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## Litigation

### Health-Care Attorneys Eyeing Medicare Fraud, Materiality Cases in 2018

Health-care fraud attorneys are looking to federal courts for guidance in 2018 on several legal theories that have been the subject of numerous False Claims Act lawsuits and lower court rulings in recent years.

Chief among these will be the question of whether lack of medical necessity can form the basis of FCA lawsuits, and the extent of FCA liability faced by Medicare Advantage (MA) providers, an issue being examined in a Department of Justice lawsuit against UnitedHealth Group.

Attorneys will be fixated on how a federal appeals court will rule in an FCA case against a hospice company accused of billing Medicare for improper claims. The DOJ suffered a critical blow when a federal district court ruled that a medical expert's disagreement with the clinical judgment used to certify a hospice patient's eligibility can't prove falsity "as a matter of law" without some additional "objective evidence of falsity."

The government appealed the ruling to the U.S. Court of Appeals for the 11th Circuit, which heard oral arguments in the matter on March 16 (*United States v. AseraCare, Inc.*, 11th Cir., No. 16-13004, oral argument 3/17/17). The impending ruling "has tremendous implication for the government's ability to bring cases based on medical necessity," according to S. Craig Holden, a shareholder with Baker, Donelson, Bearman, Caldwell & Berkowitz PC in Baltimore who represents health-care providers facing fraud matters.

The *AseraCare* ruling was "chief" among several FCA medical necessity cases he would be watching in 2018, Waller Lansden Dortch & Davis LLP partner J.D. Thomas in Nashville, Tenn., told Bloomberg Law. A federal court in Alabama granted hospice provider *AseraCare* judgment after ruling that the government's sole evidence of false claim submissions, a medical expert's disagreement with the clinical judgment used to certify *AseraCare* patients' eligibility for hospice care, wasn't sufficient to prove an FCA violation.

Other medical necessity cases include a whistleblower lawsuit against Sava Senior Care (*United States ex rel. Hayward v. SavaSeniorCare, LLC*, M.D. Tenn., No. 11-cv-821, trial scheduled 12/4/18) and Caris Healthcare (*United States ex rel. Binkle v. Caris Healthcare, L.P.*, E.D. Tenn., No. 14-cv-212, trial scheduled 3/25/19), both of which are currently in discovery, but could produce rulings in 2018.

The DOJ has usually tried to avoid medical necessity cases that are "purely a battle of the experts," a feature of the *AseraCare* trial, Stacy C. Gerber Ward, a shareholder at von Briesen & Roper SC in Milwaukee and former DOJ prosecutor, told Bloomberg Law.

The DOJ is likely to try to bolster any medical necessity allegations in future FCA cases with additional investigation into whether any improper kickbacks were also involved, Gerber Ward said. Kickbacks, Gerber Ward added, would provide "a basis independent of the lack of medical necessity" to establish a false claim.

Thomas said the DOJ might continue to bring medical necessity cases in other jurisdictions if it loses *AseraCare*, which could lead to a circuit split on the issue.

**Medicare Advantage Lawsuits** The DOJ's effort in prosecuting health insurance giant UnitedHealth Group for alleged MA fraud is continuing in one of two FCA actions, following the government's dismissal of UnitedHealth from the other action. UnitedHealth is accused of using "one-way" audits (or chart reviews) of its diagnosis code data, which are used to calculate payments for each of an MA insurer's beneficiaries, to increase risk adjustment payments (*United States ex rel. Poehling v. UnitedHealth Grp., Inc.*, C.D. Cal., No. 16-cv-8697, complaint in intervention 5/16/17).

Laurence J. Freedman, a member of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC in Washington, told Bloomberg Law that he was watching the DOJ's approach to the UnitedHealth litigation closely, given reports that the DOJ is investigating other MA insurers.

The UnitedHealth FCA case, which recently saw the insurer file a motion to dismiss, could be "precedent setting" for other MA insurers facing FCA allegations, Holden said.

United is fighting the FCA allegations through its own lawsuit against the Department of Health and Human Services as well, challenging an aspect of Medicare's 60-day repayment rule that MA insurers proactively identify incorrect MA beneficiary diagnostic codes. The U.S. District Court for the District of Columbia is considering competing motions for summary judgment from UnitedHealth and the HHS.

Success for UnitedHealth in this matter could hamper the DOJ's efforts to prosecute its related FCA action against UnitedHealth, as well as call into question whether similar one-way audits at other MA insurers can give rise to actual FCA liability (*UnitedHealthcare Ins. Co. v. Hargan*, D.D.C., No. 16-cv-157, filed 1/29/16).

**Materiality Standard Expanded** Freedman said 2018 will be "a year with significant developments" for courts to further interpret the U.S. Supreme Court's

materiality standard from its 2016 *Universal Health Services* decision.

Drugmakers Gilead Sciences and Pfizer are both facing FCA actions with questions over whether alleged false claims were material to the government's decision to pay the claims at issue.

Gilead saw a trial court win over two whistleblowers reversed July 7 by the U.S. Court of Appeals for the Ninth Circuit, which ruled that material misrepresentations made to the Food and Drug Administration could lead to FCA liability. The Ninth Circuit agreed to stay its decision to send the action back to the trial court until after the Supreme Court decides whether to take up the case.

Pfizer is also facing allegations of off-label marketing and paying illegal physician kickbacks to prescribe its anti-fungal drug Vfend. Questions remain over whether the government's continued payment of Vfend claims after the allegations became known mean that the allegations weren't material under the *Universal Health Services* standard after the U.S. Court of Appeals for the Third Circuit declined to weigh in on the matter. The trial court is currently considering a Pfizer motion for partial summary judgment.

**Off-Label Cases Could Decline** FCA cases premised on off-label marketing allegations will continue to surface in general, Melissa L. Jampol, a member of Epstein Becker & Green's health-care practice in New York, told Bloomberg Law. Jampol expected whistleblowers and the DOJ to continue to pursue these cases "despite numerous losses," including recent wins for Bristol-Myers Squibb in the Sixth Circuit and Solvay Pharmaceuticals in the Fifth Circuit.

The DOJ likely will "pick its spots" to prosecute in this area, but "companies with any conceivable First Amendment argument will want an audience with the top brass at FDA and the Justice Department" during off-label investigations, Scott B. McBride, a partner at Lowenstein Sandler LLP in Roseland, N.J., told Bloomberg Law.

Holden said he believed off-label cases would decline, "given recent rulings on materiality." However, Thomas said off-label cases would continue to be brought, but whistleblowers and the government would adjust to the changes wrought by pharmaceutical company victories.

A decline in off-label and similar "fraud on the FDA" cases going forward could be the result of enforcement efforts deterring company behavior to avoid liability, Thomas said.

Brian J. Markovitz, with Joseph Greenwald & Laake PA in Greenbelt, Md., told Bloomberg Law he expected off-label marketing allegations to be "a continuing source of FCA liability," but "the settlements and verdicts may not be as substantial as in prior years."

**Whistleblower Attorney Perspective** Markovitz, who represents whistleblowers in FCA litigation, expressed similar optimism that medical necessity allegations would continue as well. Medical necessity as a theory of FCA liability "is still an important and necessary tool in order to protect Medicare funds," Markovitz said.

Whistleblowers also will continue raising allegations that skilled nursing facilities manipulate patient data to increase Medicare and Medicaid reimbursements, and submit claims for unnecessary or unreasonable care, Markovitz added.

**Opioid Litigation 'Ramp Up'** Markovitz said he expects a "ramp up" of litigation related to the opioid crisis as well. That sentiment was echoed by several attorneys, including Gerber Ward, who said whistleblowers will look to "join the fray" by bringing FCA cases similar to one settled by long-term care pharmacy provider PharMerica for \$31.5 million in 2015. PharMerica's settlement addressed allegations that the company dispensed controlled narcotics without proper physician authorizations, and pharmacy companies could face similar liability with regard to dispensed opioids.

Thomas and Holden both predicted upticks in state and local government enforcement actions related to opioids, including hiring private attorneys to prosecute these cases. This litigation model was used against tobacco companies, and Thomas said "opioid cases could be the next 'tobacco.'"

Government prosecutors could also bring FCA cases on the theory that opioids were "prescribed and marketed unnecessarily," Thomas said. And, prescribers could be a target of government fraud actions as well, Holden noted.

McBride cautioned there could be "a good amount of [governmental] overreach" as authorities use "every tool in the shed" to hold alleged wrongdoers legally responsible for harms caused by opioids.

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