PG Bulletin
February 7, 2024

What *Chevron* Upheaval Could Mean for Health Care Enforcement

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Over the last four decades, federal agencies have been free to implement laws with minimal checks by the courts, so long as those agencies' implementing regulatory scheme is reasonable and not directly in violation of the enabling statutory structure. This judicial empowerment of federal agencies is perhaps most pronounced in the health care realm, where the Centers for Medicare and Medicaid Services (CMS) and Medicare Contractors have created an entire ecosystem of rules, advisory opinions, and guidance documents that far exceed the structure created by Congress to implement the federal government's largest federal health care programs and can be changed at the whim of the agencies and contractors.

But now it appears likely that the court's deference to federal agencies could soon be over or—at a minimum—dramatically different than the status quo of today. The Supreme Court heard oral arguments on January 17, 2024 in a pair of cases[1] that signaled that a majority of the court no longer agrees with the 1984 holding in *Chevron U.S.A. Inc. v. Natural Resources Defense Council*,[2] which sparked decades of judicial deference to federal agencies. This article considers the potential such abandonment or limitation could have on health care enforcement.

What Could *Chevron* Abandonment or Limitation Mean for Health Care Enforcement?

Given the pervasiveness of sub-statutory requirements within CMS' overall regulatory structure, health care enforcement efforts commonly turn on technical points made in guidance documents. For example, in the Justice Department's (DOJ's) recent unsuccessful prosecution of one Maryland physician for alleged health care fraud, the jury was tasked with determining whether Medicare and Medicare Contractors' policies that inform proper leveling of evaluation and management (E/M) codes allowed for conviction of a physician who billed Level 4 office visits with COVID-19 tests.[3] While the concept of E/M billing appears in statutes, the specific offense that the Maryland physician was accused of turned solely on sub-statutory concepts like the difference between "moderate" and "high" complexity when it comes to medical decision making within the confines of the CPT Manual, published by the American Medical Association.[4] Following conviction at trial, the federal judge overseeing the case granted a Rule 29 motion—a judgment as a matter of law that the government's evidence is insufficient to sustain a conviction.[5] Largely citing the ambiguity of the CPT Manual, the district court held that the evidence presented at trial failed to overcome the challenges created by the CPT Manual's ambiguous use of undefined words.[6]

Other recent examples show the prevalence of sub-statutory text as the basis for criminal health care fraud prosecutions. Those include a Texas physician's assistant who was convicted for billing a particular code to Medicare for allegedly non-qualifying products,[7] and a Louisiana physician who was convicted in his capacity of an

owner of a New Orleans hospice that billed for allegedly non-qualifying inpatient services.[8] Both of these cases turned on minutiae of guidance documents to prove illegal conduct.

While the stakes may not involve a potential prison sentence, Justice Department efforts against health care providers in the civil context also frequently depend on interpretations of sub-statutory text. In a June 2023 False Claims Act trial of the Georgia physician, the government accusations involved the physician's billing Medicare for chelation therapy codes for patients whose usage did not meet Food & Drug Administration guidance.[9]

Exactly how the U.S. Supreme Court decides the cases before it can have a dramatic impact on a range of enforcement areas. The specific rule before the Supreme Court is quite narrow—whether the National Marine Fisheries Service can impose a cost on the herring industry to place observers on fishing boats—and the Court could likewise craft a narrow holding. After all, Chief Justice John Roberts pointed out at oral argument that the Supreme Court had not relied on *Chevron* in a case in 14 years.[10] It could very well be that the Supreme Court technically strikes down *Chevron* and replaces it with a test for the judiciary to apply that permits a wide berth for agencies to create law. The result in that scenario would have very little impact on challenges to sub-statutory rules, regulations, and guidance created by CMS and Medicare Contractors.

If the Court strikes down the Fisheries rule and *Chevron* with it, there will be precedent for at least one type of rule that the Court disapproves of as invalid. Defendants across the country will seize on this as another arrow in their quiver to fight back against DOJ enforcement efforts. Although this case involves fish, the health care industry should keep close watch on how the Supreme Court approaches this issue. The Court's analysis may give a roadmap for future defenses and challenges against DOJ's efforts to rely upon sub-statutory text in criminal and civil health care prosecutions.

What Should Attorneys Defending Health Care Fraud and Kickback Cases Be Doing to Push This Issue?

While we wait to see the breadth of the Supreme Court's rulings in the two cases considering the future of *Chevron*, counsel defending health care fraud and kickback cases that turn on sub-statutory authority should check to determine how that sub-statutory authority squares with its enabling legislation and other pertinent statutes. If there are valid arguments that CMS (or some delegee, like a Contractor) has strayed too far from Congressional intent or has created some requirement in an unreasonable or arbitrary way, then those should absolutely be asserted, even though the current law gives heavy weight to those agency declarations. Should the Court insert a type of *de novo* review when it decides the coming *Chevron* cases, then challenges brought now could be the next battle for the Supreme Court to consider.

At a minimum, attacks on any charges from a legal falsity standpoint, as the defense did in the Maryland physician's E/M code trial, should be top of mind. There, the judge granted the defense's Rule 29 motion because when ambiguity is held against the government, the government must put up evidence that meets a defense-friendly interpretation of that ambiguity, and the government in that case failed to meet such a burden. Practitioners defending cases premised on sub-statutory authority should not dismiss the significance of *Chevron*'s potential coming demise and would be well served by continuing to hold the government to the high standard called for when ambiguity clouds the government's case.

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[1] *Relentless, Inc. v. Department of Commerce*, No. 22-1219; *Loper Bright Enterprises v. Raimondo*, No. 22-451.
[2] 467 U.S. 837 (1984).
[3] *See United States v. Elfenbein*, 1:22-cr-146 (D. Md.).

[4] *Id.*, Doc. 99 at 5.
[5] Fed. R. Crim Pro. 29.
[6] Note 3, *supra.* at 50–54.
[7] *See* "Assistant Convicted at Trial of Amniotic Fluid Scam," DOJ Press Release, Jan. 25, 2024, *available at* https://www.justice.gov/usao-ndtx/pr/assistant-convicted-trial-amniotic-fluid-scam.
[8] *See* "Jury Convicts Hospice Owner for Defrauding Medicare," DOJ Press Release, Nov. 8, 2023, *available at* https://www.justice.gov/usao-edla/pr/jury-convicts-hospice-owner-defrauding-medicare.
[9] *See* "Rome jury finds Dr. Charles Adams and full circle medical center liable for False Claims Act violations," DOJ Press Release, June 16, 2023, *available at* https://www.justice.gov/usao-ndga/pr/rome-jury-finds-dr-charles-adams-and-full-circle-medical-center-liable-false-claims.
[10] *Relentless Inc. v. Department of Commerce*, United States Supreme Court Oral Argument Transcript, Jan. 17, 2024, *available at* https://www.supremecourt.gov/oral_arguments/argument_transcripts/2023/22-1219_e2p3.pdf, at 33.

