

# Jarkesy Decision May Hit Key Healthcare Enforcement Tool

By **Theresa Schliep**

Law360 (July 9, 2024, 8:01 PM EDT) -- Healthcare companies battling civil fines imposed by federal health regulators are already embracing a U.S. Supreme Court decision weakening agencies' power to impose monetary penalties without a jury trial.

And while the full implications of the high court's **Jarkesy decision** are still coming into view, many healthcare attorneys predict that a first wave of industry pushback will build to something seismic for civil penalties and federal health regulation.



While the U.S. Supreme Court's Jarkesy decision was largely overshadowed by the court's decision the next day overturning Chevron deference, it dealt its own major blow to administrative proceedings. (AP Photo/J. Scott Applewhite, File)

"I view it as potentially very sweeping," said Jason E. Bring, a partner in the healthcare practice group at Arnall Golden Gregory LLP.

The U.S. Department of Health and Human Services' sprawling civil monetary penalty, or CMP, framework for deterring and punishing all types of infractions in healthcare — from Stark Law violations to poor conditions in nursing homes — could be significantly undermined by the June 27 decision in [Securities and Exchange Commission v. Jarkesy](#) .

While the case focused on a hedge fund manager, securities fraud, and the U.S. Securities and Exchange Commission, the majority issued a broad decision that many say **threatens** administrative adjudications throughout the federal government.

That includes key healthcare agencies and offices including the HHS Office of Inspector General, the Centers for Medicare & Medicaid Services, the HHS Office for Civil Rights and the U.S. Food and Drug Administration.

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## CMPs and Healthcare

Like many federal agencies, the U.S. Department of Health and Human Services can impose civil monetary penalties for a variety of alleged infractions. But the Supreme Court's decision in *SEC v. Jarkesy* might undermine the process for assessing civil monetary penalties without a jury trial.

**The Office of Inspector General** at HHS can impose civil monetary penalties for a number of purported legal violations, including submitting false or fraudulent claims to federal healthcare programs and for violating the Anti-Kickback Statute, the Stark Law and the Emergency Medical Treatment and Labor Act.

**The Office for Civil Rights at HHS** can impose civil monetary penalties for violations of the Health Insurance Portability and Accountability Act.

**The Centers for Medicare & Medicaid Services** has numerous CMP authorities, including the power to impose CMPs on providers for violating federal certification requirements, on providers who violate the No Surprises Act's protections against surprise billing for out-of-network emergency care, and on hospitals that violate price transparency requirements.

While the *Jarkesy* decision was overshadowed by the court's decision the next day overturning **Chevron deference** 🚫, it dealt its own blow to administrative proceedings and may force disputes that would have otherwise been adjudicated in agency-level proceedings to the federal courts.

In the days since the decision, Bring said he's already seen a number of nursing home providers — a frequent target of CMPs — raise the *Jarkesy* decision in their ongoing administrative proceedings. He predicted that organizations battling the federal government over smaller dollar amounts — maybe \$10,000 or \$20,000 — might want to keep their matters in administrative proceedings in front of an administrative law judge or other agency officials.

But armed with *Jarkesy*, clients facing more sizable penalties might choose to "try to shut down the administrative process and pursue your constitutional rights" and go to federal court, Bring said.

Experts are still trying to get a sense of exactly how influential the *Jarkesy* decision will be. An HHS representative declined to comment for this story.

In the high court decision, those in the minority appeared dismayed at the scope of the ruling, with Justice Sonia Sotomayor suggesting that the majority failed to cabin the decision so that it only affects the SEC.

"The constitutionality of hundreds of statutes may now be in peril, and dozens of agencies could be stripped of their power to enforce laws enacted by Congress," Justice Sotomayor wrote.

Indeed, the majority's reasoning — which focused on the absence of a jury trial and the common law roots of the SEC penalties — might implicate more than just CMPs.

Andrew Tsui, of counsel with Greenberg Traurig LLP, said the Jarkesy ruling could also implicate administrative appeals over Medicare and Medicaid reimbursement issues, which would have far-reaching consequences on the business of HHS and could require the agency to do a complete overhaul of how it handles those disputes.

While the full application of the decision remains murky, Tsui said it's close to certain that the agency will have to reevaluate how it handles CMP adjudications, considering how analogous they are to the fact pattern in Jarkesy.

"Where there are CMPs implicated, you can absolutely be sure that there's going to be a very, very serious overhaul," said Tsui, a former litigation attorney with HHS.

CMP authority varies from agency to agency. For instance, the HHS Office of Inspector General can impose penalties for submissions of false and fraudulent claims to federal healthcare programs.

That office can also issue punishments for violations of the patient dumping statute known as the Emergency Medical Treatment and Labor Act, which was the subject of a U.S. Supreme Court abortion case this term, as well as for violations of drug price reporting laws and other statutes.

The HHS Office for Civil Rights can impose CMPs for violations of the Health Insurance Portability and Accountability Act. The FDA also uses CMPs, mostly in the context of its oversight of tobacco products.

Against the backdrop of HHS's greater enforcement apparatus, the dollar value of CMPs may seem small.

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By the numbers

## **HHS and CMS Civil Monetary Penalties**

\$606.2M

The value of civil monetary penalties and assessments imposed by HHS-OIG from October 2013 through September 2023 under the Civil Monetary Penalties Law.

9,091

The number of civil monetary penalties imposed on certified nursing facilities in 2023.

145

The number of cases in which HHS-OCR has either reached a settlement or imposed a civil monetary penalty since the effective date of the HIPAA privacy rule in 2003.

\$143M

The value of those penalties and settlements imposed by HHS-OCR for HIPAA violations.

Source: HHS; CMS; KFF

For instance, according to a Law360 analysis of semiannual reports from the HHS inspector general spanning from October 2013 through September 2023, the watchdog imposed around \$606.2 million in CMPs and assessments over that 10-year period under the Civil Monetary Penalty Law.

Meanwhile, the False Claims Act generated around \$2.68 billion in settlements and judgments in the fiscal year ending September 2023.

Likewise, CMPs imposed against nursing facilities don't make up a huge chunk of HHS's overall enforcement efforts.

In the 2023 calendar year, there were \$211 million in CMPs imposed on nursing facilities, according to data from the Quality, Certification and Oversight Reports website from CMS.

But unlike other commonly used healthcare policy enforcement tools — like the False Claims Act, which provides for treble damages — CMPs are viewed not as a money-maker for the federal government but more as a deterrence tool.

Jaime L.M. Jones, a co-leader of the healthcare practice at Sidley Austin LLP, told Law360 in an email that "the ability to pursue CMPs is central to the enforcement efforts by HHS-OIG, CMS, FDA, and OCR."

"While the enforcement actions pursued against healthcare and life sciences companies and individuals by the Department of Justice for certain civil and criminal violations of the False Claims Act, Food, Drug and Cosmetic Act, and healthcare fraud and abuse laws tend to draw more press attention, CMPs are at the core of the enforcement actions HHS and its agencies can take directly," Jones added.

For some providers, CMPs can be significant. For instance, the nursing facility penalties in 2023 averaged roughly \$10,300 for "per-instance" penalties, and \$28,300 per diem, which are CMPs imposed for ongoing violations.

Alice V. Harris, a Maynard Nexsen PC partner whose clients include nursing homes, described CMPs as the main enforcement tool against nursing facilities.

These businesses typically operate on slim profit margins, she said, making the larger per-diem penalties particularly problematic.

Companies might be able to use the decision to their advantage without trying to dismantle the entire CMP regime.

Daniel A. Kracov, chair of the life sciences practice at Arnold & Porter Kaye Scholer LLP, said that companies facing CMPs from the FDA might be able to leverage the decision to get a better settlement, since the agency might be trying to avoid creating bad law.

Harris noted that she might tell providers to challenge administrative proceedings over CMPs when the penalty at issue is significant and when there's a dispute over the facts, which seems "ripe for a jury trial," she said.

Likewise, Jones said she might advise clients to "seriously consider their options to move disputes into federal courts, including to obtain the protections of the Federal Rules of Civil Procedure and Evidence."

"That consideration will be fact- and circumstances-dependent, and they should seek experienced counsel to help with the evaluation," Jones said.

--Graphics by Ben Jay. Editing by Haylee Pearl.

