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CMS Exclusions Will Join OIG's on LEIE; Medicaid Program-Integrity Pillars Are Unveiled

When CMS kicks individuals and entities out of federal healthcare programs, their names will appear on the HHS Office of Inspector General's (OIG) exclusion list, a top CMS official said. That solves the mystery of how healthcare organizations will screen for CMS exclusions now that it has exclusion power alongside OIG.

HHS formally delegated permissive exclusion authority to CMS in the Oct. 14 *Federal Register* while preserving OIG's exclusion powers.[1] Until now, exclusions were exclusively OIG's domain.

CMS will post its exclusions from federal healthcare programs on OIG's List of Excluded Individuals and Entities (LEIE), said CMS Deputy Administrator Kim Brandt.

"It's not like you have to go to a whole separate place," Brandt said Oct. 28 at HCCA's Healthcare Enforcement Compliance Conference. "We are working closely with OIG on these."

With CMS joining OIG in exclusions, their number is expected to rise. For its part, OIG shed light on the shared exclusion authority in FAQs posted Oct. 28[2] (see box, p. 4).[3]

All Federal Programs vs. Medicare

"OIG will continue to be the lead on exclusions, particularly mandatory exclusions. However, CMS now has permissive exclusion authority, which allows us to take actions when we don't just want to kick them out of Medicare," Brandt said. Exclusions block providers from receiving payment from all federal healthcare programs, directly or indirectly. Billing revocations, exclusively CMS territory, lock providers out of Medicare.

CMS already is exercising its new exclusion muscles and has issued 122 notices of intent to exclude, Brandt said. For example, "just last week we served our first three exclusion notices" to adult daycare providers in the New York City area, she said.

The exclusions were based on billing for nonemergency transports. "One facility didn't even have a wheelchair access entrance let alone anyone in a wheelchair getting services at daycare," she noted. "That's where the exclusion authority has become a valuable additional tool for us."

CMS's new authority is limited to permissive exclusions, such as misdemeanor convictions related to health fraud; provision of unnecessary or substandard services; submission of false or fraudulent claims to a federal healthcare program; and misdemeanor convictions for the unlawful manufacture, distribution, prescription or dispensing of controlled substances. Exclusions are mandatory for Medicare or Medicaid fraud convictions and patient abuse or neglect, among other things.

'Collateral Consequences'

The delegation allows CMS to "get rid of individuals" who might not be direct billers of Medicare and other federal healthcare programs, said attorney Judy Waltz, with Foley & Lardner LLP, at the HCCA conference. Although exclusions are a killer, revocations of Medicare billing privileges also hit hard and can have "collateral consequences," Waltz said. They include:

- Potential Medicare overpayment depending on effective date. "I'm working with a person now who

has a Medicaid termination based on a Medicare revocation and is looking at an effective date back to the date of Medicaid revocation," she said.

- Loss of hospital or other privileges if facility bylaws require providers to be in good standing with Medicare.
- Commercial payers "often mirror the actions of" Medicare, meaning they also will revoke the provider's credentials after CMS revokes their privileges.
- Reporting to the National Provider Data Bank (NPBD), although now organizations can directly look up credentials on the CMS website.
- Medicare overpayments for services provided by a revoked person may be asserted against the revoked person, facilities where they performed procedures and the group practice. In some regions, CMS has applied the revocation of a clinician's billing privileges to the Part A facility fee, Waltz said.

WISeR, Other Aspects of Crushing Fraud Agenda

Brandt spoke about other parts of the Trump administration's crushing fraud agenda.

For one thing, in January it implemented the Wasteful and Inappropriate Service Reduction (WISeR) model, embedding more prior authorization into original, fee-for-service Medicare (see box, p. 3).[4] The goal is to "do faster, more efficient prior authorization" of "potentially wasteful medical spending" on low-value services, which Brandt said accounts for about 25% of total Medicare spending.

Technology vendors are performing prior authorization on 13 procedure categories in six states (New Jersey, Ohio, Oklahoma, Texas, Arizona and Washington) based on compliance with local and national coverage determinations.

The lesson of WISeR so far: Technology can help CMS with program integrity oversight, reviewing vast amounts of documentation and evaluating whether services are appropriate, Brandt said. "But we need continuous oversight." Even with the use of "superintelligence"—the Trump administration's new term for AI—"we always ensure there are clinicians to validate it. You never want to rely 100% on machine learning because they don't always get it right but if you have both, hopefully you have better results."

Whether WISeR strengthens prior authorization is TBD. "We will see what happens with it," Brandt said.

Meanwhile, CMS on Oct. 26 set forth its program-integrity pillars for Medicaid and the Children's Health Insurance Program. They are claims editing and data analytics; provider enrollment; targeted reviews and audits; managed care oversight; investigations and law enforcement referrals; and robust administrative action.[5]

At the same time, CMS put out a request for information about a new path forward with a program-integrity contractor.[6] CMS said it may take a greater role in "lead development, prioritization and direction of investigations."

CMS also is moving ahead with ClaimsCore, its modernization of the claims processing system. The goal of ClaimsCore is to pay claims in real time. CMS awarded contracts in May to vendors that will help it replace its legacy system with one unified cloud-based system. "This is a win-win," Brandt said. She's also trying to figure out how to build the tools in a way that would "give you more real-time data to help with your compliance efforts."

Moratoria and Duplicate Enrollments

In other areas, CMS is tamping down duplicate enrollments: beneficiaries who enrolled in two different state Medicaid programs or in both Medicaid and a healthcare exchange under the Affordable Care Act (ACA). "We had 1.2 million people enrolled in multiple states and 1.6 million potentially enrolled in Medicaid and ACA plans," Brandt said. "We now have cleaned up those books to make sure people have enrolled only once."

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CMS also temporarily shut Medicare's door to various provider and supplier types. A six-month national enrollment moratorium was in place until August for certain durable medical equipment (DME) suppliers. Also, as of Oct. 15, CMS requires probationary prior authorization for some DME billed by newly enrolled suppliers and suppliers going through certain changes of ownership.

And there's a moratorium on enrollment of new home health agencies and hospices. Brandt added that 1,000 hospices have been dropped from Medicare.

'We Haven't Heard Complaints'

She's not worried the moves will put services out of reach. "We haven't heard complaints people aren't getting the services they need," she noted. "We are getting bad actors out."

Part A regulatory changes in the program integrity arena have also either taken effect or will soon. For example, CMS now requires Part A providers to report ownership and control interests under enrollment regulations (42 C.F.R. § § 424.516, 489.53). This is designed to identify "bad actors" who "hide behind complex or shifting ownership structures," Brandt said. "Ownership data helps CMS catch excluded or sanctioned individuals attempting to re-enter the program under a new entity name."

Also, CMS in the proposed 2027 outpatient prospective payment system regulation requires hospitals to obtain separate national provider identifiers for every off-campus provider-based department (PBD). They also must submit attestations of compliance with PBD requirements or Medicare won't pay them for services provided in provider-based space. The final version of the rule is expected any moment.

Contact Brandt at kimberly.brandt@cms.hhs.gov and Waltz at jwaltz@foley.com. ✧

Endnotes

1 Statement of Delegation of Authority, 91 Fed. Reg. 65,219 (Oct. 14, 2026), https://bit.ly/4s8mLDE.

2 U.S. Department of Health and Human Services, Office of Inspector General, "Exclusions FAQs," last updated October 27, 2026, https://bit.ly/4zzuPQV.

3 Nina Youngstrom, "OIG FAQs on Exclusions in Wake of HHS Delegation of Authority to CMS," *Report on Medicare Compliance* 35, no. 39 (November 2, 2026).

4 Nina Youngstrom, "Lessons from the WISeR Prior Authorization Model," *Report on Medicare Compliance* 35, no. 39 (November 2, 2026).

5 Centers for Medicare & Medicaid Services, "Program Integrity Pillars for Medicaid and the Children's Health Insurance Program (CHIP)," last modified October 23, 2026, https://go.cms.gov/47LVTA8.

6 Centers for Medicare & Medicaid Services, "Request for Information - Fraud Defense Contracts," Special Notice, Notice ID 270536, SAM.gov, October 5, 2026, https://bit.ly/4iLwz3c.

Lessons from the WISeR Prior Authorization Model

About 10 months into the Wasteful and Inappropriate Service Reduction (WISeR) model, CMS Deputy Administrator Kim Brandt shared some insights gleaned so far (see story, p. 1).

Early Lessons From WISeR

1. Technology can strengthen program integrity at scale

Enhanced technology can rapidly review large volumes of documentation and support identification of potentially inappropriate utilization.

2. Human clinical review remains essential

Coverage policies can involve clinical nuance that requires appropriately qualified clinicians.

3. Accuracy matters as much as speed

A fast determination is only valuable if the applicable Medicare coverage criteria are interpreted correctly.

4. Technology requires continuous oversight

Clinical logic, workflows, and quality assurance processes must be monitored and refined as real-world experience identifies issues.

5. Provider feedback is an important monitoring signal

Complaints, resubmissions, peer-to-peer discussions, and determination patterns can help CMS identify where processes require clarification or improvement.

6. Program integrity and burden reduction are not mutually exclusive

The model is testing whether Medicare can strengthen review while also making prior authorization faster and easier to navigate.

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OIG FAQs on Exclusions in Wake of HHS Delegation of Authority to CMS

HHS on Oct. 14 delegated permissive exclusion authority to CMS. The HHS Office of Inspector General (OIG) will continue to also impose exclusions, which is clarified below. A top CMS official said Oct. 28 that CMS exclusions will be posted on the OIG's List of Excluded Individuals and Entities (see story, p. 1).

Exclusions FAQs

Answers to Questions Concerning the Joint Delegation of Certain Exclusion Authority to CMS

Who will impose mandatory exclusions?
The Office of Inspector General (OIG) will continue to impose mandatory exclusions; the delegation to the Centers for Medicare & Medicaid Services (CMS) does not include mandatory exclusions. Mandatory exclusion covers individuals and entities convicted of the following types of criminal offenses:

- Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare, Medicaid, State Children's Health Insurance Program, or other State health care programs
- Patient abuse or neglect
- Felony convictions for other health care-related fraud, theft, or other financial misconduct
- Felony convictions relating to unlawful manufacture, distribution, prescription, or dispensing of controlled substances

Do I need to talk to CMS about resolving their exclusion authority if I am negotiating a False Claims Act settlement with DOJ?
No, OIG will resolve permissive exclusion authority for the Department of Health and Human Services (HHS) in False Claims Act matters. Depending on the facts and circumstances presented, OIG will usually pursue one of the following approaches when settling a health care fraud case: (1) exclusion; (2) heightened scrutiny; (3) integrity obligations; (4) take no further action; or (5) in the case of a good faith and cooperative self-disclosure, release 1128(b)(7) exclusion with no integrity obligations.

How will OIG and CMS coordinate to impose permissive exclusions?
OIG has always worked closely with our partners at CMS to fight fraud and will continue to do so with respect to exclusions. With the exclusion authority delegation, we expect to increase capacity for HHS to use this important authority to fight fraud. We do not have additional information to share regarding case allocation. We recommend contacting CMS with questions regarding its implementation of the delegated authority.

Will CMS exclusions be posted on the LEIE?
OIG is coordinating with CMS to make all exclusions public. Implementation details are under development. We will update the public when further information is available. For additional information regarding CMS's plans, please contact CMS.

SDPP for FCA Violations Goes Easier on Kickbacks; Judge Cites AI Risks

Kickbacks catch a break under a new self-disclosure pilot program (SDPP) for False Claims Act (FCA) violations from the Department of Justice (DOJ) and HHS.[1] Instead of a penalty for all "tainted" claims, DOJ would collect the actual amount of the unlawful remuneration.

"The typical way we measure damages is the value of tainted claims," said Andy Mao, deputy director of DOJ's Civil Fraud Section, at HCCA's Healthcare Compliance Enforcement Conference Oct. 17. Under the pilot program, the government "is willing to look at the remuneration itself" (e.g., payments to physicians for referrals), which presumably will be less than the value of all claims stemming from the kickbacks. "It's clearly a significant financial incentive to encourage people to self-disclose. There's a trust exercise here, but putting that in the guidance is conveying our good faith," Mao said.

Although kickbacks get special treatment in the SDPP, which was announced Oct. 22, it's available to all types of potential FCA violations in the healthcare arena. Providers that self-disclose will repay 1.25–1.6 times the amount of the allegedly ill-gotten gains and receive a release from FCA and civil monetary penalty liability if they meet certain conditions. They also will sidestep a corporate integrity agreement and enrollment revocation.

To qualify for the SDPP, "the provider has to bring us something we were unaware of or something subject to a qui tam or FCA lawsuit," Mao said. The provider also "has to make a fulsome disclosure" of the facts, relevant parties and remedial actions.

'This Would Have Blown Up Anyway'

The SDPP is the latest in a series of self-disclosure policy changes. DOJ in an Oct. 15 policy reshuffled the deck of voluntary self-disclosures by healthcare organizations for criminal matters.[2] From now on, organizations should self-disclose potential criminal matters related to federal healthcare programs to DOJ, not OIG—although the organizations will still reap the benefits of OIG's Health Care Fraud Self-Disclosure Protocol (SDP), according to the policy, which was released in tandem with OIG's updated SDP.[3]

The changes came on the heels of DOJ's recent update to the corporate enforcement policy (CEP), which offers sweeteners to companies for self-disclosures in

criminal matters, including a declination of prosecution if certain conditions are met.

Attorneys disagree on the value of self-disclosure, said attorney Kirk Ogrosky, with Goodwin Procter. Some lawyers say their clients self-disclosed in good faith and still wound up with sprawling investigations and big fines. "I said, 'If they hadn't self-disclosed, this would have blown up anyway,'" he said.

Other attorneys feel their clients had a good experience. "A lot of this comes down to trusting people on the other side," Ogrosky noted. "People who are self-disclosing want a good relationship with the government. If you're with the right people, it's an easy process." It's a matter of explaining what happened, answering their questions and responding to subpoenas, Ogrosky said.

But he doubts the SDPP's generosity to kickbacks will be all that helpful to most providers.

"It's a weird thing to try to get self-disclosures on because the majority of FCA recoveries" come from pharmaceutical and medical device manufacturers who may discover arrangements that could be perceived as kickbacks, Ogrosky said.

"The big FCA settlements that revolve around anti-kickback disputes aren't the types of cases where I would expect anyone to make a self-disclosure because everyone firmly and, in many cases, fairly believes they didn't do anything wrong."

Three Arguments in Wound Care Cases

DOJ, CMS and OIG are focused on certain hotspots in their crushing fraud agenda. They include wound care procedures and related services; hospices and sober homes; chronic care management; and remote patient monitoring.

Wound care procedures with skin substitutes are in the crosshairs of auditors, investigators and prosecutors. "On wound care, the government is making three arguments in court," Ogrosky said.

The first is that allografts (i.e., the application of skin substitutes) weren't medically necessary for the patients who received them. "That's what has drawn the government's attention," he said.

The second is related to pricing and "marketing the spread" between the average sales price (ASP) plus 6%—which is how CMS paid for skin substitutes until this year—and the prices physicians actually pay for them, Ogrosky said. Manufacturers set a price for skin substitutes and sell them to distributors with a discount or rebate on future purchases. The distributors in turn sell the products to physicians, passing along the discount or rebate. Even though physicians may pay half price because of the discount or rebate, they billed Medicare under the reported ASP without accounting for it, he said.

That's contrary to the fact that Medicare administrative contractors (MACs) have told physicians to charge Medicare the discounted price (i.e., what they paid for the skin substitutes).

Now physicians and distributors are facing indictments and whistleblower cases over their ASP billing "where they failed to reduce the price based on the discounts," he explained.

The third argument is that some allograft products are "illegally being marketed and sold without appropriate biologic licenses," Ogrosky said. Some kinds of allografts are registered with the Food and Drug Administration (FDA), but the government is targeting amniotic-fluid based allografts. "Allografts that seek to travel under Sec. 361" of the Public Health Service Act must be for homologous use (i.e., skin substitutes perform the same function in the recipient as in the donor), but some manufacturers argue that certain amniotic-fluid allografts, which are nonhomologous, "are human tissue products so we don't have to go to the FDA," Ogrosky said. "The government is saying, 'These types of products require biologic licenses and no one sought FDA approval. And the FDA told you as of May 2022, we consider these products unapproved, and they shouldn't be on the market in the U.S.'"

Legit Providers May Get Caught up in Crackdown

Ogrosky said the government has its "tentacles all over the place," and legitimate providers may get caught up in them.

The government also zeroes in on patients who don't receive conservative wound treatment before the last resort of a skin substitute, said Patrick Neubert, OIG's opioid rapid response coordinator and former acting director of the CMS Division of Provider Investigations and Audits. Also, there may be little information in the medical records about the size, depth or width of the wound, "which creates a challenge for the provider," he said. "Clear documentation is a critical component of any provider's medical record, and it's important to document what treatment you have done previously."

It's hard to fly under the radar because "AI is quickly able to take CMS data and generate lists of people involved and will do the same with manufacturers and distributors," Ogrosky noted. If it's run correctly, AI could prevent health fraud, he said. "I don't think that's far off."

AI in Litigation: Court Raises Evidentiary Questions

With the advance of AI, MACs will be able to engage with providers on the payment side in ways that prevent fraud and abuse, he said. Suppose a DME supplier repeatedly bills Medicare for the same item for the same patient with the same diagnosis. The third time the claim is submitted, it triggers a question. Are you a specialized supplier providing a unique device? Does the sale make sense in terms of where the supplier is located relative to the patient? If the answers aren't satisfying, the MAC won't pay the fourth claim.

AI also raises "interesting evidentiary questions," Ogrosky said. They came up in a recent decision from the U.S. District Court for the Southern District of New York.[4] Judge Jed S. Rakoff ruled that 31 documents generated by a defendant, Bradley Heppner, using a public AI tool weren't "protected by either the attorney-client privilege or the work product doctrine," according to the law firm Paul, Weiss. The ruling in *U.S. v. Heppner* "appears to be the first in which a court determined that interactions with a publicly accessible AI tool based on prompts that contain privileged information are not themselves privileged."

Expect more litigation on this, said Patrick Campbell, deputy chief of DOJ's National Fraud Enforcement Division. "It's coming, building off what Judge Rakoff has teed up there, with parties and attorneys putting privileged materials into AI."

CCM, RPM Attract Enforcers

Another audit and enforcement target is chronic care management (CCM). "We see a consistent number of complaints" from Medicare beneficiaries who haven't received the services, Neubert said. The services show up on their explanation of benefits, but they don't recognize the provider's name or the nature of the services. "It's an area we're focused on," he said. "There will be more enforcement."

The same is true of RPM. Again, Neubert said "there's significant concern among Medicare beneficiaries" who report that they didn't receive the services. There's a balance in CMS wanting to encourage use of CCM and RPM, which help patients manage chronic conditions, and ensuring "these patients are affirmatively opting into it."

Meanwhile, DOJ Oct. 20 announced another whistleblower rewards program with a twist. Even before cases are resolved, DOJ will give whistleblowers up to $30,000 for tips leading to criminal charges. The emphasis of the Fraud Whistleblower Incentive Program, known as WHIP, is on home health, hospice, daycare and special services fraud.[5]

DOJ already has several rewards programs for people who tip DOJ off to certain kinds of fraud, such as health fraud, and of course there are formal whistleblower lawsuits under the FCA.

Paper Tiger vs. Robust Compliance Program

While DOJ considers an effective compliance program a "potentially relevant source of information and intelligence," its evil twin may be more revealing, Mao said.

"In the best-case scenario company, the company has a robust compliance program," he said. The hallmarks include a compliance officer who has direct access to leadership, which takes concerns seriously and self-discloses overpayments, among other things. "They're ahead of the curve, identifying potential issues and nipping it in the bud," Mao said.

But DOJ has seen the other end of the spectrum "where you have a paper compliance program," Mao said. "If you have a compliance program on that end of the spectrum, that's relevant for us. It gives us a sense of how seriously they take their compliance obligations."

For example, during an investigation, DOJ discovered the target had been through three or four compliance officers in a short period of time, Mao said. When employees raised concerns to compliance, they were investigated by the department at the heart of the complaint, not compliance.

Although there are companies at both ends of the spectrum, most "are somewhere in between," Mao said.

The Criminal Division also looks at whether the compliance program exists "in name only or is a real function," Campbell said. "The key here is when we are considering a resolution" of a criminal violation, he said. "The lingering question is whether it's likely to happen again." ✧

Endnotes

1 U.S. Department of Justice, "Department of Justice and Department of Health and Human Services Healthcare Self-Disclosure Pilot Program," accessed October 29, 2026, https://bit.ly/4Bzj91N.

2 U.S. Department of Justice, National Fraud Enforcement Division, and U.S. Department of Health and Human Services Office of Inspector General, "National Fraud Enforcement Division and HHS-OIG Policy on Coordination of Voluntary Self-Disclosure in Health Care Fraud Matters," policy memorandum, October 15, 2026, https://bit.ly/3UhSh5F.

3 U.S. Department of Health and Human Services, Office of Inspector General, "Health Care Fraud Self-Disclosure Protocol," updated October 2026, https://bit.ly/4kaKKju.

4 Paul, Weiss, "S.D.N.Y. Court Considers Whether AI-Generated Documents Are Subject to Privilege Protections," February 20, 2026, https://bit.ly/3WhyGml.

5 U.S. Department of Justice, National Fraud Enforcement Division, "Fraud Whistleblower Incentive Program (WHIP)," updated October 28, 2026, https://bit.ly/4swHD7B.

How Documentation Lapses Imperil Medical Necessity of Mental Healthcare

When a patient goes to therapy for alcohol use disorder, he spends most of the time talking without a word from the therapist—or at least that's what it seems from the medical record.

The progress note explains that the patient reported struggling with sobriety while also maintaining relationships with the people he used to drink with. "Patient stated that he is trying to forge new friendships, but he isn't sure where to meet people. He became emotional when discussing his loneliness and stated he needs to remember that his sobriety is more important than spending time with people that aren't supportive of his new lifestyle."

Although the documentation checked some medical-necessity boxes of the behavioral healthcare, it may not be enough to support the claim. There's no treatment plan, and it's unclear whether the service makes sense for this patient.

"How do we demonstrate this is something we should bill for? The patient is [effectively] talking to himself in the mirror about how things are going," said Veronica Richardson, senior compliance consultant at First Class Solutions. "One of the key factors for medical necessity is the services are directed at the patient's problem or diagnosis."

Her verdict: the service isn't medically necessary.

No Blood Test for Depression

Establishing medical necessity for behavioral healthcare is a whole different ballgame than doing it for medical care, where there's more objective data (e.g., imaging), Richardson said at HCCA's Behavioral Health Compliance Conference Oct. 29.

"Consistently demonstrating medical necessity in behavioral health is a different challenge," she noted. "There's no X-ray or blood test to help determine the severity of depression," for example. It's why "thorough and descriptive documentation is imperative." Without it, auditors will deny claims.

Medicare requires medical necessity as a condition of payment for an item or service. "Entities that do not include clinical review of medical necessity in their claims audits may fail to identify important compliance concerns relating to medical necessity," according to the *General Compliance Program Guidance* from the HHS Office of Inspector General.[1]

Richardson said services are considered medically necessary when they're expected to prevent, diagnose, correct, cure or alleviate conditions or prevent them from worsening . The services should be directed at the patient's diagnosis or problem.

Three Elements to Prove Medical Necessity

To demonstrate the medical necessity of mental healthcare in the medical record, Richardson said it should have three elements:

- Assessment and diagnosis: "Assessments should clearly indicate the need for treatment," she said. They should capture the full story of the patient, with specific diagnoses that align with screening tools. For example, if clinical indicators show the patient has a trauma history greater than six months but the diagnosis is acute PTSD, "that doesn't make sense because PTSD acute would be trauma within six months."
- Treatment plans are the "foundation on which all subsequent services are built," she said. "Each need should have at least one goal, each goal should have at least one objective, each objective should have at least one intervention." Treatment plans also must be complete, signed and timely.
- Progress notes "are the meat and potatoes of the medical record," Richardson said. They should relate to the treatment plan, describe the intervention and explain the patient's response. Progress notes also must be unique to the patient/encounter and cite barriers and progress.

Common Missteps With Documentation

But things don't always go according to plan, making claims vulnerable to denial. A common documentation misstep is discrepancies, such as the use of unspecified

CMS Transmittals and *Federal Register* Regulations, Oct. 23-29, 2026

Transmittals

Pub. 100-04, Medicare Claims Processing

- 2027 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update, Trans. 14,003 (Oct. 26, 2026)
- Instructions for Retrieving the January, April, July, and October Medicare Physician Fee Schedule Database (MPFSDB) Datasets from the Cloud Service, Trans. 14,026 (Oct 26, 2026)

Pub. 100-08, Medicare Program Integrity

- Updates of Chapter 4 in Publication (Pub.) 100-08, Including Updates to the Beneficiary/Complainant Resolution Letter Process, Trans. 14,002 (Oct. 26, 2026)

Federal Register

Proposed Rule

- Patient Protection and Affordable Care Act, Exchange Pre-Eligibility Verification, 91 Fed. Reg. 67,656 (Oct. 27, 2026)

Final Rule

- Health Data, Technology, and Interoperability: ONC Deregulatory Actions To Unleash Prosperity, 91 Fed. Reg. 67,916 (Oct. 28, 2026)

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diagnoses (e.g., depression unspecified). "Sometimes we can't collect enough details in the assessment for a definitive diagnosis, so unspecified is necessary," she said. But an unspecified diagnosis after six months of treatment is a red flag.

Documentation also may not match clinical indicators, Richardson said. For example, substance use disorder of mild severity may be the diagnosis on every claim for a patient even though the documentation supports moderate or severe substance use disorder and the patient is placed in residential services. "We underdiagnosed that individual and it creates a mismatching and can create medical necessity issues because you may not be able to demonstrate why the residential services are appropriate," Richardson said.

Faulty treatment plans also may imperil the medical necessity of treatment. If they're not timely, updated and signed, "that's a red warning light."

Progress Notes Should Link to Treatment Plan

One of the most common slip-ups with progress notes is not relating them to the treatment plan, Richardson said. If progress notes focus on an area of concern that's not in the treatment plan, they may not support medical necessity (e.g., therapy focused on calming techniques for anxiety when the treatment plan talks about depression and substance use).

The same goes for progress notes without details on provider interventions. If they just focus on the patient without documenting what services were provided, "I equate it to the patient talking to themselves in the mirror."

Richardson encourages providers to be as specific as possible in detailing interventions, such as stating they used cognitive-behavioral therapy. "We can't argue there was no provider intervention in that note."

Progress notes also may fall down without documentation of patient progress and responses. "We can't have a progress note that only includes provider interventions," Richardson said. "We have to reflect on the treatment journey and how they're progressing or how they're not progressing."

Documentation also should be unique to the patient or the encounter, she said. It's a bad sign if notes are the same week after week or they could apply to any patient.

Questions for a Medical-Necessity Review

When medical records are reviewed for medical necessity, auditors expect to find all these pieces captured in the documentation.

Here are questions she suggests asking when reviewing medical records for medical necessity:

- "Why is the patient receiving the service?
- "What problems are being addressed?
- "What service is being provided?
- "How is the provider helping the patient in addressing their problems?
- "Is this service helping?
- "What progress is being made?
- "Does the service make sense for the type of problem the patient is facing?"

Contact Richardson at veronica.richardson@firstclasssolutions.com. ✧

Endnotes

1 U.S. Department of Health and Human Services, Office of Inspector General, *General Compliance Program Guidance*, November 2023, https://bit.ly/4iOM36B.

NEWS BRIEFS

◆ **Lehigh Valley Health Network (LVHN) in Pennsylvania and its affiliated covered entities have agreed to pay $800,000 and implement a corrective action plan to settle potential violations of the HIPAA privacy, security and breach notification rules, the HHS Office for Civil Rights (OCR) said Oct. 30.**[1] LVHN filed a breach report in May 2023 after it found ransomware in its IT system. Because of the ransomware attack, "protected health information (PHI) was exfiltrated and posted on the dark web," affecting 248,359 people, OCR said. LVHN didn't admit liability in the agreement.

◆ **In a false claims settlement about the COVID-19 Provider Relief Fund (PRF), SNG Bellaire Dialysis Center, LP; SNG Hillcroft Dialysis Center, LP; SNG Northwest Dialysis Center, LP; SNG Pasadena Dialysis Center, LP; SNG Sandcastle Dialysis Center, LP; and SNG Texas City Dialysis, LP have agreed to pay about $2 million, the U.S. Attorney's Office for the District of Massachusetts said Oct. 27.**[2] The dialysis centers "misrepresented their lost revenue and received more PRF funding than they were entitled to obtain."

Endnotes

1 U.S. Department of Health and Human Services, "HHS' Office for Civil Rights Settles Ransomware Investigation of Lehigh Valley Health Network," news release, October 29, 2026, https://bit.ly/3WWCGsY.

2 Resolution Agreement Between the U.S. Department of Health and Human Services and Lehigh Valley Health Network, October 9, 2026, https://bit.ly/4BB89kk.