AHLA

The New Era of Individual Responsibility in Health Care Fraud and Abuse

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Introduction

Over the last two decades, the U.S. Department of Justice (DOJ) and the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) have honed in on combating health care fraud and abuse. Indeed, in 1997, DOJ and OIG joined forces to create the Healthcare Fraud and Abuse Control Program, which has been able to recover over $27.8 billion of taxpayer money to the Medicare Trust Fund by the end of Fiscal Year 2014.[1] Historically, DOJ and OIG's primary focus in its health care fraud and abuse efforts has been to seek enforcements against corporate health care entities rather than individuals. This entity-centric focus represented a lack of necessary resources to continue pursuing individuals alongside their corporate entities, prosecutorial discretion on the part of DOJ, and the reality that individuals often cannot satisfy the large settlements and judgments that large entities can. Now, however, such limitations are rapidly dissipating as the government has both acquired significant new resources and openly announced new policy initiatives aimed at holding individuals more accountable in health care fraud and abuse investigations. This Executive Summary covers some of the major recent developments of the emerging new era of individual responsibility in health care fraud and abuse.

Data Transparency Initiatives

Over the last few years, as part of a continuing data transparency initiative, HHS and CMS have made unprecedented releases of data pertaining to services, procedures, and prescription drugs provided to Medicare beneficiaries by physicians and other health care providers. Indeed, on April 9, 2014, then-HHS Secretary Kathleen Sebelius announced the public availability of new, privacy-protected data showing payments to and charges submitted by over 880,000 distinct health care providers, who in 2012 had

[1] HHS Press Release, *Departments of Justice and Health and Human Services announce over $27.8 billion in returns from joint efforts to combat health care fraud* (March 19, 2015), *available at* www.hhs.gov/about/news/2015/03/19/departments-of-justice-and-health-and-human-services-announce-over-27-point-8-billion-in-returns-from-joint-efforts-to-combat-health-care-fraud.html.

collectively received $77 billion under the Medicare Part B Fee-For-Service (FFS) program.[2] In a press release on the newly available data, CMS noted that "[w]ith this data, it will be possible to conduct a wide range of analyses that compare 6,000 different types of services and procedures provided, as well as payments received by individual health care providers."[3]

Likewise, on April 30, 2015, CMS released detailed data on more than a billion prescriptions dispensed to Medicare beneficiaries in 2013 under the Medicare Part D (Part D) Prescription Drug Program.[4] That information is now publicly available on CMS' website. According to the agency, such transparency "will give patients, researchers, and providers access to information that will help shape the future of our nation's health for the better."[5] The data lists every prescriber, the type of drugs dispensed, the total number of prescriptions and total drug costs, along with other related information.

As with any transparency initiative, such data releases could lead to an increase in government investigations and False Claims Act (FCA) qui tam filings related to patterns in Medicare services provided, prescriptions ordered, and corresponding payments made. For example, a potential whistleblower can now search the Open Payments website to find out whether a prescribing physician received payments or anything else of value from a pharmaceutical company, and then compare that information against the Part D database to determine what types of drugs that physician prescribed. Such information could very well assist a potential whistleblower in assembling an FCA suit premised upon a violation of the Anti-Kickback Statute (AKS).

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[2] CMS Press Release, *Historic release of data gives consumers unprecedented transparency on the medical services physicians provide and how much they are paid* (April 9, 2014), *available at* www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-04-09.html.

[3] *Id.*

[4] CMS Press Release, *New Medicare prescription drug cost data available* (April 30, 2015), *available at* www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-04-30.html.

[5] *Id.* CMS also made a similar release of data relating to Medicare Parts A and B in June 2015. *See* CMS Press Release, *New Medicare data available to increase transparency on hospital and physician utilization* (June 1, 2015), *available at* www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-06-01.html.

In recent years, such payment data has even started to make headlines. For example, in 2014, reporters from the *Miami Herald*, citing to what they called "the most detailed data on physician payments ever released in Medicare's nearly 50-year history," published a story regarding the criminal investigation of Dr. Salomen Melgen, a West Palm Beach ophthalmologist.[6] After learning of the ongoing criminal investigation of Melgen in 2014, the reporters were able to search the Open Payments website and research Melgen's claims history.[7] With the headline "South Florida ophthalmologist emerges as Medicare's top-paid physician," the article states that Melgen "was paid $21 million by Medicare in 2012 – more than any other physician who billed the taxpayer-funded program that year, according to new government data."[8] Melgen was ultimately indicted in April 2015.[9]

Increased Use of Data Analytics in Health Care Enforcements

In addition to making health care provider data more readily available to the public, the government also has created (and continues to create) new tools with which to analyze that data. Ultimately, CMS hopes that the ability to conduct such technologically savvy analyses will allow it to move away from its current "pay and chase" method of fraud and abuse enforcement and to uncover potential fraud and abuse in real time.

Under the current pay and chase model, unless a provider is already under scrutiny due to past billing behaviors or other conduct, CMS typically reimburses providers for all claims submitted to CMS or one of its contractors.[10] Then, if the government later

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[6] Jay Weaver & Daniel Chang, *South Florida ophthalmologist emerges as Medicare's top-paid physician*, MIAMI HERALD (April 9, 2014, 10:01 AM), www.miamiherald.com/news/local/community/miami-dade/article1962581.html.
[7] *See id.*
[8] *Id.*
[9] Jay Weaver, *Top-billing South Florida doctor charged with Medicare fraud held in jail*, MIAMI HERALD (April 14, 2015, 7:14 PM), www.miamiherald.com/news/local/crime/article18535547.html.
[10] *See* T.R. Goldman, *Eliminating Fraud and Abuse*, HEALTH AFFAIRS (July 31, 2012), www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=72.

discovers potential fraud or abuse or other problems with the reimbursed claims (whether through a post-payment review, whistleblower suit, or some other means), the government will investigate the provider's past claims and seek to recover any claims it concludes were improperly reimbursed.[11]

Because of the obvious inefficiencies of such a model, Congress, through the Small Business Jobs Act of 2010, created the Fraud Prevention System (FPS) with the goal of allowing CMS to uncover fraudulent claim submissions in real time, as well as to prospectively deny reimbursement to providers suspected of potential abuse.[12] To do this, the FPS collects and analyzes billing data from all Medicare FFS claims.[13] It then uses predictive algorithms and data technology to compare FFS claims against billing patterns for similar providers in various regions, looking for any outliers and irregular billing patterns.[14] When irregular patterns are identified, FPS can then automatically generate payment denials and make referrals to Zone Program Integrity Contractors to review and investigate providers with irregular billing.[15]

Additionally, OIG has partnered with DOJ to increase the use of data analytics through the efforts of the Medicare Fraud Strike Force (MFSF), established in 2007.[16] The MFSF analyzes billions of data points in order to find geographical hot spots, emerging schemes, and individual providers of concern. Assistant Attorney General (AAG) Leslie R. Caldwell has stated that the MFSF has given the government "access to real-time data" that enables DOJ to "stay ahead of the curve and stop fraud schemes at the

[11] *Id.*
[12] *See* CMS Press Release, *CMS cutting-edge technology identifies & prevents $820 million in improper Medicare payments in first three years* (July 14, 2015), www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-07-14.html.
[13] *See* CMS, *Report to Congress: Fraud Prevention System Second Implementation Year* (June 2014), *available at* www.stopmedicarefraud.gov/fraud-rtc06242014.pdf.
[14] *Id.*
[15] *Id.*
[16] OIG, "Medicare Fraud Strike Force," (last visited Jan. 19, 2016), http://oig.hhs.gov/fraud/strike-force.

development stage."[17] This increased scrutiny of provider data signals a new era for provider reimbursement from CMS.

Medicare's Improper Payment Outreach and Education Program

In April 2015, President Barack Obama signed into law the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),[18] which repealed and replaced the controversial Sustainable Growth Rate formula.[19] A lesser known, but nevertheless important, provision of MACRA requires Medicare Administrative Contractors (MACs) to establish an "improper payment outreach and education program."[20] Specifically, Section 505 of MACRA requires each MAC to establish a program under which the MAC will give providers certain information, with priority placed on activities that will reduce improper payments in certain areas.[21]

In connection with these new education and outreach activities, HHS will give each MAC a list of the types of improper payments identified by Recovery Audit Contractors (RACs) with respect to providers and suppliers located in the MAC's jurisdiction.[22] Pursuant to this program, auditors (i.e., RACs) will provide administrative contractors (i.e., MACs) with various information, including, but not limited to, a list of providers and suppliers that have the highest rates of improper payments, items, and services furnished in the region and that are responsible for the greatest total dollar amount of improper payments.[23]

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[17] DOJ Press Release, *Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the American Bar Association's 25th Annual National Institute on Health Care Fraud* (May 14, 2015) *available at* www.justice.gov/opa/speech/assistant-attorney-general-leslie-r-caldwell-delivers-remarks-american-bar-association-s.

[18] Pub. L. 114-10 (April 16, 2015).

[19] *See* Mark Hagland, *President Obama Signs SGR Repeal Legislation, Shifting Medicare Physician Payment Incentives*, Healthcare-Informatics.com (April 17, 2015), www.healthcare-informatics.com/article/breaking-president-obama-signs-sgr-repeal-legislation-shifting-medicare-physician-payment-in.

[20] Pub. L. 114-10 (April 16, 2015) (codified at 42 U.S.C. § 1395kk-1).

[21] *Id.*

[22] *Id.*

[23] *Id.*

The outreach, education, training, and assistance programs provided by MACRA are to be conducted on a regular basis and will essentially require physicians and their practices to pay close attention to any communications received from their MAC and promptly take any corrective action indicated. Where the MAC flags a reimbursement, billing, or coding issue in a report to a provider, the government would likely argue that the report has "identified" any resulting overpayment that might exist. In light of the Affordable Care Act's 60-day rule (which requires providers to report and return any overpayment it receives within 60 days of identifying such overpayment or risk liability under the "reverse false claims" provision of the FCA),[24] it will be crucial for providers to address any issues raised by a MAC or any other government entity without delay in order to avoid potential FCA liability.

OIG Fraud Alert on Physician Compensation Arrangements

The government's increased focus on individual wrongdoing continued into the summer and fall of 2015. On June 9, 2015, OIG issued a Fraud Alert entitled "Physician Compensation Arrangements May Result in Significant Liability."[25] Notably, the Fraud Alert does not announce the creation or implementation of any new laws or enforcement authority. Instead, it pronounces OIG's intention to significantly increase the scrutiny authority it already possesses. Specifically, in its Fraud Alert, OIG warns physicians that it will take a hard look at physician compensation arrangements, such as medical directorships, to ensure that those arrangements reflect fair market value for bona fide services actually provided. The Fraud Alert warns that violations may result in significant liability, including criminal, civil, and administrative sanctions. OIG states that, although many compensation arrangements are legitimate, "a compensation arrangement may violate the anti-kickback statute if even one purpose of the arrangement is to

[24] 42 U.S.C. § 1320a-7k(d).
[25] OIG, "Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability" (June 9, 2015), *available at* http://oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf.

compensate a physician for his or her past or future referrals of Federal healthcare program business."[26] The Fraud Alert goes on to note that physicians are integral parts of such bad arrangements, and health systems cannot enter into such schemes without involvement from individual providers. Thus, the Fraud Alert encourages physicians to "carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering into them."[27]

The "Takedown" of 243 Individuals on Charges Related to Health Care

On June 18, 2015, just days after OIG issued its Fraud Alert, federal and state officials announced a nationwide takedown of 243 individuals on charges related to roughly $712 million in allegedly false Medicare billings, which is currently the largest action to date by the MFSF.[28] Of the 243 arrested individuals, 46 were physicians and many others were nurses or other licensed medical professionals.[29] Some of those arrested were charged with violations of the AKS.[30] In connection with this same "takedown," CMS has stated it also is suspending the billing privileges of many other providers who were not arrested.[31]

OIG's New Litigation Team

In July 2015, at the AHLA Annual Meeting in Washington, DC, OIG announced the creation of its new litigation team to hold individuals accountable for potential health

[26] *Id.*
[27] *Id.*
[28] DOJ Press Release, *National Medicare Fraud Takedown Results in Charges Against 243 Individuals for Approximately $712 Million in False Billing* (June 18, 2015), *available at* www.justice.gov/opa/pr/national-medicare-fraud-takedown-results-charges-against-243-individuals-approximately-712.
[29] *Id.*
[30] *Id.*
[31] *Id.*

care fraud and abuse.[32] This new litigation team will have approximately 10 attorneys focused exclusively on cases brought under the Civil Monetary Penalties Law (CMPL), the Stark Law, the AKS, and OIG's authority to exclude providers from federal health programs.[33] The creation of this task force demonstrates that the government is serious about potential violations of the rules and regulations governing Medicare and Medicaid. Now more than ever, the government will scrutinize physician compensation arrangements and referrals that do not comply with the Stark Law and the AKS.

However, the formation of this new team should not serve as an indication that DOJ and OIG will scale back their enforcement authority under the FCA to hold health care providers, large and small, accountable for fraud and abuse. Indeed, this specialized team of OIG attorneys will concentrate exclusively on levying civil penalties under the CMPL and exclusions from the Medicare and Medicaid programs, allowing DOJ and separate OIG teams to continue FCA and AKS enforcement.[34]

The "Yates Memo"

On September 9, 2015, U.S. Deputy Attorney General Sally Qullian Yates issued a much-publicized memorandum entitled "Individual Accountability for Corporate Wrongdoing" (Yates Memo) to all DOJ attorneys.[35] In her memo, Yates announces a new policy initiative focused on targeting individuals involved in corporate crimes, explaining that such increased scrutiny "deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system."[36] To further these goals, the Yates Memo outlines new guidelines to be followed by all DOJ

[32] *See* Jeff Overley, *New HHS OIG Unit to Specialize in Fines, Exclusions*, Law360 (June 30, 2015), www.law360.com/articles/674038/new-hhs-oig-unit-to-specialize-in-fines-exclusions.
[33] *Id.*
[34] *Id.*
[35] DOJ: Sally Quillian Yates, Memorandum Re Individual Accountability for Corporate Wrongdoing, September 9, 2015, *available at* www.justice.gov/dag/file/769036/download.
[36] *Id*. at 1.

attorneys handling cases involving corporate misconduct. Although the Yates Memo and the principles laid out therein are not health care specific, their effects will likely be greatest felt in the health care industry, where the majority of the government's fraud-fighting focus has laid over the last several years.

Under the first new guideline listed in the Yates Memo, DOJ will no longer give "any cooperation credit" to an entity under investigation unless the corporation provides DOJ with "all relevant facts about the individuals involved" in the misconduct."[37] Providing complete factual information is a "threshold requirement" whereby DOJ will not deem the corporation "eligible for consideration for cooperation credit" until the threshold is met.[38] In addition, the first guideline also instructs DOJ's attorneys to "proactively investigat[e] individuals at every step of the process – before, during, and after any corporate cooperation."[39]

The remaining guidelines provide that:

- The new focus on individuals (outlined in the first guideline) applies to both criminal and civil investigations;
- Criminal and civil DOJ attorneys should now be in "routine communication with one another" when handling corporate investigations;
- Except in extraordinary circumstances, "no corporate resolution will provide protection from criminal or civil liability for any individuals";
- Corporate cases "should not be resolved without a clear plan to resolve related individual cases"; and
- DOJ civil attorneys should not take into account an individual's ability to pay a potential judgment against him; attorneys should instead analyze potential cases against culpable individuals on the seriousness of the

[37] *Id*. at 3.
[38] *Id*.
[39] *Id*. at 4.

misconduct, whether the case is "actionable," and whether this is enough admissible evidence to sustain a judgment.[40]

On September 22, 2015, only days after the release of the Yates Memo, AAG Caldwell elaborated on DOJ's new focus on individuals: "Prosecuting the corporate entity, and imposing a fine and other impersonal conditions, simply is not enough – in most instances – to fully punish and, more importantly, deter corporate misconduct."[41] Using the context of the Foreign Corrupt Practices Act as an example, Caldwell also explained the following factors the government will likely consider when determining the quality of corporate cooperation: (1) voluntariness and timeliness of disclosures and cooperation; (2) remedial efforts of the corporation (including terminating responsible individuals); and (3) the entity's ongoing commitment to improving compliance and continual cooperation with the government.[42]

Soon after the release of the Yates Memo, the guidelines from the memo were officially implemented into the U.S. Attorneys' Manual (USAM) under Section 9-28.000 et seq., relating to DOJ's criminal prosecution of corporate entities.[43] Indeed, in November 2015, a new subsection entitled "Focus on Individual Wrongdoers" was added to the USAM outlining the general principles expressed in the Yates Memo and firmly establishing that "[p]rosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without the corporation."[44]

Similarly, because the Yates Memo applied to criminal and civil attorneys and investigations alike, the civil section of the USAM was recently amended as well. Section 4-3.100, newly entitled "Pursuit of Claims Against Individuals," emphasizes

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[40] *Id.*

[41] DOJ Press Release, *Assistant Attorney General Leslie R. Caldwell Delivers Remarks at the Second Annual Global Investigations Review Conference* (Sept. 22, 2015), www.justice.gov/opa/speech/assistant-attorney-general-leslie-r-caldwell-delivers-remarks-second-annual-global-0.

[42] *Id*.

[43] DOJ, "Principles of Federal Prosecution of Business Organizations," *in* United States Attorneys' Manual, at § 9-28.000, *available at*, www.justice.gov/usam/usam-9-28000-principles-federal-prosecution-business-organizations (last accessed Jan. 19, 2016) (hereinafter USAM).

[44] *See id.* at § 9-28.210.

DOJ's emphasis on "[h]olding individuals who perpetrate wrongdoing accountable, in addition to corporations or business entities."[45] That section now codifies the Yates Memo guidelines, specifically that: (1) civil corporate investigations should focus on individuals from their inception; (2) determinations as to whether to bring suit against an individual should not be based solely on the individual's ability to pay a judgment; (3) criminal and civil attorneys in corporate investigations should routinely communicate; (4) corporations must provide all relevant facts about individuals involved to receive cooperation credit; (5) absent extraordinary circumstances, corporate resolutions should not protect individuals from criminal or civil liability; and (6) corporate cases should not be resolved without a clear plan to resolve related individual cases, and the government's declination of a qui tam suit must be memorialized and approved by senior DOJ officials.[46] These changes to the USAM memorialize and implement DOJ's new stance on dealing with individuals. The message is clear for physicians, health professionals, hospital executives, and every person who plays a role in delivering health care funded by federal health programs.

Conclusion

The federal government has quickly but surely ushered in a new era of individual accountability and transparency in health care fraud and abuse, implementing new policies and obtaining new tools and resources to uncover and combat such conduct. Indeed, physicians and other individual health care providers now have their entire Medicare billing data online for anyone to examine. The government is now utilizing new technologies to analyze and compare provider billing data. Auditors and investigators are constantly searching for outliers and patterns that potentially indicate improper billing practices. New directives from top DOJ officials demand that both criminal and civil attorneys at DOJ actively pursue individuals in corporate investigations or, at the very least, provide reasons and obtain approvals for not taking such actions. Thus, it is

[45] *Id.* at § 4-3.100.
[46] *Id.*

clear that this paradigmatic shift toward individual accountability does not begin and end with the Yates Memo. For this reason, the need for individual health care providers to remain vigilant in their compliance efforts is perhaps more critical now than ever before.