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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."

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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.

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