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The Strike Force Approach To Combatting Health Care Fraud

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The U.S. Department of Justice (DOJ), Health and Human Services Office of Inspector General (HHS-OIG) and other federal and state agencies are aggressively prosecuting health care fraud and related offenses through a strike force approach that has its roots in DOJ's historic efforts to combat traditional organized crime (or "La Cosa Nostra"). As DOJ has advised in recent press releases, this approach has been highly impactful in the health care space:

Since its inception in March 2007, the Medicare Fraud Strike Force, now operating in nine cities across the country, has charged more than 1,700 defendants who collectively have billed the Medicare program for more than \$5.5 billion. In addition, HHS's Center for Medicare and Medicaid Services, working in conjunction with HHS-OIG, is taking steps to increase accountability and decrease the presence of fraudulent providers.¹

Below, we look at the historic organized crime strike force program, the evolution of the Medicare Fraud Strike Force (MFSF) and MFSF's current approach and seemingly everincreasing productivity.

Historic Organized Crime Strike Forces

In the 1960s, to address the long-ignored presence of organized crime and its numerous



rackets, DOJ developed an organized crime strike force program in which teams of prosecutors in cities across the country focused on the families of La Cosa Nostra operating in their local geographic jurisdictions. These prosecutors worked in partnership with investigators from a variety of federal agencies, and, sometimes local law enforcement as well. Investigations were long-term efforts, as the teams of prosecutors and agents gathered intelligence through confidential sources, electronic surveillance and other investigative techniques, and methodically built broad, deep and impactful cases.

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Early on, DOJ touted the success of its organized crime strike forces in much the same way as it now does the success of MFSF: "Individuals indicted during 1968 as a result of strike force strategy numbered 71 in Brooklyn, 67 in Detroit, 34 in Buffalo, 12 in Chicago and 5 in Philadelphia."

At the time of the merger of the strike forces with local U.S. Attorneys Offices in 1990, there were 14 strike forces across the country, located in Brooklyn, Buffalo, Chicago, Cleveland, Detroit, Kansas City, Las Vegas, Los Angeles, Miami, New Orleans and San Francisco.³

The success of the organized crime strike force approach (and continuing efforts of the U.S. Attorneys' Offices) was incontrovertible. Waves of prosecutions relentlessly taking down the successive hierarchies of the five New York City-based families of La Cosa Nostra is one of the more memorable local examples. While perhaps surprising at first blush, the use of a variation on this approach to combat white-collar crime, including health care fraud, now seems a logical, even inevitable, law enforcement strategy.

The Birth and Evolution of the MFSM

MFSF was initiated in March 2007, in what came to be Phase One, in the Southern District of Florida (Miami). A year later, in March 2008, Phase Two was kicked off in the Central District of California (Los Angeles). As part of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, a joint effort by DOJ and HHS, in 2009, MFSF expanded to Detroit, Houston, Brooklyn, Tampa and Baton Rouge. In 2011, the program expanded to the total of nine cities it is today, by adding Dallas and Chicago.

Phase One of MFSF was announced in connection with a May 2007 takedown in the Southern District in Florida involving the indictment of organizations and individuals in connection with allegedly conspiring to defraud the Medicare program, making false claims and violating the anti-kickback statute. Thirty-eight individuals were arrested. Collectively, approximately \$142 million was allegedly billed in Medicare. MFSF was then described as "a multi-agency team of federal, state and local investigators designed specifically to combat Medicare fraud through the use of real-time analysis of Medicare billing data," focusing on schemes involving infusion therapy and durable medical equipment (DMEs).4

MFSF became much more. There was the noted expansion to nine cities. In addition to takedowns of discreet cases in particular cit-

ies, in late 2009, MFSF began conducting periodic nationwide takedowns, with individuals being arrested in a number of cities simultaneously in connection with healthcare-related offenses. A July 2010 nationwide takedown appears to be the largest such takedown to date, with the arrest of 94 individuals across the country for allegedly participating in schemes to submit approximately \$251 million in Medicare claims.⁵

Over the years that MFSF has been in existence, it has utilized other hallmarks of the strike force approach to fighting organized crime besides multi-agency cooperation and sprawling takedowns, including employing electronic surveillance techniques, expanding the range of crimes charged, obtaining (and issuing press releases regarding) long prison sentences imposed on individuals, and even having "most wanted" healthcare fugitives. Penalties of fines, forfeiture and restitution have been utilized to recoup public monies and disincentivize fraudsters.

In addition to takedowns of discreet cases in particular cities, in late 2009, the Medicare Fraud Strike Force began conducting periodic nationwide takedowns, with individuals being arrested in a number of cities simultaneously in connection with healthcare-related offenses.

The Current Look of MFSF Cases

A review of MFSF prosecutions in 2013 provides numerous insights into the increasingly broad scope and continuing effectiveness of the strike force approach to combatting healthcare fraud:

Many Venues of Prosecution. DOJ and its partners brought cases across the country, including in California, Florida, Illinois, Louisiana, Michigan, New York, Pennsylvania, Texas and Utah. Certain federal districts had a particularly high concentration of MFSF cases, including the Southern District of Florida, Eastern District of Michigan and Central District of California.

Variety of Health Care Providers Targeted. Cases targeted executives of a health

maintenance organization; the owner/operator of an oncology center; the medical director of a hospice; the owner and program coordinator of an adult day care center; owners and others associated with partial hospitalization programs (PHPs); owners and others associated with home health care agencies; owners and others associated with DMEs; owners of ambulance services; and doctors, registered nurses and other medical professionals.

Types of Crimes Charged. Charges included healthcare fraud for submitting false and fraudulent claims to Medicare, violations of the antikickback statute, and, in some recent cases, money laundering.

Wide-ranging penalties. Sentences included the imposition of lengthy prison terms; fines, restitution, and forfeiture; exclusions from Medicare, Medicaid and other federal and state health programs; and compliance requirements.

Some specific matters further illustrate the scope of MFSF's efforts and its results.

- 1. May 2013 Nationwide Takedown. As noted above, MFSF's sixth nationwide takedown took place in May 2013. DOJ and HHS announced arrests in eight cities of 89 individuals, including health care company owners, doctors, nurses and other licensed medical professionals, for allegedly participating in Medicare fraud schemes involving approximately \$223 million in billings. Schemes involved billings for home health care, mental health services, psychotherapy, occupational and physical therapy, and pharmacy fraud, as well as infusion therapy and DMEs. Charges included conspiracy to commit health care fraud, violations of the anti-kickback statute and money laundering.⁶
- 2. Multi-million Medicare Fraud Scheme involving Brooklyn Clinic. In addition to the nationwide takedown, MFSF also brought or continued to prosecute individual cases that further illustrate the strike force approach and its results. One illuminating local example is a case charging a \$77 million Medicare fraud scheme involving a Brooklyn, New York clinic. The owner and employees of the clinic allegedly paid kickbacks to Medicare beneficiaries and used the beneficiaries' names to bill Medicare for services that were medically unnecessary or never provided. The kickbacks were allegedly paid so that beneficiaries would keep quiet about services that were not provided or would acquiesce to treatment that was unnecessary. A network of money launderers was allegedly used to generate the cash needed for the kickbacks.7

As of late last year, 13 individuals had been convicted in connection with the multi-million

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scheme. The owner of the clinic, who pled guilty to one count of conspiracy to commit money laundering, was sentenced to 15 years in prison and ordered to pay approximately \$51 million in restitution and \$36 million in forfeiture. Another participant—an individual described as a "noshow" doctor who allegedly let the clinic use his Medicare billing number and rarely visited the clinic except to pick up his check-was sentenced to more than 12 years in prison, ordered to pay over \$50 million in restitution and another half million in forfeiture and was excluded from Medicare, Medicaid and federal health programs; additionally, New York state revoked his medical license. An individual who "impersonated" the doctor—signing medical charts and prescriptions in the doctor's name and performing medical procedures on patients even though he was not a doctor-was sentenced to eight years in prison, as well as restitution, forfeiture and program exclusions. Among those awaiting sentencing is an individual who pled guilty to laundering the proceeds of the health care fraud through a number of shell companies and bank accounts.8

In addition to the dollar amount of the fraud scheme, the inclusion of money laundering charges and the variety and size of penalties, this case is notable because the government utilized investigative techniques historically used to investigate organized crime and, in more recent years, investigate insider trading. Specifically, the government stated in press releases regarding this case that it employed a courtauthorized audio/video device concealed in a room at the clinic where conspirators gave cash to Medicare beneficiaries. Fitting in with the organized crime analogy, the room included "a Soviet-era poster of a woman with a finger to her lips and the words 'Don't Gossip' in Russian."

Effect of Strike Force Approach

As indicated above, in 2009, DOJ and HHS formed the Health Care Fraud Prevention and Enforcement Action Team, or HEAT, which includes the strike force efforts but is more expansive. For one, HEAT is also responsible for many significant civil enforcement actions resulting in multi-million dollar settlements over the last few years. These civil enforcement actions are developed and prosecuted using what can fairly be referred to as a modified strike force approach. DOJ and HHS, often in conjunction with one or more federal or state partner, work cooperatively to investigate and bring expansive cases against pharmaceutical or medical device companies

charging violations of the False Claims Act, Food Drug and Cosmetics Act, the anti-kick-back statute or other laws and regulations. Commonly, based on a qui tam complaint, an investigation will target specified conduct like off-label marketing of pharmaceuticals or introduction of adulterated drugs into commerce, seek monetary penalties and require remediation of the violations and adherence to a compliance protocol going forward.

A case in point from 2013 involved Johnson & Johnson. On Nov. 4, 2013, DOJ announced a deal requiring Johnson & Johnson and three of its subsidiaries to pay more than \$2.2 billion to resolve criminal exposure and civil liability arising from marketing prescription drugs for uses not approved as safe and effective by the Food & Drug Administration (FDA), as well as for paying kickbacks to doctors and the country's largest long-term care pharmacy provider for prescribing and promoting these drugs. ¹⁰

To address its criminal exposure, on November 7, Johnson & Johnson subsidiary Janssen Pharmaceuticals Incorporated pled guilty to a misdemeanor charge of misbranding, in violation of the FDCA, in the U.S. District Court for the Eastern District of Pennsylvania. Specifically, Janssen was alleged to have introduced the drug Risperdal into the market for unapproved uses from March 2002 through December 2003, namely treating behaviors of elderly, non-schizophrenic patients suffering from dementia, when it had been approved only for the treatment of schizophrenia; the criminal fines and forfeiture component of the criminal resolution is \$400 million.¹¹

Civil lawsuits similarly claimed that Johnson & Johnson and Janssen promoted Risperdal to doctors and nursing homes for unapproved uses in the elderly, children and mental disabled. A complaint in the Eastern District of Pennsylvania specifically alleged that the FDA repeatedly advised Janssen that marketing Risperdal as safe and effective for the elderly would be misleading. It also alleged that Janssen downplayed health risks to the elderly posed by Risperdal and improperly promoted its use in children. Speaker fees were allegedly paid to doctors to encourage them to write prescriptions. In addition, Johnson & Johnson and Janssen allegedly engaged in off-label promotion of a newer anti-psychotic drug, Invega.¹²

Johnson & Johnson and Janssen agreed to pay over \$1.2 billion to resolve civil liability under the False Claims Act in relation to Risperdal and Invega. In addition, Johnson & Johnson agreed to pay another \$149 million in connection with the alleged kickbacks that were allegedly paid to the large long-term care pharmacy.¹³

An additional component of the resolution was a five-year Corporate Integrity Agreement, described as requiring major changes to the way Johnson & Johnson's pharmaceutical subsidiaries do business. Annual compliance certifications are required by certain management employees and board members. As the government stated, "[t]his agreement is designed to increase accountability and transparency and prevent future fraud and abuse." ¹⁴

A telling remark by U.S. Attorney General Holder Eric Holder, who delivered remarks at the press conference on this resolution, is that pharmacists, who were supposed to be "gate-keepers" providing independent review of patient medications, instead recommended the drugs for unapproved uses at the companies' request.¹⁵

Conclusion

In 2014, MFSF is in full flower. There is every reason to expect the strike force approach to be utilized for the foreseeable future, unless and until health care fraud significantly diminishes as a public concern. The specific cases arising from MSFS' efforts in 2013 can help drive risk assessments and fine-tuning of compliance programs to avoid repeating the expensive mistakes made by some in the health care industry in the past. The resolutions of these cases serve as a reminder of the need to prioritize compliance.

- 1. See, e.g., DOJ press release 13-1283.
- "United States Attorneys Bulletin, Vol. 17, No. 2 (Executive Office for U.S. Attorneys, Department of Justice, Washington, D.C., Jan. 10, 1969).

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- 3. See The New York Times, "Mafia Prosecutors Quitting as Strike Forces Disband," Jan. 4, 1990.
 - 4. See, e.g., DOJ press release 07-339.
 - 5. See Holder speech of July 16, 2010.
- 6. See DOJ press release 13-553.
- 7. See, e.g., DOJ release 13-1207.
- 8. See DOJ press releases 13-865, 13-1032 and 13-1207.
- 9. See, e.g., DOJ release 13-1207.
- 10. See DOJ release 13-1170.
- 11. See *U.S. v. Janssen*, Criminal No. 13-cr-00605 (TJS) (E.D. Pa).
- 12. See DOJ release 13-1170; see also *U.S. ex rel. Barry v. Janssen*, Civil Action 10-cv-0098.
- 13. See DOJ release 13-1170; Holder Remarks of Nov. 4, 2013; see also *U.S. ex rel. Lisitza and Kammerer*, Civil Action Nos. 07-10288 and 05-11518 (D. Mass.).
 - 14. DOJ release 13-1170.
 - 15. See Holder Remarks of Nov. 4, 2013.

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