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# Compliance Today - June 2022
# The emerging battle over 'objective reasonableness' in False Claims Act cases

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The Medicare and Medicaid programs are exceedingly complex, and navigating the myriad statutes, regulations, rules, and guidance presents significant challenges for all healthcare providers and compliance professionals—even the United States Supreme Court has recognized that the Medicare program is a "complex and highly technical regulatory program."[1] This job is sometimes made even more difficult because program regulations can be ambiguous, and government officials are often unable or unwilling to provide further clarification. Add to the mix that failure to comply with Medicare and Medicaid regulations can result in False Claims Act (FCA) liability, and many healthcare providers can't help but express frustration. A new battle emerging in the courts may afford healthcare providers some relief when confronted with ambiguous Medicare and Medicaid regulations.

In *United States ex rel. Schutte v. SuperValu Inc.*, decided on August 12, 2021, the Seventh Circuit Court of Appeals held that a defendant does not knowingly submit a false claim "if (a) it has an objectively reasonable reading of the statute or regulation and (b) there was no authoritative guidance warning against its erroneous view."[2] In it, the Seventh Circuit joined the Third, Eighth, Ninth, and D.C. Circuits in endorsing an objective reasonableness standard under the FCA. However, the Seventh Circuit, over a vigorous dissent, went further than the other courts, which have recognized an objective reasonableness standard, setting up a battle that could significantly affect future FCA cases.

## False Claims Act's definition of 'knowingly'

The FCA imposes liability if a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."[3] The statute also imposes liability if a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation…to the Government" or "knowingly conceals or knowingly and improperly avoids or decreases an obligation…to the Government."[4]

In 1986, Congress defined the term "knowingly" as having "actual knowledge of the information," "deliberate ignorance of the truth or falsity of the information," or "reckless disregard of the truth or falsity of the information."[5] The term "knowingly" requires "no proof of specific intent to defraud."

In cases involving the violation of an ambiguous regulatory requirement, federal courts historically held that a defendant could still act with knowledge. For example, a defendant could actually know "that the [government] interpreted the regulations in a certain way."[6] A defendant could also recklessly disregard notice of a contrary interpretation or fail to make reasonable inquiries. And a defendant could act with deliberate ignorance by engaging in "ostrich-like" conduct and ignoring red flags that its conduct is illegal.[7] At most, an ambiguous regulatory requirement was considered one relevant factor to be considered by the jury in determining whether the defendant acted knowingly under the FCA.

This standard often left healthcare professionals frustrated at the prospect of facing FCA liability for failing to comply with Medicare and Medicaid billing regulations they view as ambiguous and complex. Attorneys representing healthcare providers often argued that their clients should not be forced to pay the treble damages and substantial civil monetary penalties required by the FCA if their clients erroneously interpreted those ambiguous regulations. Until relatively recently, those arguments were largely ineffective.

## Supreme Court's *Safeco* decision

In *Safeco Insurance Co. of America v. Burr*, decided in 2007, the Supreme Court interpreted the Fair Credit Reporting Act (FCRA) scienter requirement, under which plaintiffs must show that defendants acted "willfully."[8] The Supreme Court held that a defendant who acted under an incorrect interpretation of the relevant statute or regulation did not act with reckless disregard if (1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it. Critically, the Supreme Court emphasized that a defendant's subjective intent is irrelevant for purposes of liability.

Following the Supreme Court's decision, defendants in many FCA cases have urged lower federal courts to apply the *Safeco* standard to the FCA's scienter requirement. Defendants have argued that both the FCRA and FCA apply the common law definition of the term "knowingly," and thus the *Safeco* objectively reasonable standard should apply to FCA cases. Plaintiffs have argued that: (1) the FCA is different than the FCRA, (2) the Supreme Court did not intend to extend *Safeco* beyond the FCRA, and (3) FCA caselaw predating *Safeco* does not support applying an objectively reasonable standard of scienter. To date, each circuit court asked to decide the issue has held that the *Safeco* standard applies to FCA cases.[9]

## *SuperValu* opens the door to future battles

In *SuperValu*, the qui tam whistleblower argued that SuperValu violated the FCA when it billed Medicare a higher amount for prescriptions than what it billed its customers. The relators argued that in order to remain competitive in a market where Walmart was offering a $4 per 30-day prescription program for many generic drugs, SuperValu adopted a "price-match" program.[10] However, when Medicare beneficiaries obtained prescriptions, SuperValu billed Medicare at the unmatched price, asserting this to be the "usual and customary" (U&C) price even though it was many times higher than what most customers were paying. The relators alleged that SuperValu violated the FCA by not billing Medicare the lower, price-matched charge.

The District Court rejected the relators' argument, finding that "SuperValu did not act with the requisite knowledge under the FCA." Applying the *Safeco* standard, "the court held that it was unclear that SuperValu's program fell within the U&C definition," and that "there was no authoritative guidance to warn SuperValu away from its interpretation of U&C price."[11] The Seventh Circuit affirmed and joined other circuits in endorsing the *Safeco* objective reasonableness standard under the FCA.

In applying the first prong of the *Safeco* standard, the Seventh Circuit held that it is irrelevant whether the

defendant actually held the objectively reasonable reading of the applicable regulation at the time it submitted the false claim. The majority reasoned that under *Safeco*, "a defendant's subjective intent does not matter for its scienter analysis—the inquiry is an objective one. This standard reflects the limits of FCA liability."[12] The dissent criticized this reasoning as "extraordinary" in that it creates "a safe harbor for deliberate or reckless fraudsters whose lawyers can concoct a post hoc legal rationale that can pass a laugh test."

Whether you agree with the majority or the dissent, the *SuperValu* decision will likely usher in an important new battle in FCA cases, particularly those involving complex government programs such as Medicare and Medicaid. Defendants in future cases will defend against FCA allegations by pointing to objectively reasonable interpretations of the applicable regulation, even if they were unaware of that interpretation at the time they submitted the alleged false claims. For healthcare providers who have struggled to comply with ambiguous Medicaid and Medicare regulations, the *SuperValu* decision may, in certain cases, provide some degree of protection against FCA liability. That said, compliance professionals should continue seeking guidance from their legal counsel when interpreting ambiguous Medicare or Medicaid regulations.

## *SuperValu* definition of 'authoritative guidance' remains unsettled

In applying the second prong of the *Safeco* standard, the Seventh Circuit held that "a permissible interpretation [of an ambiguous regulation] is no defense if there existed authoritative guidance that should have warned defendants away from their erroneous interpretation." However, the Seventh Circuit recognized that the Supreme Court did not flesh out the boundaries of what qualifies as "authoritative guidance." Rather than answer this question directly, the Seventh Circuit held that, at a minimum, authoritative guidance "must come from a governmental source—either circuit court precedent or guidance from the relevant agency." While this standard appears narrow, healthcare compliance professionals know that the Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services, and state Medicaid agencies issue many forms of guidance materials. Future courts will have to grapple with the question of which of these guidance materials are authoritative for purposes of the FCA.

Perhaps recognizing that agencies like the Centers for Medicare & Medicaid Services issue significant amounts of guidance, the Seventh Circuit cautioned that not all agency pronouncements regarding a particular topic will qualify as authoritative guidance. Rather, the Seventh Circuit held that authoritative guidance must be "sufficiently specific" to warn the defendant away from their interpretation of the ambiguous regulation at issue. In *SuperValu*, the Seventh Circuit held that the Centers for Medicare & Medicaid Services' *Medicare Prescription Drug Benefit Manual*, which did not directly discuss "price-match" programs, was not sufficiently specific to warn SuperValu that the prices it charged as part of its discount program should have been extended to Medicare. As such, the Seventh Circuit held that "no authoritative guidance warned SuperValu away from its permissible interpretation" of the applicable Medicare regulations.

## The battle over objective reasonableness continues

The *SuperValu* decision did not end the battle over the role of objective reasonableness in FCA cases. To the contrary, the *SuperValu* decision is likely to result in more litigation. The relators in *SuperValu* have asked the entire Seventh Circuit to reconsider the panel's decision. Meanwhile, another panel of judges in the Seventh Circuit is currently deciding a similar FCA case against Safeway.[13] During oral argument, the *Safeway* judges questioned the lawyers on how the *SuperValu* decision might apply to Safeway's own drug discount program. Additionally, the Fourth Circuit is now considering whether to endorse the *Safeco* objective reasonableness standard in an FCA case against the pharmaceutical manufacturer Allergan.[14]

These cases highlight that the battle over scienter under the FCA, and the impact of *Safeco*, will likely intensify in

the near future. Compliance professionals should pay close attention and monitor the developments in *SuperValu* and the other cases grappling with the issue of objective reasonableness under the FCA. While most Medicare and Medicaid regulations may not qualify as ambiguous, for those that do, this emerging legal battle may provide the healthcare industry with an important new defense against future FCA allegations.

## Takeaways

- Courts are embracing a "reasonable interpretation" defense to scienter in False Claims Act (FCA) cases, allowing defendants to, in many cases, avoid liability if they acted consistently with a reasonable, albeit erroneous, interpretation of a government mandate.
- The defense may apply even when the defendant did not actually adopt the reasonable interpretation, permitting post hoc efforts to negate scienter.
- The defense is unavailable where "authoritative guidance" warned one against the incorrect interpretation.
- Courts are still defining what guidance materials are authoritative for purposes of the FCA scienter defense.
- Given the complex nature of healthcare regulation, there will likely be future court battles over this emerging FCA defense.

**1** Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994).
**2** United States ex rel. Schutte v. SuperValu Inc., 9 F.4th 455, 468 (7th Cir. 2021).
**3** 31 U.S.C. § 3729(a)(1)(A).
**4** 31 U.S.C. § 3729(a)(1)(G).
**5** 31 U.S.C. § 3729(b)(1).
**6** Minnesota Ass'n. of Nurse Anesthetists v. Allina Health System Corp., 276 F.3d 1032, 1053 (8th Cir. 2002).
**7** United States ex rel. Schutte v. SuperValu Inc., 9 F.4th at 476.
**8** Safeco Ins. Co. of America v. Burr, 551 U.S. 47, 70 (2007).
**9** *See* U.S. ex rel. Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1155 (11th Cir. 2017). ("Scienter is not determined by the ambiguity of a regulation, and can exist even if a defendant's interpretation is reasonable.")
**10** United States ex rel. Schutte v. SuperValu Inc., 9 F.4th at 459–461.
**11** United States ex rel. Schutte v. SuperValu Inc., 9 F.4th at 463.
**12** United States ex rel. Schutte v. SuperValu Inc., 9 F.4th at 470–476.
**13** U.S. ex rel. Proctor v. Safeway, Inc., No. 20-3425 (7th Cir. 2022).
**14** U.S. ex rel. Sheldon v. Allergan Sales, LLC., No. 20-2330 (4th Cir. 2022).