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Health Care Enforcement Reflections And Forecasts: Part 3


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Law360, New York (January 26, 2016, 12:14 PM ET) -- In part 1 of this three-part series we recapped the 2015 policy developments that will impact health care fraud enforcement going forward. In part 2, we reviewed some of last year's notable cases and criminal prosecutions. To conclude, in part 3 we will provide an overview of some of the most important joint criminal and civil matters, including notable settlements and significant decisions, and a forecast for what to expect in 2016.

Significant Joint Criminal/Civil Matters

Perhaps serving as an early example of the Yates memo in practice, the U.S. Department of Justice reached a notable settlement in October 2015 with pharmaceutical company Warner Chilcott to resolve criminal liability and False Claims Act allegations, and the DOJ simultaneously announced the indictment of Warner Chilcott's former president.

Warner Chilcott Resolution

On Oct. 29, 2015, the United States and Warner Chilcott PLC, together with its subsidiary Warner Chilcott U.S. Sales LLC, reached a global resolution in connection with the allegedly illegal marketing of certain drugs, including Actonel and Atelvia that treat osteoporosis. As further discussed, the settlement included a guilty plea by the subsidiary and a settlement totaling $125 million to resolve criminal liability and civil False Claims Act claims. Additionally, the U.S. charged a former president of Warner Chilcott's pharmaceutical division, W. Carl Reichel, with one count of conspiring to pay kickbacks to physicians to induce them to prescribe Warner Chilcott drugs. Several other individuals had previously pleaded guilty in connection with related activities. See DOJ release 15-1330; see also U.S. v. W. Carl Reichel.

To resolve its criminal exposure, the Warner Chilcott subsidiary pled guilty to a felony count of "paying kickbacks to physicians throughout the U.S. to induce them to prescribe its drugs, manipulating prior authorizations to induce insurance companies to pay for prescriptions of Atelvia that the insurers may not have otherwise paid for, and making unsubstantiated marketing claims for the drug Actonel." See id. Subsidiary employees, at the direction of management, paid remuneration to physicians through (i) "medical education events," held at expensive restaurants, that offered little, if any, education and (ii) speakers' fees for

physicians who often did not speak about clinical topics. Another component of the scheme involved sales representatives filling out and submitting physician prior authorization forms for patients regardless of whether the stated justifications were true. See DOJ release 15-1330.

The civil settlement resolved FCA allegations that Warner Chilcott made false claims to government health care programs and violated the federal anti-kickback statute by paying illegal remuneration to physicians through the medical education events and speaker programs and causing the submission of false prior authorization requests.

In announcing the global resolution of the case and Reich's indictment, Principal Deputy Assistant Attorney General Benjamin Mizer of the Civil Division stated that the DOJ was "committed to protecting the integrity of prescribing physician decisions and ensuring that financial arrangements in the healthcare marketplace comply with the law." In a nod to the Yates memo, he added that the DOJ would "continue to hold companies and responsible individuals accountable when they use improper incentives … to promote their products." See id. Emphasizing the point, the U.S. Attorney for the District of Massachusetts, where the cases were brought, stated that "Today's enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud." See id.

Civil Matters

The DOJ's Aggressive Enforcement Agenda

On Dec. 3, 2015, the DOJ announced that in fiscal year 2015 (Oct. 1, 2014, to Sept. 30, 2015) it obtained more than $3.5 billion in settlements and judgments from civil cases involving fraud and false claims against the government. Of the $3.5 billion, the DOJ reported that $1.9 billion was from cases involving allegations of health care fraud for "allegedly providing unnecessary or inadequate care, paying kickbacks to health care providers to induce the use of certain goods and services, or overcharging for goods and services paid for by Medicare, Medicaid and other federal health care programs." See DOJ press release 15-1478. The DOJ also reported that there were 638 new cases filed under the qui tam provisions of the FCA in FY 2015, and $2.8 billion of the $3.5 billion was recovered in cases filed under the qui tam provisions. From the settlement proceeds of $2.8 billion in these cases, the DOJ awarded qui tam relators $597 million.

In health care fraud matters in particular, the DOJ recovered $1.4 billion in health care cases in which it intervened, and a record $468 million in health care cases in which it declined. Additionally, 423 new qui tam matters alleging health care fraud were filed in FY 2015.

Looking forward to 2016, DOJ Civil Division Deputy Assistant Attorney General Joyce Branda, who had served as the director of the Civil Fraud Section, discussed the Civil Division's enforcement priorities at an American Health Lawyers Association conference in September 2015. She noted the department's renewed focus on individual culpability and reminded the bar that the principles outlined in the Yates memo extend to health care FCA cases.

Branda also described DOJ enforcement priorities as including the following programs, providers, and predicate acts:

- Medicare Advantage Program Payments: The DOJ will be closely scrutinizing allegations of inflated Medicare Advantage plan risk scores.
- Hospice Claims: The DOJ will pursue allegations of hospice providers falsely certifying

individuals for hospice care when they do not meet hospice admission criteria.

- Stark Law Violations: The DOJ is focused on hospital compensation to physicians and is particularly concerned about arrangements with physicians under which they are paid more than fair market value for the services they perform or where compensation from a hospital clearly takes into account the "volume or value" of their referrals.

In addition, Branda noted such other areas of enforcement priority as skilled nursing facilities to ensure that therapy provided to residents is both medically necessary and beneficial, and she emphasized the DOJ's and U.S. Department of Health and Human Services' Office of the Inspector General's (HHS-OIG) increasing use of data analysis in investigations and prosecutions.

Notable Settlements

1. Hospitals and Implantation of Cardiac Devices

Taking a page out of the Medicare Fraud Strike Force's playbook, the DOJ's Civil Division, on Oct. 30, 2015, announced that it had "reached 70 settlements involving 457 hospitals in 43 states for more than $250 million [to resolve False Claims Act allegations] related to cardiac devices that were implanted in Medicare patients in violation of Medicare coverage requirements." See DOJ press release 15-1339. Not surprisingly, the DOJ, the U.S. Attorney's Office for the Southern District of Florida, and the HHS-OIG were partners in this case, which was triggered by a qui tam filing in the Southern District of Florida by a cardiac nurse and a health care reimbursement consultant, who have received $38 million from these settlements.

In announcing the settlements, Mizer stated the philosophy of the Civil Division under his leadership: "While recognizing and respecting physician judgment, the department will hold accountable hospitals and health systems for procedures performed by physicians at their facilities that fail to comply with Medicare billing rules." He added that the department was confident that the settlements would lead to "increased compliance" and result in "significant savings." See id.

2. Clinical Laboratories

Not since the 1990's has the DOJ been as actively and aggressively pursuing allegations against clinical laboratories, including urine drug testing laboratories, cardiovascular laboratories, and traditional blood testing laboratories. In one significant investigation, triggered by multiple qui tam filings, Millennium Laboratories, one of the largest urine drug testing laboratories, agreed in October 2015 to pay $256 million to resolve allegations that it had billed Medicare, Medicaid and other federal health care programs for medically unnecessary drug testing and genetic testing and had provided kickbacks to physicians to induce referrals. See DOJ press release 15-1289. The DOJ reported that this resolution included the payment of $227 million to resolve FCA allegations that Millennium caused physicians to order excessive numbers of urine drug tests, in part through the promotion of "custom profiles," which, instead of being customized for individual patients, were in effect standing orders that resulted in physicians ordering large numbers of tests without individualized assessments of each patient's needs. The DOJ also alleged that Millennium violated the Stark Law and Anti-Kickback Statute by providing physicians with free drug test cups on the express condition that the physicians return the specimens to Millennium for additional testing.

Likewise, as to cardiovascular disease testing laboratories, the DOJ reached some notable settlements. On April 9, 2015, the DOJ reported that, in a case stemming from three qui

tam filings, Health Diagnostics Laboratory Inc. (HDL) and Singulex Inc. agreed to pay $47 million and $1.5 million, respectively, to resolve allegations that they had violated the FCA and the Anti-Kickback Statute by paying remuneration to physicians in the form of processing and handling fees in exchange for patient referrals and by billing federal health care programs for medically unnecessary testing. See DOJ press release 15-431.

3. Pharmaceutical Manufacturers and Specialty Pharmacies

On Nov. 20, 2015, in a head start for FY 2016, the U.S. Attorney for the Southern District of New York announced that Novartis Pharmaceuticals had agreed to a $390 million settlement (including a $20 million civil forfeiture) and to make factual admissions to resolve allegations under the FCA, the Anti-Kickback Statute and state statutes that it gave kickbacks to specialty pharmacies in return for recommending two of its drugs, Exjade, an iron chelation drug, and Myfortic, an anti-rejection drug for kidney transplants. See United States Attorney's Office for the Southern District of New York press release 15-300. This agreement follows settlements in January 2015 and April 2015 in this case with two specialty pharmacies, Bioscrip Inc. and Accredo Health Group, that agreed to pay a total of $75 million to resolve federal and state claims against them based on the same allegations.

This much-watched case had been litigated heavily by the DOJ since April 2013. Consistent with the Southern District's practice and the DOJ's initiative to obtain factual admissions in civil cases where appropriate, Novartis agreed to 33 detailed factual admissions about its relationships and interactions with specialty pharmacies in connection with distribution of Exjade and Myfortic, and in the settlement agreement agreed to "accept responsibility" for this conduct.

4. Stark Law Settlements Involving Physician Compensation from Hospitals

Culminating a number of significant investigations and, in the case of Tuomey, years of litigation, the DOJ, in September and October of 2015, resolved a cluster of cases involving allegations that hospitals had paid compensation to physicians in violation of the Stark Law, thus giving rise to substantial liabilities under the FCA.

On Sept. 4, 2015, the DOJ announced a settlement of $25 million, plus an additional contingent payment of $10 million, with Columbus Regional Healthcare System and a $425,000 settlement with one of its employed physicians to resolve allegations of FCA and Stark Law violations. See DOJ press release 15-1089. This settlement resolved allegations that Columbus Regional compensated its employed physician in excess of fair market value and in excess of the revenue received on services he personally performed. This settlement also resolved allegations that, between 2003 and 2013, Columbus Regional provided excessive salary and directorship payments to a physician that violated the Stark Law.

Shortly after this settlement, on Sept. 15, 2015, the DOJ announced a $69.5 million FCA settlement with North Broward Hospital District based on allegations that a hospital engaged in a scheme of over-compensating physicians in violation of the Stark Law and the FCA. See U.S. Attorney for the Southern District of Florida press release dated Sept. 15, 2015. This civil settlement resolved allegations that the hospital district paid compensation to nine employed physicians that exceeded the fair market value for their services. In that case, the qui tam whistleblower alleged that the compensation to the physicians generated significant losses, which were offset by profits received from those physicians' referrals, and that this compensation arrangement reflected the fact that the hospital district weighed the volume and value of anticipated referrals when setting physician compensation, in violation of the Stark Law. The qui tam whistleblower further alleged that the hospital district generated "contribution margin reports," which continually tracked referral profits, for cardiologists, oncologists and orthopedic surgeons who collected salaries of $1 million and higher.

In short order, on Sept. 21, 2015, the DOJ announced that Adventist Health System agreed to pay $115 million to resolve allegations under the Stark Law and the FCA that Adventist maintained improper compensation arrangements with referring physicians and miscoded claims. See DOJ press release 15-1146. The DOJ alleged that Adventist submitted false claims to the Medicare and Medicaid programs for services rendered to patients referred by employed physicians who received bonuses based on a formula that improperly took into account the value of the physicians' referrals to Adventist hospitals. Not unlike the North Broward Hospital District matter, the qui tam complaints alleged that the overall physician compensation was above fair market value, as evidenced by Adventist's "substantial and consistent losses" on their physician practices, which were tolerated only because Adventist recovered those losses and profited by capturing referrals.

To top off this hat trick, on Oct. 16, 2015, to help kick-off FY 2016 recoveries, the DOJ announced a $72.4 million settlement to resolve a $237 million judgment against Tuomey Healthcare System for billing the Medicare program between 2005 and 2010 for services referred by 19 physicians with whom the hospital had improper financial relationships under the Stark Law. See DOJ press release 15-1285. This settlement resolved litigation that had been ongoing since 2007, when the DOJ intervened in this qui tam action filed in 2005. Under the terms of the settlement agreement, Tuomey will be sold to Palmetto Health, a multi-hospital health care system. The DOJ argued that Tuomey, fearing that it could lose lucrative outpatient procedure referrals to a new freestanding surgery center, had entered into contracts with 19 specialist physicians that required the physicians to refer their outpatient procedures to Tuomey and, in exchange, paid them compensation that exceeded fair market value and included part of the money Tuomey received from Medicare for the referred procedures.

The DOJ retried this case after the Fourth Circuit vacated the district court's initial post-trial judgment in favor of the U.S., and in May 2013 the jury determined that the contracts violated the Stark Law and the FCA and resulted in the submission of false claims in the amount of $39 million. On Oct. 2, 2013, the trial court entered an FCA judgment in favor of the U.S. for more than $237 million, based on trebling the damages plus civil penalties of $5,500 per claim for over 21,000 claims. The U.S. Court of Appeals for the Fourth Circuit affirmed the judgment on July 2, 2015.

5. DaVita

In the DOJ's year-end press release, it noted the settlement in June 2015 with DaVita HealthCare Partners Inc., the largest provider of dialysis services in the U.S., under which DaVita agreed to pay $450 million in a declined case to resolve allegations that it knowingly generated and billed the government for "unnecessary waste" in administering the drugs Zemplar and Venofer to dialysis patients, see DOJ press release, 15-797. This settlement terminated years of litigation between DaVita and the qui tam relators who brought the action and represents one of the most significant recoveries in a declined qui tam case. The DOJ also noted a settlement with DaVita in the amount of $350 million to resolve allegations under the FCA that it violated the Anti-Kickback Statute with respect to physician ownership in its dialysis centers. See DOJ press release, 14-1167.

Selected Significant Decisions

1. Wartime Statute of Limitations and First-to-File Bar

Once again, the U.S. Supreme Court weighed in this term on FCA issues, this time to clarify a provision of the FCA and decide once and for all what "pending" means in the context of the "first to file" rule, and to determine whether the Wartime Suspension of Limitations Act (WSLA) has tolled civil actions under the FCA since the Authorization for Use of Military Force Against Iraq Resolution of 2002, as the Fourth Circuit held.

On May 26, 2015, in Kellogg Brown & Root Services Inc. v. United States ex rel. Carter, the Supreme Court unanimously held that the WSLA does not toll the statute of limitations for civil actions under the FCA. Instead, the court held that the WSLA, which tolls claims for "any offense" involving fraud against the federal government, applies only to criminal offenses. The FCA has a six-year statute of limitations, with a discovery rule exception that permits claims to be brought for up to 10 years. Under the DOJ interpretation, which it argued before the court, the WSLA's tolling for FCA actions would have been triggered by the Authorization for Use of Military Force Against Iraq Resolution of 2002, and thus would have permitted the DOJ or relators to bring actions going back to 1996, or even earlier.

The court also settled a split between the U.S. Courts of Appeals for the D.C. Circuit and the Fourth Circuit regarding the "first to file" bar in the FCA. The qui tam provisions of the FCA provide that "no other person other than the government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The Supreme Court considered only the ordinary meaning of the word "pending" and decided that a dismissed FCA case is not a "pending" case. Thus, the court explained, a later FCA action is not barred simply because an earlier, but now dismissed, FCA action based on the same underlying facts had been filed.

2. Statistical Sampling to Prove Liability under the FCA

Perhaps one of the most significant FCA issues percolating in federal courts this year is whether statistical sampling of claims, and extrapolation of that sampling, can be used to prove liability under the FCA. The Court of Appeals for the Fourth Circuit, on Sept. 29, 2015, agreed to hear an appeal that will address whether statistical sampling can be used in this fashion. United States ex rel. Michaels et al. v. Agape Senior Community Inc.

This appeal is of critical importance to the government's and relator's ability to prove liability in FCA cases that often allege tens of thousands of individual Medicare claims. Recently, a number of district courts have permitted, at least at the motion to dismiss stage, such use of sampling and extrapolation, even though typically these tools have been employed only for proving FCA damages.

If the DOJ and relators are permitted to prove FCA liability by taking a relatively small sample of claims, demonstrating "falsity" and "knowledge" as to some of those claims, and then extrapolating the "error rate" to a large universe of claims, defendants in these cases will potentially be subject to enormous liabilities for claims that are never specifically identified and that cannot be individually defended.

The DOJ seeks to have the litigation and trial tools to demonstrate that no alleged fraud is "too big to prove," and argues that providers should not have the incentive to submit false claims on a large scale. However, the use of statistical sampling to prove liability under the FCA, a quasi-criminal statute, seems to run counter to the statute's requirements that attach very significant liability for the "knowing" submission of a "false" or "fraudulent" claim, which in cases involving allegations of unnecessary services based on medical records is inherently individualized.

3. Implied False Certification

Once again, the U.S. Supreme Court has taken on an FCA case, this time to consider a core theory of liability under the FCA, as compared to some of the more procedural issues it has ruled on in recent terms. On Dec. 4, 2015, the Supreme Court granted certiorari in Universal Health Services Inc. v. United States ex rel. Escobar to review whether the "implied false certification" theory of legal falsity under the FCA is a viable theory of liability and, if so, whether a claim can be legally "false" under that theory if the provider failed to comply with a statute, regulation or contractual provision that does not explicitly state that it is a condition of payment.

The DOJ embraces and relies on this theory in a wide range of cases under the FCA, and it underlies a wide swath of allegations by relators in qui tam filings. A decision by the Supreme Court, expected before the end of the term, typically in late June, could have a substantial impact on investigations and litigation in health care matters under the FCA.

Conclusion

As in past years, 2015 saw health care enforcement continue unabated. On both the criminal and civil sides, federal prosecutors emphasized their ongoing cooperation with each other, including on qui tam cases, and their commitment to holding individuals accountable. An important counterpoint, however, is the government's views about compliance, which offer important guidance about potential risk reduction. And 2016 could see significant appellate decisions about the scope of the FCA and proving cases under it. These decisions will be important as, at least for now, the FCA and its qui tam provisions remain the government's most potent enforcement tool.

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