When Interpreting Ambiguous Federal Healthcare Laws, Practice “Safe Driving”

namas.co/when-interpreting-ambiguous-federal-healthcare-laws-practice-safe-driving

By NAMAS September 13, 2023

September 15, 2023 | By: Edward Baker, Of Counsel | Lieff Cabraser Heimann & Bernstein

If you lie awake at night worrying about whether your coding, auditing, or compliance practices might be based on misinterpretations of federal law, opening up your healthcare employer—or yourself!—to treble damages and penalties under the False Claims Act (FCA), you may be able to draw some comfort from the U.S. Supreme Court’s recent decision in *U.S. ex rel. Schutte, et al. v. SuperValu, et al.*, Nos. 21-1326, 22-111 (2023).

In the *SuperValu* decision, released on June 1, 2023, the Supreme Court clarified the FCA’s “knowledge” or “scienter” requirement, which is notoriously broad, encompassing not only the submission of false claims to the Government based on “actual” knowledge, but also “deliberate ignorance” and “reckless disregard.” 143 S.Ct. 1391. For the first time, the Supreme Court addressed the question of whether facial ambiguity in federal laws,

regulations, or guidance makes it impossible for the Government to meet its burden of proof as to the FCA knowledge element if a defendant correctly understood a relevant legal standard and thought their claims were inaccurate at the time submitted.

As a whistleblower attorney and former Assistant U.S. Attorney, I, too, anxiously awaited the Supreme Court's decision. At stake was nothing less than the viability of the False Claims Act as an effective enforcement tool to recoup taxpayer money lost to fraudulent schemes and protect free and fair competition between private entities that participate in public programs.

Defendants in the *SuperValu* case—grocery chains that operate pharmacies in their stores and were required by various laws (*e.g.,* 42 C.F.R. § 447.512(b)(2)) to report their "usual and customary" prices for prescription drugs to CMS, state Medicaid agencies, and Part D plans —had argued that there was an objectively reasonable interpretation of the phrase "usual and customary" at odds with the Government's interpretation. Therefore, they could not have submitted false claims for payment even though they understood at the time they submitted their claims that the Government's interpretation was correct.

Had the defendants prevailed, it would have been a simple matter in many cases for defendants to escape FCA liability by coming up with creative interpretations of legal requirements after being challenged by the Government or a whistleblower, including a competitor, for submitting claims for payment that it knew to be false.

But in a 9-0 decision, the Supreme Court held that "[t]he FCA's scienter element refers to respondents' knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed." 143 S.Ct. at 1399. More succinctly, "facial ambiguity alone is not sufficient to preclude a finding that respondents knew their claims were false." *Id.*

In an interesting aside, the Court analogized the interpretation of federal laws, regulations, and guidance to a driver speeding down a highway who sees a road sign that says "Drive Only Reasonable Speeds." *Id.* at 1402. The Court reasoned that the hypothetical driver, "without any more information, might have no way of knowing what speeds are reasonable and what speeds are too fast." *Id.* But if the driver was informed by a police officer earlier in the day that "speeds over 50 mph are unreasonable" and noticed that all the other cars around him were going 48 mph, he "might know that 'Reasonable Speeds' are anything under 50 mph; or, at the least, he might be aware of an unjustifiably high risk that anything over 50 mph is unreasonable." *Id.* And if "the same police officer later pulled the driver over, we imagine that he would be hard pressed to argue that some other person might have understood the sign to allow driving at 80 mph." *Id.*

The lesson that the Supreme Court seems to wish us to draw from this hypothetical is that ambiguity in federal statutes, regulations, and guidance is no excuse for ignoring reliable interpretations of those legal obligations, as well as reasonable industry practice. When interpreting ambiguous laws, we should not rely solely on personal whim or our own self-interested and idiosyncratic views.

As I instructed my daughters when they were learning to drive, when driving on the highway, try not to be an outlier. Stay safely within the "pack." Don't go too fast, or too slow. And, obviously, check your speed and slow down if you see or suspect a trooper around the bend. You don't want to be the car that the trooper pulls over for speeding and be given a ticket. This is just common sense and safe driving practice.

Likewise, when interpreting federal law (whether statutes, regulations, or guidance), make an honest and diligent effort to understand how the government agencies responsible for implementing and protecting public programs interpret those same laws. You can do this by carefully studying guidance issued by the relevant agencies, following DOJ enforcement actions under the False Claims Act, attending NAMAS conferences and webinars, and speaking to peers or advisors whom you trust. If you disagree with the government's own interpretations of ambiguous laws, engage with the appropriate federal agencies in a constructive and transparent dialogue.

Meanwhile, make a good faith effort to conform with the government's interpretation of the ambiguous law. Otherwise, like the driver in the Supreme Court's hypothetical who gets pulled over for driving 80 mph, you can't legitimately claim to have an honest belief that your interpretation is correct. And you might then be accused of "knowingly" violating the FCA by acting with deliberate ignorance or reckless disregard when you or the healthcare entity for whom you work cause claims that violate the government's interpretation of those laws to be submitted for payment.

By following this "safe driving" practice, you will not remove the ambiguity in the multitude of healthcare laws and regulations that govern the role of private entities and individuals in our healthcare system, but at least you will know how the government interprets those laws and regulations, and be able to reduce your chance of being given an FCA "ticket." Hopefully, knowing that there is a method to manage regulatory ambiguity will also help you sleep better at night.

Safe driving!

Your next steps:

1. **Contact NAMAS** for full auditing, documentation, and compliance consultation.
2. Read more blog posts to stay updated on the 2023 Revisions to the 2021 E&M Guidelines.
3. Subscribe to the NAMAS YouTube channel for more auditing and compliance tips!

4. Check out the **agenda** for the **15th Annual NAMAS Auditing & Compliance Conference** and register to attend!

NAMAS is a division of DoctorsManagement, LLC, a premier full-service medical consulting firm since 1956. With a team of experienced auditors and educators boasting a minimum of a CPC and CPMA certification and 10+ years of auditing-specific experience, NAMAS offers a vast range of auditing education, resources, training, and services. As the original creator of the now AAPC-affiliated CPMA credential, NAMAS instructors continue to be the go-to authorities in auditing. From DOJ and RAC auditors to CMS and Medicare Advantage Auditors to physician and hospital-based auditing professionals, our team has educated them all. We are proud to have helped so many grow and excel in the auditing and compliance field.

Looking to start up a medical practice or grow your existing practice? Contact our parent company, DoctorsManagement.