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News Briefs

CMS Now Has the Power of Exclusion in Addition to Revocation; Effect on Screening Is Hazy

Healthcare organizations may be scratching their heads about how to screen for exclusions from federal healthcare programs handed down by CMS, not the HHS Office of Inspector General (OIG).

HHS on Oct. 14 formally gave CMS the power to exclude individuals and entities, according to a *Federal Register* notice on the delegation of authority.¹ Until now, it was exclusively OIG's territory.

Permissive and mandatory exclusions are reported on OIG's List of Excluded Individuals and Entities (LEIE). The LEIE is the principal way to identify whether employees, vendors and others (e.g., independent physicians) have been thrown out of federal healthcare programs.

The delegation of authority indicates that CMS wants to wield a bigger stick, said attorney Judy Waltz, with Foley & Lardner LLP. "Maybe this authority provides CMS with a broader catchment for a group of people they can't get at through billing revocations but conclude shouldn't be in the business of providing services to Medicare beneficiaries."

Exclusion packs a bigger punch than revocation because it blocks individuals and entities from receiving payments from all federal healthcare programs (including Medicare and Medicaid), directly or indirectly, while revocation just locks them out of Medicare billing, Waltz said. She noted, however, "there can be collateral impact from a revocation, such as a reciprocal termination under Medicaid."

CMS Asked for It

According to the delegation notice, CMS is only authorized to do permissive

exclusions, which are the lion's share of exclusions, said Greg Demske, former OIG chief counsel. OIG has the discretion to impose permissive exclusions for certain offenses, such as license revocation, but exclusions are mandatory for other offenses.

The delegation was CMS's idea. "CMS requested that the permissive exclusion authority under Section 1128(b) of the SSA [Social Security Act] be formally delegated to the CMS Administrator. As the agency directly responsible for administering Medicare and Medicaid, CMS is uniquely positioned to investigate, identify, and develop the evidentiary basis underpinning permissive exclusion determinations," according to the notice.

Where's OIG in all this? "It's not clear from this delegation whether CMS is being swapped in or having concurrent authorities" with OIG, Waltz said. In 1984 and 2011 delegations, HHS parked authority with OIG for "controlling fraud and abuse in healthcare programs" under certain sections of the SSA, including exclusions.²

An HHS spokesperson told *RMC* that OIG will keep doing its thing. The delegation of permissive exclusion authority strengthens CMS's program integrity efforts, while "OIG retains its existing authority. This collaborative model means more eyes on the problem and faster response times, while preserving OIG's independence as the dedicated watchdog," the spokesperson said.

Among the reasons for permissive exclusion: misdemeanor convictions related to health fraud; provision of unnecessary or substandard services; submission of false or fraudulent claims

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to a federal healthcare program; and misdemeanor convictions for the unlawful manufacture, distribution, prescription or dispensing of controlled substances.³ Exclusions are mandatory for Medicare or Medicaid fraud convictions and patient abuse or neglect, among other things.

What Does This Mean for Exclusion Screening?

The new world order raises the question of whether healthcare organizations can still rely on OIG's LEIE for comprehensive exclusion screening. Although it's TBD, "for now, they should just check the LEIE," Waltz said. She assumes exclusions will be there whether they come from CMS or OIG because otherwise CMS would have to build its own exclusion database.

"Organizations should continue to rely on the LEIE for exclusion screening unless/until HHS gives additional guidance," Demske added. It's also a good idea for organizations to "ensure that the screening questions they ask their employees/agents/vendors (e.g., are you excluded?) are written broadly enough to cover CMS exclusions as well as OIG exclusions."

But Michael Rosen, president of ProviderTrust, predicts that CMS will create a separate searchable database similar to its Medicare Advantage (MA) Preclusion List. If that happens, he hopes access won't be limited like the preclusion list is limited to MA plans and Part D sponsors, because providers often outsource exclusion screening to vendors.

He's also concerned about the searchability of any potential CMS list of excluded people or entities. "We don't know what identifiers they would use," Rosen noted. The LEIE, which is available to anyone, requires a Social Security number to verify a possible match. Just listing the name of the person or entity and their offense "is not very helpful."

It's possible that OIG will continue to do most permissive exclusions and report them on the LEIE, Demske said. Most are derivative, which means the exclusion stems from other actions, such as a clinician losing their license to practice.

"I don't see CMS taking the lead on those," said Demske, with Goodwin Procter. "I see them using it as additional leverage" on top of CMS's other administrative authorities (e.g., revocation of Medicare billing privileges, payment suspensions, overpayment demands). "Exclusion is different from existing CMS remedies in that it's not tied to a particular program through being a provider or supplier. It applies to anyone," he explained. "It opens a much broader universe of potential targets of CMS action and that's outside of CMS's traditional expertise, which is focused on providers and suppliers."

For example, when a nurse loses their license for drug abuse, CMS wouldn't strip them of their billing privileges because, as a nurse, they don't have any and under most circumstances couldn't get billing privileges "because there's no direct payment for their services," Waltz said. But if CMS thinks the nurse is bad news, it could use an exclusion to keep them away from federal healthcare programs.

Who Will Give the Exclusion Release?

The exclusion delegation to CMS also confuses the matter of whether defendants in False Claims Act (FCA) cases should engage with OIG or CMS for an exclusion release in addition to negotiating with the Department of Justice (DOJ), Demske said. Will there be separate releases or will OIG and CMS streamline the process? "It would be inefficient for every case to go through DOJ, CMS and OIG," he noted.

However, Waltz said if CMS is at the table for settlement discussions, maybe it can also discuss a release of its ability to revoke billing privileges.

Hopefully HHS will issue guidance clarifying the circumstances in which the respective agencies will exclude people and entities, Demske added.

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Endnotes

- 1 Statement of Delegation of Authority, 91 Fed. Reg. 65,219 (Oct. 14, 2026), <https://bit.ly/4s8mLDE>.
- 2 Delegation of Authority; Centers for Medicare & Medicaid Services, 76 Fed. Reg. 13,618 (Mar. 14, 2011), <https://bit.ly/4yPMvHz>.
- 3 U.S. Department of Health and Human Services, Office of Inspector General, “Background Information & Exclusion Authorities,” accessed October 16, 2026, <https://bit.ly/4zz7Wwu>.

Hospital Settles Case on Commercial Reasonableness in Physician Deals

In a reminder that commercial reasonableness shouldn't take a back seat to fair-market value in hospital-physician agreements, Petaluma Valley Hospital in California has agreed to pay \$2.924 million to settle a case with the HHS Office of Inspector General (OIG).

OIG alleged the hospital paid remuneration to physicians for services provided under agreements that weren't commercially reasonable. No mention is made of fair-market value, which is often the star of Stark Law and Anti-Kickback Statute (AKS)-related civil money penalty or False Claims Act settlements.

“You can meet the fair-market standard and fail on the commercial reasonableness side,” said attorney Bob Wade, with Wade Health Law, although he wasn't saying that's what happened at Petaluma Valley Hospital.

According to the settlement, OIG alleged the hospital paid remuneration to certain physicians in two forms:

- ◆ Compensation that wasn't commercially reasonable and that was for services not provided in connection with an operating room (OR) management agreement from Sept. 1, 2019, to March 25, 2025.
- ◆ Compensation that wasn't commercially reasonable and that was for services not performed under two management physician director agreements from Sept. 1, 2019, through June 30, 2024.

The alleged conduct subjects the hospital to civil money penalties, OIG said. Because the remuneration created a financial relationship between the hospital and physicians that didn't satisfy an exception to the Stark Law, and the physicians referred patients to the hospital for designated health services, the Medicare claims for the “improperly referred services violated the Stark Law,” OIG alleged.

Settlement Amount Is ‘Nothing to Sneeze At’

The settlement, which was obtained through the Freedom of Information Act, stems from the hospital's self-disclosure to OIG. The hospital didn't admit liability in the settlement.

Almost \$3 million “is nothing to sneeze at, but I'm sure this is a better settlement as a result of the fact they self-disclosed than if a whistleblower brought it to the government's attention,” said attorney Charles Oppenheim, with Hooper, Lundy & Bookman.

A hospital spokesperson said “Petaluma Valley Hospital identified and voluntarily self-disclosed this matter to the U.S. Department of Health and Human Services Office of Inspector General. We cooperated with the government's review and have resolved the matter, and we remain committed to meeting legal and regulatory obligations.”

No Talk of Fair-Market Value

The settlement doesn't mention fair-market value, Wade said. This time around, it's about commercial reasonableness. The message: Hospital agreements with physicians pose as much risk if they run afoul of commercially reasonable requirements under the Stark Law as they do if payments aren't fair-market value, he noted (see box, p. 4).¹

“Commercially reasonable is such a big deal,” Wade said. “When you are approving compensation arrangements, there should be two forms going into that physician file”: one on why the hospital believes the arrangement is fair-market value and the other on why it's commercially reasonable. Both are required for Stark compliance, but “they are two separate tests,” he noted.

The 2020 update to the Stark regulation explains that a commercially reasonable arrangement “furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.”²

What's the Business Rationale?

Commercially reasonable “gets to the underlying question of what the business rationale is for entering into the agreement,” said Carol Carden, a managing principal at PYA. If the hospital doesn't require a certain medical directorship or management arrangement—or the services aren't performed—it's not commercially reasonable at any payment rate, she said. The problem is providers often “lump those things together.”

Agreements also may not be commercially reasonable if their terms aren't consistent with similar agreements, Carden said. For example, a hospital may give one physician group “a sweetheart deal you wouldn't give” to others with a similar agreement.

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