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Absentee Doctor Sentenced to Jail

By Daniel O. Carroll, Esq.

On December 18, 2017, a doctor and his chiropractor son from Cherry Hill, New Jersey, were sentenced to prison for conspiring to commit health care fraud. Robert Claude McGrath, D.O. and his son Robert Christopher McGrath pled guilty and were sentenced to prison for 30 months and 12 months, respectively. Atlantic Spine & Joint Institute (the "Practice"), which was owned and operated by the McGraths, provided physical therapy services at office locations in New Jersey and Pennsylvania. Importantly, Robert Claude McGrath, D.O. was the only licensed physician at the Practice. As required by Medicare billing regulations, physical therapy could only be provided at the Practice by the elder McGrath or by a trained physical therapist under his supervision. However, from January 2011 through April 2016, the McGraths sought to defraud Medicare by employing unlicensed and untrained persons to provide physical therapy to Medicare patients at the Practice and billing for such services under Robert Claude McGrath's name. Not only did the elder McGrath not render these services, but he was not even in the office to supervise such services at the Practice. That the actual service providers were unlicensed and untrained exacerbated the violations and potentially jeopardized the well-being of patients.

In addition to the prison terms, the McGraths were ordered to pay restitution of $890,000. Separately, in a related civil settlement, the McGraths agreed to pay $1.78 million plus interest to the federal government to resolve allegations brought by a former billing manager at the Practice that the fraudulent billing violated the False Claims Act.

This is yet another case reinforcing the dangers of improper billing and the use of untrained and unlicensed personnel to perform professional services. SPSK's Health Care Law Practice Group is available to provide legal assistance to health care providers with matters of corporate governance and regulatory compliance.

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FDA Provides Guidance on the Regulation of Digital Health Software

By Meghan V. Hoppe, Esq.

On December 8, 2017, the U.S. Food and Drug Administration ("FDA") issued three new guidance documents — two draft and one final — that provide clarity on the FDA's role in regulating digital health tools. These guidance documents also address certain provisions of the 21st Century Cures Act ("Cures Act"), in which Congress removed certain low risk digital health software from the FDA's jurisdiction.

The first draft guidance, *"Clinical and Patient Decision Support Software,"* outlines the FDA's approach to clinical decision support software ("CDS"), as well as a related category of patient decision support ("PDS") software intended for use by patients or non-healthcare professionals. The FDA aims for this draft guidance to "make clear what types of CDS would no longer be defined as a medical device, and thus would not be regulated by" the FDA. Press Release, U.S. Food and Drug Administration, Statement from FDA Commissioner Scott Gottlieb, M.D., on advancing new digital health policies to encourage innovation, bring efficiency and modernization to regulation (Dec. 7, 2017), available at the FDA's website. Similarly, this draft guidance also proposes to not enforce regulatory requirements for PDS software when such software allows a patient or a caregiver to independently review the basis of the treatment recommendation. However, the FDA will

"continue to enforce oversight of software programs that are intended to process or analyze medical images, signals from in vitro diagnostic devices or patterns acquired from a processor like an electrocardiogram that use analytical functionalities to make treatment recommendations, as these remain medical devices under the Cures Act." *Id*.

The second draft guidance issued by the FDA, *"Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act,"* addresses digital health provisions of the Cures Act where certain categories of low-risk software functions were excluded from the definition of "device". This second draft guidance outlines the FDA's interpretation of the types of software that are no longer considered medical devices (e.g., fitness or wellness apps). The FDA states that these types of technologies "tend to pose a low risk to patients, but can provide great value to consumers and the healthcare system." *Id*. This second draft guidance also describes changes that the FDA intends to make to several previously published guidance documents in order to "be consistent with the Cures Act and reflective of the agency's new, more modern approach to digital health products." *Id*.

Lastly, the FDA issued a final guidance document entitled, *"Software as Medical Device: Clinical Evaluation,"* which was developed by the International Medical Device Regulators Forum ("IMDRF"). This final guidance establishes common principles for regulators to use in evaluating the safety, effectiveness and performance of Software as a Medical Device ("SaMD") and provides globally recognized principles for analyzing and assessing SaMD based on the overall risk of the product. This final guidance underscores that the level of evaluation and independent review should be commensurate with the risk posed by the specific SaMD, and encourages manufacturers to use continuous monitoring to understand and modify software based on real-world performance.

In announcing these three new policy documents, the FDA emphasized that it "must, whenever possible, encourage the development of tools that can help people be more informed about their health," and went on to add that the FDA's "approach to regulating these novel, swiftly evolving products must foster, not inhibit, innovation." *Id*. Comments on the two draft guidance documents are due to the FDA by February 6, 2018.

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OIG Issues Advisory Opinion 17-07 on Pilot Program for Medication Therapy Management

By Deborah A. Cmielewski, Esq.

On December 4, 2017, the Office of Inspector General ("OIG") issued Advisory Opinion 17-07, in which a pharmaceutical manufacturer (the "Requester") proposed to implement, fund and evaluate a pilot program (the "Pilot Program") in collaboration with a Vendor, a Medicare Advantage Plan (the "MA Plan"), a hospital system (the "Hospital") and a trade association (the "Association") (each, a "Collaborator" and collectively, the "Collaborators"). The OIG determined that, although the arrangement outlined by the Requestor (the "Proposed Arrangement") could potentially generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent existed, it would not impose sanctions in connection with the Proposed Arrangement.

Under the Pilot Program, MA Plan pharmacists who provided medication therapy management ("MTM") services would receive real-time access to certain discharge information for approximately 200 eligible MA Plan beneficiaries who were admitted to the Hospital with one of several enumerated diagnoses. Eligibility for the Pilot Program would be determined based on discharge condition, MA Plan enrollment and eligibility for the MTM services.

Each of the Collaborators would have a specific role in the Pilot Program. The Vendor would create an interface to enable the pharmacists to view clinical data for the eligible patients that would help improve transitions of care and reduce readmissions. The interface would be used solely for the Pilot Program, and at its conclusion, the intellectual property for the interface would belong to the Vendor.

The Requestor's roles would be limited to ensuring that the Pilot Program complies with applicable law and regulations and to funding the Pilot Program. Funding would not exceed $257,000 and would be disbursed in specified stages. The Requestor would have no involvement in developing the interface, nor would it have any access to the interface or to the data transmitted through it.

The Association would serve as the Project Manager for the Pilot Program. In that role, it would engage parties to participate and manage the contracts between the Collaborators. The contracts would clearly state that the collaboration under the Pilot Program would have no direct or indirect bearing on formulary recommendations or referrals of business by and between the parties; likewise, it would not be intended to induce or reward any purchases, recommendations or prescribing decisions in favor of any of the Requestor's products. The Association would analyze the data and render a report at the conclusion of the Pilot Program. If the Pilot Program is successful, the Association would also prepare a product-neutral training and implementation toolkit that would be branded with the Requestor's name and provided to managed care professionals.

The MA Plan would ensure that the Hospital's discharge notification system is integrated into its existing workflows for initiating MTM services. Finally, the Hospital would engage appropriate leadership to facilitate understanding that the Pilot Program would be a process improvement that aligns the goals across members of the acute care team responsible for patient discharge.

In analyzing the Proposed Arrangement, the OIG noted that various sources of remuneration existed in the Pilot Program but not all of the parties to the Proposed Arrangement were referral sources of one another. It also noted that the Proposed Arrangement was limited in both scope and funding and would be unlikely to lead to increased costs or overutilization of Federally reimbursable services. Although it noted that the free technology could present a high level of risk, the OIG determined that the Proposed Arrangement included a number of critical safeguards that mitigated those risks. The OIG stated that the Proposed Arrangement would be unlikely to interfere with the clinical decision-making of the MTM pharmacists or to have a negative impact on the quality of patient care. Accordingly, it determined that it would not impose administrative sanctions in connection with the Proposed Arrangement.

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OIG Finds HHS Needs Improvement in Cybersecurity

By Sharmila D. Jaipersaud, Esq.

On December 19, 2017, Office of Inspector General ("OIG") reported that the U.S. Department of Health and Human Services ("HHS") had vulnerabilities in their cybersecurity. The OIG audited four HHS operating division networks ("OPDIVs") and found that security controls needed improvement to more effectively detect and prevent cyberattacks. The report was based on an audit done by the OIG for the 2016 Fiscal Year. As a part of the audit, the OIG performed network and web application penetration testing at the OPDIVs. During the audit, the OIG found that HHS had configuration management and access control vulnerabilities.

The OIG reported on six observations to HHS and asked them to respond with proposed corrective actions. HHS generally agreed with all six of the OIG observations in the draft report. After receiving the report on the vulnerabilities, each of the OPDIVs indicated that the vulnerabilities were corrected or were in the process of being corrected. The OIG release was only a summary of the report, which was restricted and did not list the flaws found with specificity. The full report and OIG recommendations on how to correct the identified vulnerabilities were shared only with senior-level HHS information technology personnel.

The OIG listed "Protecting HHS Data, Systems, and Beneficiaries from Cybersecurity Threats" as one of the top management and performances challenges facing HHS in 2017. *See* Office of Inspector General, U.S. Dep't of Health & Human Services, Top Management and Performance Challenges Facing HHS, pg. 44 (2017), available at the OIG's website. In such recognition, the OIG stated in part, HHS "must ensure that it takes appropriate actions

to protect all HHS data and systems from cybersecurity threats. Similarly, HHS must protect its beneficiaries by fostering a culture of cybersecurity among its partners and stakeholders. Key components of the challenge are protecting HHS's data and systems and fostering a culture of cybersecurity beyond HHS." *Id*.

This is not the first time that the OIG found issues with HHS cybersecurity. In March of 2016, the OIG found that the HHS was making progress with security but still had weaknesses. At that time, the OIG found flaws in the following areas: continuous monitoring, configuration management, ID and access management, risk management, incident response, security training, contingency planning and contractor systems. The OIG expressed concern even then, stating that the weaknesses "could potentially compromise the confidentiality, integrity and availability of HHS sensitive information and information systems." *See* Office of Inspector General, U.S. Dep't of Health & Human Services, Audit A-18-15-30300, Review of the Department of Health and Human Services' Compliance with the Federal Information Security Modernization Act of 2014 for Fiscal Year 2015, (2016), available at the OIG's website. Notably, the OIG has scheduled another audit for HHS in 2018.

Congress has recognized the cyber issues that HHS is facing. In November 2017, House representatives introduced the HHS Cybersecurity Modernization Act (the "Act"), which seeks, in part, to improve coordination between HHS offices. The Act would also designate an officer within HHS as having primary responsibility for the information security programs of HHS.

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Tax Reform Affecting Tax-Exempts

By Farah N. Ansari, Esq.

The President signed the tax bill last week originally known as the Tax Cuts and Jobs Act (the "Act"), which implements numerous tax changes. A Tax Alert summarizing key changes to the tax law was published by our firm last week. In addition to the changes discussed in the Tax Alert, additional changes were made that affect tax-exempt entities. The changes include: (i) an increase in the limit for deductible cash contributions to public charities and certain private foundations from 50% of adjusted gross income to 60% of adjusted gross income and (ii) requiring that a tax-exempt organization that carries on more than one "unrelated trade or business" calculate the "unrelated business taxable income" of each "unrelated trade or business" separately, not allowing for deductions from one to offset income from another. A copy of the Tax Alert can be found here.

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