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Health Care Enforcement Reflections And Forecasts: Part 2


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Law360, New York (January 25, 2016, 2:56 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. Here, in part 2, we review some of last year's notable cases and criminal prosecutions.

Criminal Prosecutions

Medicare Fraud and Related Offenses

In 2009, the U.S. Department Of Justice and the U.S. Department of Health and Human Services kicked off the Health Care Fraud Prevention & Enforcement Action Team (or HEAT), "focus[ing] their efforts to prevent and deter fraud and enforce current anti-fraud laws around the country." See DOJ press release 15-757. HEAT built upon the Medicare Fraud Strike Force that had been initiated a few years earlier. The strike force approach employs multiagency cooperation and a variety of investigative techniques harkening back to those used by the DOJ's organized crime task force to interdict a large swath of perpetrators for a variety of health care-related crimes in the targeted cities. See Rohde, B., New York Law Journal, "The Strike Force Approach to Combatting Health Care Fraud," Feb. 10, 2014.

These efforts have been increasingly effective. As the DOJ reported in a recent press release, "[s]ince its inception in March 2007, the Medicare Fraud Strike Force, now operating in nine cities across the country, has charged nearly 2,300 defendants who have collectively billed the Medicare program for more than $7 billion. In addition, the HHS Centers for Medicare and Medicaid Services, working in conjunction with the HHS-[Office of Inspector General], is taking steps to increase accountability and decrease the presence of fraudulent providers." See DOJ press release 15-1370. This reflects the charging in 2015 of approximately 300 defendants for collectively billing Medicare approximately $1 billion.

Takeaways from 2015 include:

- Hot Spot Venues Targeted: The DOJ and its partners continued to bring cases across the country in jurisdictions with allegedly high levels of Medicare fraud, including California, Florida, Louisiana, Michigan, New York and Texas. The Southern District of

Florida remained a particularly active venue for these cases. The Central District of California remained a locus of durable medical equipment fraud prosecutions.

- Licensed Health Care Professionals Increasingly Prosecuted: The DOJ and its partners regularly prosecuted doctors, nurses and other medical professionals.

- Health Care and Financial Crimes Charged: Cases typically included charges of conspiracy to commit health care fraud, the related substantive offense or anti-kickback statute violations, with other crimes such as money laundering or identity theft sometimes rounding out the alleged criminal conduct.

- Long Prison Terms and Other Penalties Obtained: Sentences included lengthy prison terms, as well as fines, restitution and forfeiture. Collateral consequences included exclusion from Medicare, Medicaid and other federal and state health programs. CMS suspended a number of providers using its Affordable Care Act authority.

Some examples of these trends included the following:

1. The Medicare Fraud Strike Force conducted the largest coordinated nationwide takedown in DOJ history.

In June 2015, the strike force conducted its annual nationwide takedown, the eighth in its history. Specifically, U.S. Attorney General Loretta Lynch and HHS Secretary Sylvia Mathews Burwell announced charges against 243 defendants in 17 federal districts for allegedly participating in Medicare fraud schemes involving approximately $712 million in false billings. The defendants included doctors, nurses and other licensed medical professionals (46 of the total defendants); home health care providers; pharmacy owners; and patient recruiters. The charges were based on "alleged fraud schemes involving various medical treatments and services, including home health care, psychotherapy, physical and occupational therapy, durable medical equipment, and pharmacy fraud. More than 44 of the defendants arrested [were] charged with fraud related to the Medicare prescription drug benefit program known as Part D," which was described as "the fastest growing component of the Medicare program overall." See DOJ press release 15-757; see also, e.g., Justice News, Attorney General Loretta Lynch Delivers Remarks at the Press Conference to Announce a National Medicare Fraud Takedown, June 18, 2015; Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the Press Conference to Announce a National Medicare Fraud Takedown," June 18, 2015.

The 2015 annual nationwide takedown merits careful scrutiny. From one year to the next, the total dollar amount of alleged false billings in the numerous Medicare fraud cases comprising the nationwide takedown typically rises. For example, alleged false billings grew from $223 million in 2013 to $260 million in 2014. Notably, the Medicare fraud cases interdicted as part of the 2015 takedown totaled approximately $712 million, marking an almost threefold increase. The number of individual defendants rose to 243 from 89 in the 2013 takedown and 90 in the 2014 takedown. Forty-six of the 2015 defendants were licensed medical professionals, compared to 27 in 2014. (The press release for the 2013 takedown did not identify the number of licensed medical professionals charged that year.) Compare DOJ press release 15-757 to DOJ press releases 14-503 and 13-553.

Viewed another way, the Miami portion alone of the 2015 takedown, with 73 defendants and approximately $263 million in false billings, was on par with the entirety of last year's nationwide takedown. Compare DOJ press release 15-757 to DOJ press release 14-503.

Aside from remarking on the historic size of the 2015 takedown, high-level officials at the DOJ and the HHS made other notable comments. Both Burwell and Assistant Attorney General Leslie Caldwell spoke about preventing fraud before it starts, catching fraud at an

earlier stage, and better detecting and fighting fraud. They also noted that health care enforcement efforts more than pay for themselves. See DOJ press release 15-757. With this measure of success, we can expect to see a continuation and strengthening of these efforts in 2016.

2. Licensed medical professionals were front and center in health care fraud prosecutions.

For the last few years, the DOJ's highest level officials have repeatedly said that doctors, nurses and other licensed medical professionals will be prosecuted to the fullest extent of the law if they are involved in health care fraud. In connection with the annual nationwide takedown, Caldwell specifically noted that the DOJ was "really focusing on bringing corrupt medical professionals in particular, as well as their accomplices, to justice more quickly than ever." Justice News, Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the Press Conference to Announce a National Medicare Fraud Takedown, June 18, 2015.

In 2015, the strike force pursued a number of cases against licensed medical professionals in addition to those that were part of the annual nationwide takedown. A representative case is highlighted below.

In the culmination of a case tried in March 2014, two physician owners of Spectrum Care PA, a community mental health clinic in Houston purportedly providing partial hospitalization program (PHP) services, were sentenced in January 2015 for their roles in a $97 million Medicare fraud scheme. According to the DOJ, the evidence at trial showed that Drs. Mansour Sanjar and Cyrus Sajadi signed documents certifying that patients qualified for PHP services when they did not, in fact, qualify for or need such services.

The evidence allegedly showed that the doctors billed Medicare for these services, as well as for recreational activities that were not covered by Medicare, and that they paid kickbacks to group care operators and patient recruiters. Sanjar was sentenced to 148 months in prison, and Sajadi was sentenced to 120 months in prison; both were ordered to pay over $8 million in restitution. Other participants in the scheme have also been prosecuted and sentenced to prison time and financial penalties. See DOJ press release 15-033.

In announcing the sentences of Sanjar and Sajadi, Caldwell observed that: "Doctors are not only bound by oath to serve the health of their patients, they are bound by duty to serve as gatekeepers for Medicare spending. In this case, without the criminal participation of Sanjar and Sajadi, this fraud simply could not have happened." Id.

Securities Fraud

In an April 2015 speech at New York University regarding the role of criminal law enforcement in addressing conduct that may also be subject to regulatory enforcement, Caldwell drew upon the securities fraud prosecution of ArthroCare Corp., which we have chronicled in our last two year-in-review reports, to illustrate her view that criminal prosecution is the best way to punish culpable individuals. See Justice News, Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the New York University Center on the Administration of Criminal Law's Seventh Annual Conference on Regulatory Offenses and Criminal Law, April 14, 2015.

To briefly recap, ArthroCare is a publicly traded medical device manufacturer based in Texas. In January 2014, the DOJ announced that ArthroCare had agreed to pay a $30 million monetary penalty to resolve charges that senior executives had engaged in a securities fraud scheme that involved inflating the company's earnings through end-of-quarter shipments to distributors and resulted in more than $400 million in shareholder losses. The DOJ filed a criminal information against the company, charging one count of conspiracy to commit securities and wire fraud, which the company resolved by entering

into a deferred prosecution agreement with the government.

In addition to the monetary penalty, the company agreed to cooperate in the continuing investigation and prosecution of its executives and to implement an enhanced compliance program and internal controls designed to prevent and detect violation of federal laws through its relationships with health care providers. See Foster, H. and Rohde, B., Mintz Levin alert, Health Care Enforcement in 2015: A Look back on 2014 and Forecasting the Year Ahead (citing DOJ press release 14-013).

In spring 2014, ArthroCare's former CEO and CFO went to trial and were convicted of conspiracy, securities fraud and wire fraud; the CEO was also convicted of false statements to the U.S. Securities and Exchange Commission. In August 2014, the former CEO was sentenced to 20 years in prison and the former CFO was sentenced to 10 years in prison. Other former senior executives, who had pled guilty to participating in the scheme, were sentenced to lesser but still significant prison terms. See id. (citing DOJ press releases 14-588 and 14-923).

Wrapping up her speech at NYU, and punctuating what she believes to be the advantages of criminal prosecution, Caldwell singled out the ArthroCare case. She stated, "[t]hat case — involving egregious accounting fraud and where one of the defendants lied during a SEC deposition — shows the role that criminal prosecution can play in holding individuals accountable for their criminal conduct." See Justice News, Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the New York University Center on the Administration of Criminal Law's Seventh Annual Conference on Regulatory Offenses and Criminal Law, April 14, 2015.

Upcoming securities fraud cases in the health care space will likely look like ArthroCare.

Global Anti-Corruption

The SEC brought a notable Foreign Corrupt Practices Act (FCPA) case involving the New York-based pharmaceutical company, Bristol-Myers Squibb, based on conduct by a Chinese affiliate. The DOJ did not bring a criminal case against the U.S. company. We discuss the Bristol-Myers Squibb case and the DOJ, SEC and global health care enforcement, below.

1. Bristol- Myers Squibb

In October 2015, the SEC announced that Bristol-Myers Squibb had agreed to pay more than $14 million to settle alleged violations by BMS and its majority-owned joint venture operating in China (BMS China) of the internal controls and record-keeping provisions of the FCPA. BMS did not admit or deny the SEC's findings. See In the Matter of Bristol-Myers Squibb Company, Securities and Exchange Act Release No. 76073, Oct. 5, 2015, (the "SEC's Cease-and-Desist Order" or the "Order"); see also SEC release 2015-229.

According to the SEC's cease-and-desist order, certain BMS China employees provided cash and other inducements to foreign officials such as health care providers at state-owned and state-controlled hospitals to generate prescription sales. The relevant transactions were then falsely recorded as legitimate business expenses in the BMS/BMS China books and records. See the SEC's cease-and-desist order.

The order emphasized a number of perceived BMS/BMS China deficiencies, beginning with a failure to respond to red flags indicating that the improper payments were being made. The red flags included documents such as "noncompliant claims, fake and altered invoices and receipts, and consecutively numbered receipts," id. at 3, that BMS China had identified through an internal review of travel and entertainment expenses submitted for reimbursement. The results of this internal review, as well as of monthly post-payment reviews of false or unsubstantiated claims conducted by a local accounting firm, were

provided to BMS China management and to compliance managers who reported to senior management at BMS. See id.

The order additionally stated that BMS China employees admitted they submitted false reimbursement claims and used the funds to make the improper payments, and terminated employees sent emails to the BMS China president about the necessity of providing incentives to meet sales targets. BMS China nonetheless did not investigate. See id. The order also noted BMS's failure to: implement a formal FCPA compliance program until 2006, despite having begun operations in China many years earlier; have appropriate compliance professionals in place, and training available, until even later; and remediate controls deficiencies in a timely manner. See id. at 4.

Despite focusing on these early compliance weaknesses, the order noted that BMS "implemented significant measures to enhance its anti-bribery and general compliance training and policies and to strengthen its accounting and monitoring controls relating to interactions with health care providers ... " Id. at 6. Examples of these efforts included 100 percent prereimbursement review of all expense claims; implementation of an accounting program to track each expense claim and the retention of a third-party vendor to conduct surprise checks at sales representative-sponsored events. BMS also terminated over 90 BMS China employees, disciplined an additional 90, and replaced certain officers in order to enhance the tone at the top and overall culture of compliance. Notably, BMS revised the compensation structure for BMS China employees to reduce the portion of incentive-based compensation for sales and distribution. See id.

Based on all the circumstances, the settlement of the books and records, and internal controls related allegations required disgorgement, prejudgment interest, a civil penalty totaling over $14 million, and prompt reporting of any questionable or corrupt payments or transfers and submission over the subsequent two-year period of three status reports regarding FCPA and anti-corruption remediation and compliance implementation. See id. at 7-9.

Following the resolution with the SEC, the DOJ advised BMS that it had closed its related FCPA investigation. See Form 10-Q filed by Bristol-Myers Squibb Company on Oct. 27, 2015, at page 23. The DOJ does not appear to have publicly commented about this decision or its underlying rationale.

Nonetheless, the conduct and remediation by BMS set forth in the SEC cease-and-desist order, as well as the resolution of the SEC matter with a fine and self-monitoring and the closing of the DOJ's criminal investigation, brings into sharp focus how these government entities expect companies to conduct themselves: (1) identify and heed red flags, investigate them, undertake appropriate remediation and (2) develop and maintain a robust compliance program fine-tuned to the risks presented by a company's business.

The better this self-policing is, the better any resolution with the government will be if misconduct nonetheless occurs. For example, if BMS had instituted an appropriate compliance program earlier and jumped on the red flags, perhaps its resolution with the SEC would have been less onerous, carrying an even more modest financial penalty. On the other hand, had it not undertaken the extensive remediation set forth in the order, BMS might have faced a stiffer penalty, and perhaps an external monitor, and the DOJ might not have closed its investigation without exacting its own penalty. The takeaway is to pay attention to the government's often repeated message that compliance efforts are a key factor in the government's decision-making about the appropriate resolution of corporate wrongdoing.

2. A Note on the DOJ, the SEC, the FCPA and Health care Enforcement

Last year, we reported on the November 2014 agreement by Bio-Rad Laboratories Inc., a

California-based medical diagnostics and life sciences manufacturing and sales company, to pay $14.35 million to the DOJ to resolve allegations that it had violated the FCPA's books and records and internal controls provision in connection with a French subsidiary paying commissions to intermediary companies purportedly in exchange for services in connection with government sales in Russia. High-level managers allegedly approved the commission payments even though they knew that the services had not been provided. Bio-Rad also agreed to disgorge $40.7 million to the SEC. See Foster, H. and Rohde, B., Mintz Levin alert, Health Care Enforcement in 2015: A Look back on 2014 and Forecasting the Year Ahead (citing DOJ press release 14-1221 and SEC release 2014-245).

Caldwell used the announcement of the Bio-Rad resolution early in her tenure as an occasion to explain the circumstances under which the DOJ may give credit, such as a nonprosecution agreement, to a corporation. The circumstances that she mentioned included self-disclosure of wrongdoing, making U.S. and foreign employees available for interviews, voluntarily producing documents from overseas, summarizing investigative findings, enhancing anti-corruption policies globally, improving compliance and internal controls, and conducting extensive training. See id.

She has repeated her message of cooperation and compliance many times in the ensuing year, driving home the importance of these two factors which are within a company's control even after alleged wrongdoing has occurred. Caldwell has also addressed the question of why the DOJ pursues criminal prosecutions to address corporate fraud, given the availability of regulatory enforcement and civil actions. She has said that the DOJ prosecutes cases criminally because of the perceived egregious nature and extent of the conduct, its view that the conduct was undertaken knowingly and willfully and, with respect to culpable individuals, the punitive and deterrent effect of incarceration on others. She also added that cases involving other types of facts and circumstances may be best resolved by means other than criminal prosecution. See Justice News, Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the New York University Center on the Administration of Criminal Law's Seventh Annual Conference on Regulatory Offenses and Criminal Law, April 14, 2015.

While the DOJ did not release a statement as to why it closed its FCPA investigation of BMS, it likely performed this type of analysis and determined that, under all the facts and circumstances, the SEC enforcement action was the appropriate response to BMS's alleged conduct.

Examining FCPA cases brought against health care companies and how they are resolved helps to explain the DOJ's decision-making process. Among other things, the DOJ appears to consider whether regulatory or other action is sufficient under the circumstances. Moreover, while compliance is not a legal defense, a robust compliance program addressing company-specific risks (or line of business-specific risks for a larger company) that is implemented, enforced and refined in response to evolving circumstances is likely to go a long way in affecting: (1) whether the government charges a criminal violation, (2) the type of resolution that the government is willing to agree to, and (3) the consequences of such resolutions.

In part 3 of this series, we will provide an overview of some of the year's most important joint criminal and civil matters, including notable settlements and significant decisions, and a forecast for what to expect in 2016.

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