Schenck Price
SCHENCK PRICE SMITH & KING, LLP
www.spsk.com

HEALTH LAW DISPATCH

February 2019

FRAUD & ABUSE

OIG Permits Temporary Loans of Smartphones to Eligible Patients

By Daniel O. Carroll, Esq.

On January 24, 2019, the Office of the Inspector General ("OIG") issued OIG Advisory Opinion No.19-02, in favor of a proposed arrangement of a pharmaceutical manufacturer ("Manufacturer") to temporarily loan smartphones to certain eligible patients in order to receive data from an ingestible sensor embedded in the Manufacturer's drug ("Proposed Arrangement"). The digital medicine version of the Manufacturer's drug embedded with the ingestible sensor ("DM Drug") was recently approved by the U.S. Food & Drug Administration ("FDA"). As described by the OIG, the DM Drug emits a signal detected by a wearable sensor on the patient's abdomen, which collects data regarding the patient's rest patterns and activity and transmits such data to an application on the patient's smartphone (the "App"). The patient can also supplement the information collected on the App. All of the patient information collected and transmitted to the App is then transmitted to a secure cloud-based server. With the patient's consent, the patient's health care providers can access this information via web portals.

It is apparent that, in order to effectively use and realize the full benefits of the DM Drug, the patient must have a smartphone capable of running the App. Accordingly, the cost of owning a smartphone may be a barrier for certain patients to access and use the DM Drug. With the Proposed Arrangement, the Manufacturer seeks to remove any such barrier by loaning smartphones with significantly limited functionality (i.e., functionality to only make domestic calls and use the App) to patients who: (1) have a prescription for the DM Drug; (2) meet insurance prior-authorization requirements; (3) have an annual income below a specified percentage of the Federal poverty level; (4) do not already possess a smartphone capable of running the App; and (5) are United States citizens or legal permanent residents. The Manufacturer will contract with a specialty pharmacy to verify patient eligibility and, if the patient is eligible, provide the loaner smartphone. The Proposed Arrangement would not be generally advertised to patients. Rather, without any additional compensation, providers would make patients aware of the Proposed Arrangement and assist with patient onboarding. The loaner smartphones are only provided for a limited period of time (i.e., duration of DM Drug therapy, but no more than two 12-week periods).

The OIG found that while the limited functionality of the loaner smartphones to make domestic calls would constitute remuneration, the Proposed Arrangement would actually promote access to care and increase patient safety and quality of care. As such, the Proposed Arrangement satisfied the promotion of access to care exception to the beneficiary inducements prohibition under the civil monetary penalties law. Based on this finding, the OIG concluded that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties and, in light of the lack of advertising to patients and the other safeguards noted above, it would not impose administrative sanctions under the Federal anti-kickback statute. See, U.S.C. 42 §§ 1320a-7a and 1320a-7b.

For more contact Daniel O. Carroll, Esq. at doc@spsk.com or 973-631-7842.

HHS Proposes Amendments to Discount Safe Harbor Protections for Drug Rebates

By Meghan V. Hoppe, Esq.

On January 31, 2019, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) published a proposed rule that would amend the Federal Anti-Kickback Statute ("AKS") discount safe harbor to

eliminate protection for certain drug discounts and create two new safe harbors (the "Proposed Rule").

Under the Proposed Rule, the existing AKS discount safe harbor would be amended to eliminate protection for prescription drug price reductions paid by manufacturers to plan sponsors under Medicare Part D or Medicaid managed care organizations ("MCOs"), either directly or through pharmacy benefit managers ("PBMs"). However, the amendment to the Proposed Rule excludes any rebates or reductions required by law (e.g., rebates under the Medicaid Drug Rebate Program) and rebates paid by manufacturers to drug wholesalers, hospitals, physicians or pharmacies. The Proposed Rule also creates two new AKS safe harbors.

The first new safe harbor would protect certain price reductions offered at the point-of-sale by pharmaceutical manufacturers to consumers on pharmaceutical products that are covered under Medicare Part D or by Medicaid MCOs.

The second new safe harbor introduced by the Proposed Rule protects certain fixed payments from pharmaceutical manufacturers to PBMs for services that PBMs provide to pharmaceutical manufacturers in connection with the services it provides to health plans (e.g., contracting with a network of pharmacies, negotiating rebate arrangements, performing drug utilization review and operating disease management programs). This proposed safe harbor would only protect a pharmaceutical manufacturer's payment for those services that the PBM furnishes to the pharmaceutical manufacturer and not any services that the PBM may also be providing to a health plan.

Safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. For details regarding the specific conditions that an arrangement must meet to be protected under the proposed safe harbors, please feel free to contact any member of the firm's Health Care Law Practice Group.

The Proposed Rule will be open for public comment until April 8, 2019. If implemented, the discount safe harbor amendment will take effect on January 1, 2020 and each of the new AKS safe harbors would go into effect 60 days following the publication of the final rule.

For more information, contact Meghan V. Hoppe, Esq. at mvh@spsk.com or (973) 540-7351.

PRIVACY & HIPAA

HIPAA Enforcement Reaches Record Levels

By Deborah A. Cmielewski, Esq.

It is a well-publicized fact that HIPAA enforcement has been on the rise in recent years. The Office for Civil Rights ("OCR") has now released its annual report, which confirmed that 2018 was a record year for HIPAA enforcement activities. The OCR settled ten (10) cases in 2018, with fines and penalties totaling nearly $29 million and individual settlements ranging from $100,000 to $16 million.

The report underscored the fact that entities subject to HIPAA continue to disregard basic requirements. As in previous HIPAA settlements, the OCR sanctioned entities last year for violations that included failure to implement physical safeguards to shield protected health information ("PHI"); theft of an unencrypted laptop and the loss of thumb drives containing unencrypted data; failure to perform a risk analysis; failure to terminate the remote access of a workforce member following separation of employment; and numerous instances of failure to maintain business associate agreements. Other instances of blatant disregard of rudimentary HIPAA requirements included a medical provider discussing a patient's case with a television reporter without obtaining the patient's consent and a hospital enabling film crews to film a documentary on premises without obtaining patient authorization.

2018 brought the largest-ever settlement against an entity subject to HIPAA when the OCR resolved a matter against Anthem, Inc., a business associate, for $16 million. That settlement followed Anthem's report of a breach and a subsequent compliance review by the OCR, which uncovered failures to conduct an accurate and thorough risk analysis and to adhere to various other HIPAA Security Rule requirements. In addition to the significant settlement, Anthem agreed to a rigorous corrective action plan with the OCR.

In addition to these noteworthy settlements, the OCR prevailed in an administrative litigation filed against the University of Texas MD Anderson Cancer Center ("MD

Anderson"). An administrative law judge ordered MD Anderson to pay $4.3 million in civil monetary penalties for failing to adopt an enterprise-wide solution to encrypt electronic devices containing PHI.

The OCR annual report again highlights to need to be proactive – rather than reactive – in your HIPAA compliance efforts. Schenck Price can assist in creating a culture of HIPAA compliance in your organization.

For more information, contact Deborah A. Cmielewski, Esq. at dac@spsk.com or 973-540-7327.

NONPROFITS & TAXATION

New IRS Guidance on Executive Compensation Excise Tax

By Farah N. Ansari, Esq.

The 2017 Tax Cuts and Jobs Act enacted Section 4960 of the Internal Revenue Code ("Section 4960") which imposes an excise tax on certain executive compensation. On December 31, 2018, the Department of the Treasury and Internal Revenue Service issued Notice 2019-09 providing interim guidance on the excise tax. The Treasury and IRS will issue additional guidance in the form of proposed regulations in the future, however any future guidance will be prospective and will not apply to tax years beginning before that guidance is issued.

In general, Section 4960 imposes an excise tax at the corporate tax rate, which is currently 21%, on applicable tax-exempt organizations ("ATEOs") that pay, during a tax year, excess compensation to "covered employees." The excise tax is on the sum of (i) remuneration that exceeds $1 million and (ii) an "excess parachute payment." A "covered employee" is an employee of an ATEO who is among the five highest paid for the current year and any prior tax year beginning after December 31, 2016. Compensation that is paid by a related organization is also included.

Section 4960 is effective for a tax-exempt organization's first tax year beginning after December 31, 2017.

There is an exception in Section 4960 relating to certain medical services. Remuneration that is paid to a licensed medical professional or veterinarian for the direct performance of medical or veterinary services is not counted towards the $1 million amount or the "excess parachute payment." However, important to note is that administrative and management services are not excluded and therefore, count towards the Section 4960 excise tax. The Notice defines a "licensed medical professional" as an individual licensed under state or local law to perform medical (including nursing) and veterinary services. Medical services must constitute "medical care" as defined in Internal Revenue Code Section 213(d)(1)(A), which include services for the diagnosis, cure, mitigation, treatment, or prevention of disease. A "reasonable, good faith" allocation must be made for those who perform both medical services and for instance, administrative services.

For more information, contact Farah N. Ansari, Esq. at fna@spsk.com or 973-540-7344.

STATE LAW

New Jersey Adds Opioid Abuse as an Illness Approved for Medical Marijuana Treatment

By Sharmila D. Jaipersaud, Esq.

Governor Phil Murphy is trying to broaden New Jersey's attack on opioid addiction by adding it as an illness that is treatable by medical marijuana. By adding the addiction to the list of treatable illness, Gov. Murphy has also expanded Medicaid coverage for the addiction to be treated by medical marijuana. Notably, marijuana (for any use) remains illegal under federal law.

Drug overdoses in New Jersey have increased for the fourth straight year. New Jersey has taken a sharp approach against opioid addiction, such as filing suit against pharmaceutical companies for alleged misconduct and deceptions about the "viability of long-term opioid use in the minds of doctors and patients," as stated by Attorney General Gurbir Grewal.

For months, New Jersey has also been extending its efforts to support the medical marijuana program. In December 2018, Gov. Murphy sought a large expansion

of the program. He increased the number of dispensaries from 6 to 12. At that time, the New Jersey Department of Health received 146 applications for the 6 new dispensary licenses.

Medical marijuana is currently used to treat a number of different ailments, such as chronic pain, anxiety, migraines, Lou Gehrig's disease, lupus and other diseases. While it is expanding, the program does have some troubles.

In January, New Jersey sought to suspend the license of NJ Green founder, Dr. Anthony Anzalone. According to the complaint filed against Dr. Anzalone, he allegedly wrote prescriptions for more than 3,000 patients for medical marijuana use. However, he allegedly never examined them and the patients would not have qualified for the program. The State Board of Medical Examiners has suspended Dr. Anzalone based on the allegations and he has been forced to close his practice. According to the announcement by Attorney General Grewal, Dr. Anzalone allegedly made more than $1 million just off of the consultation fees.

Practitioners may be interested in growing their practice by incorporating medical marijuana as a treatment for patients with various ailments. While New Jersey has taken a broad-based approach to expanding the use of medical marijuana, Dr. Anzalone's case tells us that regulations will be enforced. Proper patient screening must be followed to determine whether a patient is appropriate candidate for the program. Furthermore, practitioners must be aware that while medical marijuana is lawful in New Jersey, federal law remains unchanged. Practitioners could face different issues if they choose to add medical marijuana to their treatments. For example, lease provisions or other contracts, like lending documents, may be breached if the practitioner is prescribing marijuana. Close scrutiny should be done prior to embarking on this practice.

For more information, contact Sharmila D. Jaipersaud, Esq. at sdj@spsk.com or 973-631-7845.

MEDICARE REIMBURSEMENT

CMS Rolls Out New Plan to Expand Medicare Reimbursement for 911 Medical Transportation Services

By Divya Srivastav-Seth, Esq.

The Center of Medicare and Medicaid Services ("CMS") has announced that in the Summer of 2019, it will begin accepting applications from Medicare enrolled ambulance providers and suppliers to participate in its new voluntary, five (5) year innovation project expanding benefits under a new payment model for Emergency Triage, Treatment and Transport Services ("ET3").

Existing Medicare regulations only permit reimbursement for emergency ambulance services when patients are transported to hospitals, skilled nursing facilities, and dialysis centers. This incentivizes the transport of all beneficiaries to the emergency department of a hospital, even when an alternative treatment option for a low acuity service may be more appropriate.

Under ET3, Medicare would cover three (3) more situations when a beneficiary receives care pursuant to a 911 call for help as demonstrated in the following scenario. After the 911 call is received, the dispatcher will either initiate an ambulance service or connect the patient to a medical triage line of service where a health care professional is made available to discuss health concern(s). If an ambulance is initiated, either the ambulance transports the individual to an emergency department or to another facility such as urgent care or if no medical transportation is required, a qualified health care practitioner could provide treatment in place, either on the scene or by means of telehealth, including audio and videoconferencing.

The medical triage line of service, the flexibility to provide ambulance transportation to another facility other than the emergency department, and the onsite provision of treatment in place or by telehealth by a qualified health care professional are all additional covered services that will be paid for by Medicare under ET3. Notably, an individual can also elect to be transported to a hospital emergency room.

CMS will also provide cooperative agreement funding to selected local governments, their designees, or to other entities that operate or have authority over 911 dispatches in order to facilitate integration and participation in ET3.

ET3 encourages high-quality provision of care by enabling participating ambulance suppliers and providers to earn up to a five percent (5%) payment adjustment in the later years of the model based on their achievement of key quality measures. Qualified healthcare practitioners or alternative destination sites that partner with participating ambulance suppliers and providers would receive payment as usual under Medicare for any services rendered. CMS is also encouraging ET3 participants to partner with additional payers, including state Medicaid agencies, to provide similar services to others they serve in their geographic areas.

ET3 will have a five (5) year performance period beginning in January of 2020 and ending in 2025. The performance period for participants will not vary; therefore, only applicants selected initially can participate for the entire five (5) year period.

ET3 aims to improve quality and lower costs by reducing avoidable transports to the emergency room. CMS intends to supply more details, including participation guidelines, at a later date. Interested health care entities or providers should review existing medical transport arrangements and consult with legal counsel regarding any potential conflict with state and local laws and ordinances concerning emergency transport and telehealth services.

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