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New Exception to Codey Law for Intraoperative Monitoring Services

By Divya Srivastav-Seth, Esq.

On August 1, 2016 and effective immediately, Governor Christie signed into law a bill, S1164/A1835, which establishes a new exception for certain intraoperative monitoring services ("IOMS") from the New Jersey prohibition against physician self-referrals, N.J.S.A. 45:9-22.5, et seq., also known as the "Codey Law." Subject to certain exceptions, the Codey Law prohibits referrals of a patient by a practitioner for healthcare services in which the practitioner or the practitioner's family has a significant beneficial interest. The new law adds an exception for medically-necessary IOMS rendered during a neurosurgical, neurological, or neuroradiological surgical procedure that is performed in a hospital. See N.J.S.A. 45:9-22.5(c)(4). IOMS consist of stimulating nerves and muscles in order to monitor patient reactions and minimize the risk of neurological damage. Under the Codey Law, if an exception applies, the referring practitioner must also disclose the practitioner's significant beneficial interest to the patient in writing and conspicuously post a copy of the disclosure in the practitioner's office.

In addition to the Codey Law, the physician will also have to adhere to Federal Stark Law requirements regarding physician self-referral prohibitions. See 42 C.F.R. § 411. 353. The Stark Law prohibits physicians from making referrals to an entity for designated health services ("DHS"), in which physicians or their immediate family members have a financial interest, unless an exception applies to the arrangement. DHS include inpatient and outpatient hospital services. See 42 C.F.R. § 411.351. The new IOMS exception implicates the Stark Law on its face by requiring the service to be performed in a hospital. Accordingly, any prospective arrangement should be analyzed under both Codey and Stark for compliance.

For more information, contact Divya Srivastav-Seth at dss@spsk.com, or (973) 631-7855.

Settlement Reached in Reverse False Claims Act Case

By Meghan V. Hoppe, Esq.

On August 24, 2016, the Department of Justice announced a $2.95 million settlement with the defendants in *U.S. ex rel. Kane v. Healthfirst, Inc.*, 120 F. Supp. 3d 370 (S.D.N.Y. 2015), which provided the first judicial interpretation of the Affordable Care Act's 60-day repayment requirement in the context of a False Claims Act case.

The Kane case involved allegations that the defendants overbilled Medicaid due to a software error and failed to make timely repayment of such overpayments. Of the 890 claims identified by the relator as potentially fraudulent, 444 were determined to have been erroneously billed to Medicaid and were refunded in full from 2011 to 2013. Under this settlement, the defendants admit liability for mistakenly submitting claims to Medicaid that resulted in more than $800,000 in overpayments and for failing to fully reimburse Medicaid for over two years. The defendants have agreed to pay nearly 3.5 times the amount of improperly billed claims to Medicaid to resolve the matter.

Following the district court's denial of the defendants' motion to dismiss, the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS") published a final rule on the 60-day repayment requirement. The CMS final rule clarified that an overpayment has been identified when a provider has, or should have through the exercise of "reasonable diligence," determined that the provider received an overpayment and "quantified the amount of the overpayment." CMS also made clear that absent "extraordinary circumstances," the completion of such reasonable diligence should take no more than six months from the provider's receipt of credible information.

The full text of the settlement can be found here.

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Enforcement Continues for Failure to Maintain Proper Business Associate Agreements

By Deborah A. Cmielewski, Esq.

HIPAA enforcement has intensified and the failure to maintain proper business associate agreements continues to result in significant fines and penalties for both covered entities and business associates. The U.S. Department of Health and Human Services, Office of Civil Rights ("OCR"), which is responsible for HIPAA enforcement, pursued a number of cases in 2016 against health care providers related to the absence of these critical contracts. These included a $750,000 fine against Raleigh Orthopaedic Clinic, P.A. of North Carolina (resulting from a 2013 breach notification and subsequent investigation) and a $1.55 million fine against North Memorial Health Care of Minnesota (resulting from a 2011 notification and investigation). The OCR also imposed a $650,000 fine against Catholic Health Care Services of the Archdiocese of Philadelphia ("CHCS"), a business associate that provided management and information technology services to nursing homes, following a 2014 breach notification and investigation. While the OCR gives priority to investigating breaches that involve more than 500 patients, notably, the CHCS notification involved the protected health information of 412 patients. The CHCS action was consistent with the OCR's August 2016 announcement that it intends to increase its review of smaller breaches.

Most recently, Care New England Health System ("CNE"), on behalf of the covered entities under its common ownership or control, entered into a settlement with OCR resulting from a November 5, 2012 breach notification involving the loss of unencrypted backup tapes containing the protected health information of approximately 14,000 patients. The settlement included a comprehensive corrective action plan as well as a $400,000 monetary payment by CNE. CNE serves as the business associate of Women & Infants Hospital of Rhode Island ("WIH"), furnishing centralized corporate support for WIH's information systems. Throughout the course of the breach investigation, OCR determined that CNE and WIH maintained a business associate agreement dated March 15, 2005 that was not updated until August 28, 2015 (during the course of the investigation); that document failed to include specifications required by the 2013 HIPAA Omnibus Final Rule. Notably, the Massachusetts Attorney General's Office also entered into a settlement with WIH in the amount of $150,000 relative to the underlying breach.

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New Jersey Division of Consumer Affairs Extends October 31, 2016 Expiration Date of All CDS Registrations to December 31, 2016

By Brian M. Foley, Esq.

On October 13, 2016, the New Jersey Office of the Attorney General, Division of Consumer Affairs (the "Division") officially extended the expiration date of all physicians, pharmacy, and veterinary controlled dangerous substances ("CDS") registrations with an October 31, 2016 expiration date, until December 31, 2016. As such, all CDS registrations with an expiration date of October 31, 2016 will be valid until December 31, 2016.

The Drug Control Unit of the Division is extending the expiration dates to ensure that CDS registrants experience no interruption in their employment or ability to order, prescribe, or dispense CDS as the State integrates an updated licensing system. The Division Director has issued a formal letter to New Jersey licensees and has stated that if a health care provider, credentialing service, employer, or drug wholesaler requires confirmation of the extension, a licensee may provide a copy of the letter.

A copy of the Director's letter dated October 13, 2016, can be accessed here.

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OIG Advisory Opinion Allows for Copayment Discount on Statutorily Excluded Drug

By Sharmila D. Jaipersaud, Esq.

The U.S. Department of Health and Human Services, Office of Inspector General ("OIG") recently posted Advisory Opinion 16-07, where it determined that it would not impose sanctions under the Federal Anti-Kickback Statute for an arrangement that offered Medicare Part D beneficiaries discounts on prescriptions for an erectile dysfunction drug. Notably, the drug is statutorily excluded from Part D. The arrangement allowed individuals covered under Part D to use a savings card to receive a discount on their out-of-pocket costs for the drug. The savings were applied to out-of-pocket costs greater than $15 and up to a maximum of $75 per prescription, with a limit of 12 prescriptions for the drug. Individuals covered by commercial insurance could use the discount toward the drug; however, individuals covered by other federal or state health care programs other than Part D were not eligible to participate in the savings.

The OIG began its analysis by reiterating its position that copayment coupons constitute remuneration that may induce the purchase of federally payable items. The OIG cited two ways that this can occur: (1) coupons can induce the purchase of items that are the subject of the coupon and (2) coupons can induce beneficiaries to purchase other federally payable products that are manufactured, marketed, or distributed by the manufacturer that issued the coupon. In permitting the arrangement, the OIG found that certain safeguards were in place; therefore, minimal risks of fraud and abuse were presented under the Anti-Kickback Statute. The OIG also placed great emphasis on the fact that this discount was different from other copayment coupons because this drug was excluded from Medicare Part D.

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