "applies inappropriate payment standards and reflects a misunderstanding of the clinical and financial realities of the dialysis industry, particularly those facing nonprofit companies such as DCI."

◆ **Physician Christopher B. Bjarke of Renton, Washington, pleaded guilty to conspiring to accept kickbacks in connection with a genetic testing scam that targeted Medicare beneficiaries**, the U.S. Attorney's Office for the Eastern District of Washington said Sept. 28.[2] According to his plea agreement and court proceedings, Bjarke placed orders for genetic testing for Medicare beneficiaries he wasn't treating and with whom he had no physician-patient relationship, the U.S. attorney's office said. The physician's "sole contact with these patients was when he was connected with the beneficiaries for a telephone call for a few minutes through telemarketers. After Dr. Bjarke had ordered the tests, the laboratories then billed Medicare for the test, while another company billed Medicare for a purported 'telemedicine' visit, sometimes for as much as tens of thousands of dollars," the U.S. attorney's office said. "Dr. Bjarke's orders were responsible for more than $18.6 million paid by Medicare."

Endnotes

1. Amy J. Frontz, *Medicare Dialysis Services Provider Compliance Audit: Dialysis Clinic, Inc.*, A-05-20-00010, Office of Inspector General U.S. Department of Health and Human Services, September 2022, https://bit.ly/3USJumc.
2. U.S. Department of Justice, U.S. Attorney's Office for the Eastern District of Washington, "Renton Doctor Pleads Guilty to Conspiring to Accept Kickbacks in Connection with Fraudulent Genetic Testing Scheme," news release, September 28, 2022, https://bit.ly/3dYUWw0.