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Terminally Ill Patients Given the "Right To Try"

By Daniel O. Carroll, Esq.

On May 30, 2018, President Donald Trump signed into law the "Trickett Wendler, Frank Mongiello, Jordan McLinn, and Mathew Bellina Right to Try Act of 2017". See 21 U.S.C. § 360bbb-0a (the "Right to Try Act"). Generally, the drug development process in the United States can take more than a decade before government approval, and the overwhelming majority of investigational drugs never complete the full development process or receive approval due to ineffectiveness or serious adverse side effects. The Right to Try Act allows eligible terminally ill patients to use experimental medication not otherwise available as a treatment option. Eligible patients under the new law are those who have been diagnosed with a life-threatening disease or condition, have exhausted approved treatment options and are unable to participate in a clinical trial involving the experimental medication. The Right to Try Act is intended to supplement, and act as an alternative path to, the existing expanded access policies of the Food and Drug Administration ("FDA"). Such experimental medication must have completed a Phase 1 clinical trial and be in active development and production, but it will not yet have received approval from the FDA. Notwithstanding the new pathway for access to investigational drugs provided by the Right to Try Act, drug manufacturers are still under no obligation to permit or provide such investigational drugs to requesting physicians for use by their terminally ill patients.

A major difference between the Right to Try Act and the requirements for expanded access or compassionate use of investigational drugs is that the Right to Try Act allows patients to use the investigational drug without the need for FDA approval. Before the Right to Try Act, a terminally ill patient's only avenue for seeking access to an investigational drug would be for his or her physician to submit a single patient, compassionate use investigational new drug application (IND) to the FDA for approval. Proponents of the new law note that removing the additional requirement of applying to the FDA for access to the investigational drug will remove an administrative hurdle and allow patients quicker access to the investigational drug when time may be of the essence. However, critics of the new law are quick to note that the FDA authorizes over 99% of the expanded use requests that it receives. In addition, without FDA's review, the patients and their physicians will not have access to FDA input that could facilitate patient safety.

Drug manufacturers are required to submit to the FDA an annual summary of any use of an eligible investigational drug pursuant to the Right to Try Act. However, aside from certain limited exceptions, the FDA may not use a clinical outcome associated with the use of an eligible investigational drug under the Right to Try Act to delay or adversely affect the review or marketing approval of the drug.

Finally, and importantly, the Right to Try Act provides protection against liability for acts or omissions of drug manufacturers, sponsors, prescribers, dispensers or other individual entities related to the provision of eligible investigational drug to eligible patients, provided that such conduct does not amount to reckless or willful misconduct, gross negligence or an intentional tort.

The ability of patients to take advantage of this alternative pathway is dependent on physicians and drug manufacturers agreeing to pursue the use of eligible investigational drug after considering their own legal and business interests. As such, many critical of the new law are skeptical that this alternative pathway will signifi-

cantly expand access to investigational drugs and may offer false hope with fewer safety protections. See, e.g., Letter to U.S. House of Representatives, www.asco.org/sites/new-www.asco.org/files/content-files/February-2018-Right-to-Try-Coalition-Letter.pdf (February 6, 2018).

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

OIG Permits Limited Provision of Free Telemedicine Items and Services

By Meghan V. Hoppe, Esq.

On May 31, 2018, the Office of Inspector General ("OIG") issued Advisory Opinion No. 18-03 concerning a not-for-profit Federally qualified health center look-alike's ("Provider") proposal to provide, at no charge, certain information technology-related equipment and services to a County Department of Health clinic (the "County Clinic") for use in telemedicine encounters with the County Clinic's patients (the "Proposed Arrangement"). The OIG determined that, although the Proposed Arrangement could potentially generate prohibited remuneration under the Federal Anti-Kickback Statute if the requisite intent to induce or reward referrals of Federal health care program business is present, the OIG would not impose administrative sanctions on Provider or the County Clinic (together, the "Requestors") in connection with the Proposed Arrangement.

Under the Proposed Arrangement, Provider would furnish to the County Clinic certain telemedicine hardware (e.g. laptop, speakers and cameras) ("Telemedicine Items") as well as services related to the Telemedicine Items (e.g. installation, maintenance, training and technical assistance) ("Telemedicine Services"). Provider would pay for the Telemedicine Items and Telemedicine Services with grant funds received from the State Department of Health, AIDS Institute for the primary purpose of increasing access to HIV prevention services in the State. The Requestors indicated that the Proposed Arrangement is intended to improve patient access to HIV prevention services, making it more likely that patients will seek out and receive such services.

The Telemedicine Items would be used only for telemedicine encounters related to HIV prevention, including consultations regarding pre-exposure prophylaxis ("PrEP") and post-exposure prophylaxis ("PEP"). Currently, the County Clinic is unequipped to provide PrEP and PEP consultations and prescribing services to its patient population and must refer patients outside of the clinic. The Proposed Arrangement would allow the County Clinic to refer patients to Provider, or other qualified providers, for virtual PrEP and PEP consultations and prescriptions. According to the Requesters, patients seeking in-person PrEP and PEP consultations and follow-up services would need to travel approximately 25 to 30 minutes by car in order to obtain the same services that Provider could furnish virtually at the County Clinic. Both the County Clinic and Provider could submit claims to a Federal health care program for the virtual PrEP and PEP consultations and follow-up services.

In analyzing the Proposed Arrangement, the OIG noted that Provider would provide remuneration to the County Clinic consisting of the Telemedicine Items and Telemedicine Services as well as the opportunity to earn originating site fees for services furnished using the items provided. In turn, the County Clinic could serve as a potential source of referrals of Federal health care program business for certain consultations, follow-up items and services that Provider would provide. On its face, the Proposed Arrangement implicates the Federal Anti-Kickback Statute since one purpose of the remuneration to the County Clinic could be to induce referrals of Federal healthcare program business to Provider. However, the OIG concluded that the Proposed Arrangement would present a low risk of fraud and abuse under the Federal Anti-Kickback Statute, and, based upon the following factors, administrative sanctions would not be imposed on Provider or the County Clinic:

- The Proposed Arrangement would include safeguards intended to prevent patient steering to Provider. The County Clinic would be free to refer patients to other qualified providers and would advise all patients

who want to receive the PrEP or PEP consultations that they could obtain them either virtually via the Telemedicine Items or in person from Provider or other providers. Additionally, the Telemedicine Items would not be used to inappropriately limit or restrict the flow of information and nothing inherent to the Telemedicine Items would: (i) limit or restrict the use or compatibility of the Telemedicine Items with different information technology systems, software applications or networks or (ii) inhibit the ability of any users of the Telemedicine Items to communicate or exchange data accurately, effectively, securely and consistently with different information technology systems, software applications and networks.

- The Proposed Arrangement would be unlikely to result in inappropriate patient steering to Provider's pharmacy since the Requesters certified that neither would recommend a specific pharmacy to fill orders for medications and patients would be free to choose their own pharmacy. The OIG also found that it was unlikely that a patient would choose to use Provider's pharmacy because it was 80 miles away and did not offer mail-order services.

- The Proposed Arrangement would be unlikely to inappropriately increase costs to the Federal health care programs since the preliminary tests, consultations and follow-up services would have been provided regardless of whether the Proposed Arrangement was in place. Although the Arrangement would increase utilization, the increase in HIV prevention services would be consistent with the purpose of the grant funds from the State and could also reduce the prevalence of HIV and promote public health.

- Finally, although Provider and the County Clinic could both potentially benefit from the Proposed Arrangement, the primary beneficiaries would be the patients, who could receive HIV prevention services more conveniently and efficiently through use of the Telemedicine Items. The OIG found this to be particularly important in light of the fact that certain PEP medications need to be taken within 72 hours after exposure to HIV.

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

Third Circuit Weakens Out-of-Network Providers' Ability to Sue Health Insurance Plans

By Divya Srivastav-Seth, Esq.

In a recent decision, the United States Third Circuit Court of Appeals held that anti-assignment clauses in ERISA-governed health insurance plans are enforceable. The Third Circuit's decision in American Orthopedic & Sports Medicine v. Independence Blue Cross Blue Shield, et al., 2018 U.S. App. LEXIS 12637, removes one of the more effective strategies that out-of-network ("OON") providers had utilized to recover amounts due for services provided to beneficiaries of such plans, as it eliminates the providers' standing to pursue claims on behalf of their patients.

The Employee Retirement Income Security Act, 29 U.S.C. § 1002(1)(2) ("ERISA"), is a comprehensive legislative scheme enacted to protect the interests of participants in employee benefit plans by conferring on employees the right to sue to recover benefits due under the terms of the plan. 29 U.S.C. § 1132(a) (1) (B). That right, however, is limited to the participant or beneficiary under the plan. See Id. at § (a) (1). However, the majority of courts, including the Third Circuit, have held that a valid assignment of benefits by the patient to the OON provider would allow the OON provider to step into the shoes of the patient for purposes of disputing the reimbursement of the benefit. See North Jersey Brain & Spine Center v. Aetna, Inc., 2015 U.S. App. LEXIS 16158.

The ruling in American Orthopedic upholds the validity of boilerplate anti-assignment clauses in these plans based on black-letter law stating that the terms of an unambiguous private contract must be enforced. American Orthopedic at 14. In addition, the Third Circuit found that the routine processing of checks and payments to the OON provider would not be considered a waiver of the plan's anti-assignment protections because a waiver requires a "clear, unequivocal and decisive act of

the party with knowledge of such right and an evident purpose to surrender it." Id. at 15.

Although the Third Circuit held that a provider did not have standing when an anti-assignment clause exists, to claim for benefits due to a plan participant, it did leave open the hope for such recovery if the OON provider has a power of attorney from the patient authorizing it to act on its behalf. Id. at 16.

The Third Circuit's ruling, in conjunction with the recently enacted "Out-of-Network Consumer Protection, Transparency, Cost Containment and Accountability Act" P.L. 2018, c.32, (the "Act"), poses another hurdle for out-of-network providers to operate profitably in the current healthcare marketplace. Although the Act does not automatically include ERISA plans within its protection, if the plan opts to incorporate the Act's mechanisms, it will be enforceable against the out-of-network provider and prevent that provider from balance billing any patients for sums due in the absence of a knowing, voluntary election by the patient to pay any amounts not covered by the patient's carrier or plan. Providers should review their intake processes relating to assignments, OON disclosures and power of attorney forms, which will need updating in order to preserve the ability to recover payment for professional services rendered.

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

New Charges Against Bergen County Neurologist Allege Fraudulent Billing in Statewide Medical Kickback Scheme

By Sharmila D. Jaipersaud, Esq.

On June 1, 2018, New Jersey Attorney General Gurbir S. Grewal and the Office of Insurance Fraud Prosecutor (the "Prosecutor") announced that Dr. Terry Ramnanan would face additional charges in connection with a statewide medical kickback scheme, which included charges of health care claims fraud, misconduct by a corporate official and other second-degree offenses, as a result of a superseding indictment.

Dr. Ramnanan operates the Interventional Spine and Pain facility in Paramus and had already been charged with and plead guilty to lesser charges relating to the same alleged fraudulent conduct in July 2016. In August of 2017, he was indicted on one charge of third-degree conspiracy, commercial bribery and the criminal use of runners. See N.J.S.A. 2C:21-22.1 (providing that it is a third degree crime to employ or act as a runner by procuring patients for healthcare providers who will bill insurance for providing services to such patients).

In July 2016, Ronald Hayek, a chiropractor, plead guilty to criminal charges of conspiracy, money laundering and commercial bribery filed by the Division of Criminal Justice and admitted to accepting tens of thousands of dollars in kickbacks from several healthcare providers, including Dr. Ramnanan and others, in exchange for referring patients to them and their related medical facilities. In his plea, Hayek also admitted paying commercial bribes to attorneys in exchange for the referral of clients to his practice.

As a result of Hayek's guilty plea, Dr. Ramnanan is now accused of bribing another health care professional for patient referrals and then fraudulently submitting insurance claims for medical treatment performed on those patients. The new allegations against Dr. Ramnanan include the alleged use of his medical facility to fraudulently bill insurance carriers for more than 637 medical procedures totaling $682,000 related to patients involved in the kickback scheme.

This use of a superseding indictment against Dr. Ramnanan is the latest example of New Jersey's continued aggressive approach to fighting medical fraud. In 2016, the Attorney General formed a Commercial Bribery Task Force (the "Task Force"), which was created to target commercial bribery in the healthcare industry. In the string of indictments that have stemmed from the Task Force, chiropractors and pain management doctors refer patients for medical treatment for remuneration. The treating physician then bills for services rendered

to the patient, which triggers alleged fraudulent billing. The chiropractors may also bill for services rendered to patients who are steered to them through the scheme.

The superseding indictment and the string of cases associated with it are a candid reminder that practitioners must be mindful of the structure of their referral relationships. Practitioners should take caution in setting up these relationships and revisit those that may have been in place for some time to insure regulatory compliance.

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

OCR Imposes $4.3 Million Penalty on Texas Cancer Center for HIPAA Violations

By Deborah A. Cmielewski, Esq.

On June 18, 2018, the U.S. Department of Health and Human Services ("HHS") Office of Civil Rights ("OCR") announced that the Honorable Steven T. Kessel, Administrative Law Judge ("ALJ") of the HHS Appeals Board, entered summary judgment in favor of the OCR and against the University of Texas MD Anderson Cancer Center ("MD Anderson") for violations of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). In the second summary judgment ever entered in favor of OCR, Judge Kessel ordered MD Anderson to pay $4.3 million in civil monetary penalties. The penalty represents the fourth largest judgment or settlement entered in favor of OCR for HIPAA violations.

MD Anderson, a HIPAA covered entity, operates six (6) cancer treatment hospitals and two (2) diagnostic imaging centers in the Greater Houston, Texas area. OCR began a compliance investigation of MD Anderson following its submission of three (3) separate breach reports in 2012 and 2013, which collectively involved the potential threat to the protected health information of nearly 35,000 individuals. The breach reports identified the theft of an unencrypted laptop and loss of USB thumb drives; the lost and stolen items were ultimately never recovered. Of note, MD Anderson maintained written policies that mandated the encryption of mobile devices as far back as 2007.

MD Anderson also had actual knowledge that the lack of encryption presented a significant risk to the organization. The entity's Information Security Program and Annual Reports for calendar years 2010-2011 identified the lack of encryption of mobile devices as a key risk area. Moreover, its 2011 Corporate Compliance Risk Analysis highlighted the fact that there was no enterprise-wide solution for the encryption of mobile devices, such as laptops and USB drives. That report concluded that this issue presented a high risk to the security of protected health information. Nonetheless, MD Anderson failed to adopt the encryption standard, or to implement a reasonable and necessary alternative, as required by HIPAA. MD Anderson actually delayed the launch of its encryption program until 2011, and by 2013, still had failed to encrypt its entire inventory of devices.

The MD Anderson decision should serve as a warning to entities covered by HIPAA to conduct their risk assessments and to address the risks and vulnerabilities identified in those assessments. Providers and vendors alike need to be proactive—rather than reactive—in implementing their HIPAA compliance plans in this era of increased regulation and enforcement.

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