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Providers Beware—New Standard Established in False Claims Actions

Healthcare providers enrolled in Medicare and Medicaid should take note of the recent U.S. Supreme Court decision concerning the intent requirement of the False Claims Act (**FCA**).[1] The FCA imposes liability on anyone who "knowingly" submits a false claim to the federal government.[2] The Supreme Court's decision in *United States ex rel. Schutte v. SuperValu Inc.*, issued on June 1, 2023, clarifies the meaning of the term "knowingly" in the context of the FCA.[3] The Court held that "knowingly" is a subjective standard based on actual knowledge rather than an objective reasonableness standard.[4] Providers should understand the meaning of this decision and the implications for their practices.

Background

The FCA was originally enacted in 1863 to stop government contractor fraud during the Civil War.[5] Under the FCA, a person may bring a civil action in the name of the United States against any party they believe has defrauded the government, and it rewards such whistleblower with up to one-third of the recovery.[6] The FCA imposes criminal penalties of up to five years and civil penalties of up to $27,018 per claim.[7] FCA fines can be huge; the Department of Justice obtained more than $2.2 billion in FCA settlements and judgments for the fiscal year ending September 30, 2022.[8] FCA lawsuits are of great concern in the healthcare industry because claims for reimbursement under Medicare or Medicaid are claims to the federal government and subject to FCA penalties.

United States ex rel. Schutte v. SuperValu Inc.

The claims at issue in *United States ex rel. Schutte v. SuperValu Inc.* were submitted by retail pharmacies that sought reimbursement under Medicare and Medicaid for allegedly inflated drug prices.[9] The pharmacies had set up membership discount programs for their customers, but they reported to the government that their usual and customary prices were much higher than those offered through these programs. The lower courts found that these claims were false, but they determined, using an *objective* standard, that the pharmacies did not have the requisite "knowing" state of mind to be held liable under the FCA. The Supreme Court disagreed, holding that the pharmacies did have the required state of mind, as determined using a *subjective* standard.

Takeaways for Providers

There are a few key takeaways from this decision for healthcare providers, as the knowledge standard has changed from an objective to a subjective standard, which may be easier for the government to prove. First, providers should be mindful of any notices they may receive related to errors or overcoding in their Medicare or Medicaid billings, as such notices could serve as future evidence of their state of mind in an FCA case. The Supreme Court noted in *United States ex rel. Schutte* that the pharmacies had received prior notice that they were improperly reporting their usual and customary drug prices, and their failure to heed these warnings served as evidence of their intent to submit false claims.[10]

Second, providers should know that not understanding the rules or failing to get guidance to clarify any ambiguity that they may identify in their billing processes will not protect them under the subjective standard in the way it might have under the previous standard. The pharmacies in *United States ex rel. Schutte* argued that the term "usual and customary" was inherently ambiguous, but the Supreme Court responded that any facial ambiguity in that term did not preclude a finding of liability under the FCA.[11]

Finally, all members of the workforce, not just billers and coders, must be mindful of proper billing practices. *United States ex rel. Schutte* does not specify whose state of mind must be knowing for a false claim to occur, but the Court discussed incriminating emails by executives in which they stated the companies would take the "stealthy approach" to usual and

customary pricing, as well as internal communications to employees not to put certain discount policies in writing.[12] Thus, all levels of employees—including executives—could be implicated under the FCA, and they should be focused on proper billing practices and communications regarding billing practices.

Day Pitney can counsel providers on compliance with Medicare and Medicaid billing requirements, and we can advise providers on other issues related to the FCA.

[1] 31 U.S.C. 3729-3733.

[2] 31 U.S.C. 3729(a).

[3] 143 S. Ct. 1391, 1396 (2023).

[4] *Id*.

[5] 143 S. Ct. 1400.

[6] 31 U.S.C. 3730(b).

[7] 28 C.F.R. part 85.

[8] https://www.justice.gov/civil/false-claims-act.

[9] 143 S. Ct. 1396.

[10] 143 S. Ct. 1398.

[11] 143 S. Ct. 1402.

[12] 143 S. Ct. 1398.

Authors

Phoebe A. Roth
Senior Associate

Hartford, CT | (860) 275-0145

proth@daypitney.com

Kritika Bharadwaj
Partner

New York, NY | (212) 297-2477

kbharadwaj@daypitney.com

Richard D. Harris
Of Counsel

Hartford, CT | (860) 275-0294

New Haven, CT | (203) 752-5094

rdharris@daypitney.com

William J. Roberts
Partner

Hartford, CT | (860) 275-0184

wroberts@daypitney.com

Mindy S. Tompkins
Partner

Hartford, CT | (860) 275-0139

mtompkins@daypitney.com

Thomas A. Zalewski
Partner

Parsippany, NJ | (973) 966-8115

tzalewski@daypitney.com

Stephanie M. Gomes-Ganhão

Associate

Hartford, CT | (860) 275-0193

sgomesganhao@daypitney.com

John F. Kaschak

Associate

Parsippany, NJ | (973) 966-8034

jkaschak@daypitney.com

Colton J. Kopcik

Associate

Washington, D.C. | (203) 977-7362

ckopcik@daypitney.com