JONES DAY

FALL 2012

HEALTH CARE COMPLIANCE AND ENFORCEMENT UPDATE

CONTENTS

KEY LEGAL DEVELOPMENTS AFFECTING THE HEALTH CARE INDUSTRY

This Update highlights significant legal developments affecting the health care industry that occurred during the second and third quarters of 2012.

JUDICIAL DEVELOPMENTS

GlaxoSmithKline Pays $3 Billion Health Care Fraud Settlement. In July 2012, GlaxoSmithKline ("GSK") agreed to pay $3 billion to resolve criminal and civil issues relating to its promotional and reporting practices. GSK pleaded guilty to two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about Avandia to the Food and Drug Administration ("FDA"). GSK will pay a criminal fine of $956 million and forfeit $43 million. In addition, the company will pay $2 billion to resolve allegations related to civil liability under the False Claims Act ("FCA"). The FCA allegations include: promoting various drugs for off-label use, making false statements concerning the safety of Avandia, and reporting false prices. According to the Department of Justice ("DOJ"), the $3 billion in total penalties represents the largest health care fraud settlement in U.S. history. GSK also entered into a five-year corporate integrity agreement ("CIA") with the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG"). For more, see here.

Janssen Pharmaceuticals Enters into Consent Decree with States and Settles Consumer Protection Claims. On August 30, 2012, Janssen Pharmaceuticals (a Johnson & Johnson company) announced that it had reached a settlement with 36 states and the District of Columbia over allegations related to promotional and marketing practices for Risperdal. The company will pay approximately $181 million to resolve claims based on state consumer protection laws. In addition, the company has entered into a Stipulated General Judgment that contains specific compliance provisions relating to the company's distribution of medical information. Specifically, the consent decree states: "Janssen Scientifically Trained Personnel shall be responsible for the identification, selection, approval and dissemination of Reprints Containing Off-Label Information regarding Atypical Antipsychotics. Neither Janssen Sales nor Janssen Marketing personnel shall disseminate these materials, unless Janssen has a pending filing with FDA for approval of the new indication described in the Reprint." The restriction placed on the dissemination of reprints is more stringent than available FDA guidance and implies support for FDA's position that off-label promotion does not have First Amendment protection as argued in several recent cases. The consent decree also provides that only Janssen "Scientifically Trained Personnel" may respond in writing to an unsolicited request for off-label information regarding an atypical antipsychotic. "Scientifically Trained Personnel" is defined as "personnel who are highly trained experts with specialized scientific and medical knowledge, usually with an advanced scientific degree (e.g., an MD, PhD, or PharmD), whose roles involve the provision of specialized, medical or scientific information, scientific analysis and/or scientific information to health care professionals and includes Regional Medical Research Specialists, but excludes anyone performing sales, marketing, promotional ride alongs, or other commercial roles." Separately, Johnson & Johnson disclosed that it has reached an agreement in principle with DOJ regarding civil FCA matters related to sales and marketing practices, rebates, and payments for Risperdal and other drugs. Some industry experts estimate that the settlement of those matters may involve payments of approximately $2 billion. For more, see here and here.

D.C. Circuit Rules that Discretionary Exclusion Period Under Responsible Corporate Officer Doctrine Must Be Supported by Substantial Evidence. In July 2012, the U.S. Court of Appeals for the D.C. Circuit ruled on the appeal filed by three former Purdue Frederick Co. executives regarding their 12-year exclusion imposed by the Secretary of HHS. While the court noted that the Secretary does have authority to impose an exclusion, it remanded on the ground that the duration of the exclusion was not supported by an adequate "reasoned explanation." More specifically, reviewing the agency determination under the "arbitrary and capricious" standard, the court observed that 42 U.S.C. § 1320a-7(b)(1)(A) "authorizes exclusion of an individual whose conviction was for conduct factually related to fraud," but took issue with the agency's reliance on precedents that did not involve the type of exclusion at issue (i.e., discretionary exclusions based on misdemeanor), but instead arose out of mandatory exclusions for felony convictions. Concluding that the precedents cited by the Secretary did not justify the Purdue executives' 12-year exclusion, the court was nevertheless careful not to opine as to whether the 12-year period might be justified; the agency will have an opportunity to present its justification to the district court on remand. For more, see here.

REGULATORY AND LEGISLATIVE DEVELOPMENTS

Public–Private Initiative Formed to Prevent Health Care Fraud. On July 26, 2012, HHS and DOJ announced a new collaborative arrangement among the federal government, state officials, private health insurance organizations, and other anti-fraud groups to combat and prevent health care fraud. This new partnership will build on enforcement tools made available by the Affordable Care Act, including increased sentences for those convicted of health care fraud, enhanced screening of Medicare and Medicaid providers and suppliers, and suspended payments to providers and suppliers allegedly engaged in fraudulent activity. The partnership is designed to improve detection and prevent payment of fraudulent claims. One specific goal of the partnership is to facilitate the sharing of information on issues such as fraudulent billing schemes and "fraud hotspots" to prevent losses to both government and private health plans. Eventually, data analytics will be employed to scan industry-wide health care data to supplement fraud detection efforts. Data analytics are a recurring theme in current fraud and abuse enforcement efforts, with the government touting the use of data analytics to increase efficiency in

program integrity activities. According to OIG's Spring and Fall 2012 Semi-Annual Reports to Congress, advanced data analytics have already been in use by OIG to conduct risk assessments and pinpoint oversight efforts. Data analytics and other technological advancements in fraud prevention were also a key topic of conversation during the April 4, 2012 Health Care Fraud Prevention Summit hosted by HHS and DOJ. For more, see here.

CMS Delays Implementation of ICD-10. According to a final rule released August 24, 2012, the Centers for Medicare & Medicaid Services ("CMS") has officially delayed the implementation of the International Classification of Diseases, 10th Revision (ICD-10) coding system until October 1, 2014, a full year after the originally scheduled compliance deadline. The one-year delay was granted in direct response to providers' concerns about a lack of resources and ability to adapt their systems in time to meet the original ICD-10 deadline. According to CMS, 26 percent of the providers CMS surveyed in November and December 2011 indicated that they were at risk of not being able to meet an October 1, 2013 compliance date. CMS selected the one-year delay over several other options also on the table to address provider concerns regarding implementation. Such options included foregoing ICD-10 altogether and waiting for implementation of ICD-11, or implementing only the ICD-10 procedure codes in 2013 but delaying implementation of the ICD-10 diagnosis codes. Not all providers were in favor of a delay in implementation. CMS received comments from numerous health plans, large hospitals, physician practices, and IT vendors describing the large investment already made in upgrading systems and personnel, generating a forward momentum that will be disrupted by a delay. CMS acknowledged these concerns but stated that they are outweighed by the potential for a major nationwide disruption in reimbursement resulting from the significant numbers of providers that are reportedly unprepared for implementation. For more, see here.

Senators Urge CMS to "Let the Sunshine In" and Implement the Physician Payments Sunshine Act. At a September 12, 2012, roundtable discussion of the Senate Special Committee on Aging, Senator Chuck Grassley accused CMS of "dragging its feet" on implementation of the Sunshine Act. Nine months have passed since publication of the proposed rule, yet despite numerous requests by the Act's authors, Senators Grassley and Kohl, as well as leading industry groups, CMS has yet to issue the much-anticipated final rule. Senator Grassley stated that efforts to engage CMS "have been met with resistance and silence." While some companies have already invested in development of systems necessary to capture relevant data, the absence of final regulations impedes the full testing and implementation of these systems. Frustrated with CMS's failure to answer for the delay, Senator Grassley cited a "rumor" that CMS has completed the final rule and forwarded it to the Office of Management and Budget ("OMB")—yet OMB is delaying its issuance until after the election. Senator Grassley stated that there is a need to "find out what the hold-up is, deal with it, and get the job done." According to the OMB dashboard, the OMB received the final rule on November 27, 2012. For more, see here.

Lawmakers Investigate 340B Drug Discount Program. In May 2012, Senator Grassley asked the University of Alabama Hospital to provide information regarding its policies associated with 340B patients. The request was prompted by a February 2011 presentation in which a Senior Pharmacist at the hospital discussed changing treatment protocol and location in order to maximize saving opportunities associated with the 340B drug discount program. In July, Representatives Joseph R. Pitts and Bill Cassidy, citing oversight problems outlined in a September 2011 Government Accountability Office ("GAO") report, requested that the Health Resources and Services Administration issue an updated definition of "340B patient" in order to curb any misuse of the program. The GAO report identified the risk of improper purchase of 340B drugs since the program is increasingly used in settings that serve both 340B and non-340B eligible patients. For more, see here and here.

DEVELOPMENTS INVOLVING PROVIDERS

Recovery Audit Contractors. In a much-anticipated opinion filed on September 11, 2012, the Ninth Circuit ruled that a Medicare contractor's decision to reopen Medicare claims cannot be challenged after conclusion of an audit that resulted in a revised claim determination. The case at issue concerned inpatient rehabilitation services provided by Palomar Medical Center to a patient following hip surgery. Palomar received Medicare reimbursement for the services,

but a recovery audit contractor ("RAC") reopened Palomar's claim nearly two years later to determine whether the services were reasonable and necessary. Medicare regulations provide that a contractor may reopen a determination within one year for any reason or within four years for good cause. 42 C.F.R. § 405.980(b)(1)-(2). The decision on whether to reopen a claim is "final" and "not subject to appeal." 42 C.F.R. § 405.980(a)(5). The RAC concluded that the services were not covered by Medicare because they were provided in a hospital when they could have been provided in a less-intensive setting. The RAC's initial determination was later affirmed at four levels of administrative review, although an administrative law judge ("ALJ") granted relief to Palomar on the basis that the RAC did not have good cause for reopening the claim. The Medicare Appeals Council did not agree and reversed the ALJ's decision. Palomar did not challenge the determination that the services were not reasonable and necessary, but appealed the decision on the reviewability of the reopening of the claim. The Ninth Circuit reasoned that while providers have a legitimate interest in the finality of claim determinations, the government has an interest in the integrity of the RAC program, which was designed to reduce Medicare overpayments. The court ultimately ruled in favor of a strict reading of the governing regulations, holding that a decision to reopen a claim is final and not appealable.

Home Health. In August 2012, the owner of Ronat Home Health Care Inc., a Miami home health staffing agency, pleaded guilty to one count of conspiracy to defraud the government in connection with a $60 million false billing scheme. The owner, Rodolfo Nieto, Jr., allegedly accepted kickbacks from Nany Home Health Inc., a Miami-based home health agency, in return for recruiting Medicare beneficiaries for Nany. In December 2011, three operators of Nany pleaded guilty to a conspiracy charge for participation in a scheme whereby patient files were allegedly falsified to make it appear as though the beneficiaries qualified for home health services when they did not in fact qualify. Nany also allegedly paid bribes and kickbacks to patient recruiters and staffing agencies, such as Ronat, to recruit Medicare patients and provide certifications for medically unnecessary home health services. Of the $60 million in allegedly false claims submitted to Medicare, approximately $40 million were paid. The three operators were sentenced in April 2012. They received multiyear prison terms and were ordered to pay $40 million in restitution, jointly and severally with other codefendants. Nieto was sentenced on October 23 to 37 months in prison, three years of supervised release, and $1.1 million in restitution.

Nursing Home. In August 2012, a former nursing home operator was sentenced in federal court to 20 years for submitting claims totaling more than $41 million for "worthless services" to Medicare and Medicaid and for tax fraud. George D. Houser and his wife operated two nursing homes in Georgia and purported to provide residents with a safe, clean environment, nutritional meals, and appropriate medical care. It was alleged, however, that the residents at the facilities were subjected to poor sanitary conditions, food shortages, leaking roofs, mounds of uncollected garbage, humid conditions that facilitated the growth of mold and mildew, and staffing shortages. Prosecutors argued that, due to these conditions, all of the services rendered to residents were essentially of no value. Houser was alleged to have been aware of the conditions at the two facilities and to have diverted more than $8 million in Medicare and Medicaid funding for his own personal use.

Pharmacy. On August 1, 2012, a federal district court in Florida reversed an HHS determination that Teamcare Infusion Orlando, Inc., a pharmacy that also provides durable medical equipment ("DME"), received more than $1.6 million in overpayments for claims submitted for DME. The court agreed with one of the arguments advanced by Teamcare and concluded that the amount of the overpayment was not supported by substantial evidence. A program safeguard contractor ("PSC") made the initial determination that Teamcare was responsible for more than $1.6 million in overpayments for claims submitted for DME. PSC calculated the overpayment by extrapolating data from an audit of a random sample. The overpayment determination was upheld by a Medicare qualified independent contractor, an ALJ, and the Medicare Appeals Council. The court noted, however, that the record did not include the audit performed by PSC, its initial determination, the total universe of claims reviewed, any information about the random sample, or how the data was extrapolated to arrive at the overpayment. Moreover, at each level of administrative review, the agency reviewer created a separate spreadsheet detailing the claims and beneficiaries at issue—all representing different numbers of claims and

beneficiaries. In reversing, the district court concluded that based on the record, it would be "nearly impossible" to "conduct any meaningful review."

Corporate Integrity Agreement Enforcement. In March 2012, for the first time, OIG invoked a divestiture provision in response to a violation of a CIA. In January 2010, Church Street Health Management ("CSHM"), a dental services provider, entered into a civil settlement with DOJ to resolve fraud allegations. As part of that settlement, CSHM paid $24 million in fines and penalties and entered into a five-year CIA. In February 2012, CSHM filed for bankruptcy, citing the cost of the settlement, CIA compliance, and subsequent litigation as the primary causes. In March 2012, OIG notified the company of numerous material breaches, but CSHM was unable to cure all breaches during the 30-day period allowed. In exchange for CSHM's agreement to divest one of its clinics within 90 days, OIG agreed to not commence an exclusion action.

INTERNATIONAL DEVELOPMENTS

European Commission Considers Reforms to EU Clinical Trials. On July 17, 2012, the European Commission ("EC") adopted a proposal that would significantly simplify the current framework relating to clinical trials in Europe. This proposal is not yet final as it must be reviewed by the European Council and European Parliament (both of which might make changes), and it is not likely to be implemented before 2016. The EC proposes to replace the current Clinical Trials Directive with a regulation. Under EU law, regulations automatically apply to all Member States immediately, unlike directives, which require the passage of individual national laws for implementation. The proposed regulation would eliminate the "otherwise significant" category of post-authorization modifications requiring approval, and establish only two categories: those affecting the safety or rights of the subjects and those dealing with the reliability and robustness of the data. In addition, the proposed regulation provides for a single application submitted to the Commission. The application would be assessed jointly by all the Member States, but a single "reporting Member State" would render the decision as to acceptability (with each Member State assessing the ethical and local aspects individually). This move toward simplification and uniformity promises to increase the clinical research in Europe and advance the state of medical research generally. For more, see here.

German Court Re-Enforces Incentives Ban Against Manufacturer: No Touchpads for Increased Sales. Medical device manufacturers whose products more closely resemble consumer goods may be inclined to lose sight of German health care compliance legislation. On September 6, 2012, a manufacturer of optical lenses for glasses was reminded that the legislation applies to medical device manufacturers. In the context of a "partnering program," the manufacturer had incentivized opticians with a touchpad worth €428 if they achieved an increase of sales of optical lenses by €3,000 on a year-by-year basis. The Court of Appeal Karlsruhe enjoined the manufacturer, holding that the offer violated the German ban on incentives other than direct cash or volume discounts for medical devices (decision of September 6, 2012, case no. 4 U 110/12). This ruling is a reminder that it is of paramount importance for medical device manufacturers to vet carefully their sales offerings in Europe.

JONES DAY NEWS

Former Chief of the Major Frauds Section for U.S. Attorney's Office (C.D. Cal.) Joins Jones Day. In June 2012, Jones Day welcomed Beong-Soo ("Beong") Kim to its partnership. Mr. Kim joins the Firm after a distinguished career with the U.S. Attorney's Office for the Central District of California, where he served as both the Major Frauds Chief and the Financial Fraud Enforcement Task Force Coordinator. As Major Frauds Chief, Mr. Kim led the largest federal white-collar prosecution unit in the country, while personally investigating and trying numerous significant fraud cases, including those involving health care fraud. During his governmental tenure, Mr. Kim supervised numerous cases involving Medicare fraud, private insurance fraud, health privacy violations, the Anti-Kickback statute, and money laundering. Mr. Kim also helped spearhead the Medicare Fraud Strike Force's work in Los Angeles and coordinated civil and criminal enforcement actions arising from whistleblower complaints. Mr. Kim will be based in Jones Day's Los Angeles Office.

LAWYER CONTACTS

For more information regarding matters related to any of the above issues, please contact your principal Jones Day representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com. Jones Day prepares summaries of significant health care litigation and policy events as a service to clients and interested readers in order to provide timely insight on these matters. Please use our Publications Sign-Up Form, available at www.jonesday.com/newsknowledge/PublicationSignup.aspx, to add your name to our distribution list.

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