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HEALTH LAW DISPATCH

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Telehealth

President Trump Signs Executive Order on Improving Rural Health and Telehealth Access

By Meghan V. Hoppe, Esq.

On August 3, 2020, President Donald Trump signed an executive order ("Executive Order") to permanently extend Medicare's broader telehealth coverage beyond the COVID-19 public health emergency and increase access to care in rural areas.

The Executive Order directs the Department of Health and Human Services ("HHS") to:

- Propose a Centers for Medicare & Medicaid Services ("CMS") rule to extend parts of Medicare's broader coverage of telehealth beyond the end of the current public health emergency;
- Propose a payment model to improve rural healthcare through the Center for Medicare and Medicaid Innovation;
- Launch a rural health action plan with a range of actions that different components of HHS will take to 1) build sustainable models for rural communities, 2) focus on preventing disease and mortality, 3) leverage innovation and technology, and 4) increase access to care; and
- Reach a memorandum of understanding with the Federal Communications Commission and the Department of Agriculture to promote rural access to telehealth via broadband.

During the COVID-19 public health emergency, CMS added 135 services, such as emergency department visits, initial inpatient and nursing facility visits, and discharge day management services, that could be paid by Medicare when delivered by telehealth. Internal analysis performed by CMS found a staggering weekly increase in telehealth visits for CMS beneficiaries from approximately 14,000 to almost 1.7 million in the last week of April.

Following President Trump's Executive Order, CMS issued its Medicare Physician Fee Schedule for calendar year 2021 that includes proposed changes to permanently allow some services to be done by telehealth. These services include home visits for the evaluation and management of a patient (in the case where the law allows telehealth services in the patient's home) and emergency room evaluation and management virtual visits for minor to moderately severe health issues. CMS is also proposing to temporarily extend payment for a variety of telehealth services through the calendar year in which the public health emergency ends. This extension will give clinicians and patients time to prepare to provide in-person care again and to consider which services should be delivered permanently through telehealth beyond of the COVID-19 pandemic. "At President Trump's direction, CMS has dramatically expanded the availability of telehealth during the pandemic, extending a lifeline to patients and providers amid stay-at-home orders. In an earlier age, doctors commonly made house calls. Given how effectively and efficiently the healthcare system has adapted to the advent of telehealth, it's become increasingly clear that it is poised to resurrect that tradition in modern form," said CMS Administrator Seema Verma.

CMS is seeking public input on which services to permanently add to the telehealth list. Those interested in submitting comments on the Physician Fee Schedule must do so by October 5, 2020.

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

Cannabis

FDA Issues Draft Guidance for Clinical Research Involving Cannabis

By Daniel O. Carroll, Esq.

On July 21, 2020, the United States Food and Drug Administration ("FDA") issued guidance outlining its current thinking on certain issues relevant to clinical research involving the development of drugs containing cannabis or cannabis-derived compounds ("Guidance"). While non-binding, the Guidance does provide the industry some insight on the impact of recent legislative changes and how the federal government will regulate research involving cannabis or cannabis-derived compounds. The Guidance covers permitted sources of cannabis for clinical research, considerations regarding quality and recommendations about calculating levels of tetrahydrocannabinol ("THC"). Notably, it does not address development of fully synthetic versions of substances that occur in cannabis or cannabis-related compounds.

The Guidance recognizes that the 2018 Farm Bill (Agriculture Improvement Act of 2018, Public Law 115-334) changed and added permitted sources of cannabis and cannabis-derived compounds for clinical research. Prior to these legislative changes, the only federally legal source for cannabis in the United States was the cannabis grown by the University of Mississippi at the National Center for Natural Products for the National Institute on Drug Abuse Drug Supply Program ("DSP"). The 2018 Farm Bill removed hemp, which includes cannabis and cannabis-derived compounds not containing delta-9 THC at more than 0.3 percent by dry weight ("Hemp"), from the definition of marijuana in the Controlled Substances Act and thereby expanded cannabis sourcing options beyond the DSP for clinical research sponsors and investigators.

Underscored throughout the Guidance by the FDA, cannabis or cannabis-derived compounds with a delta-9 THC content above 0.3 percent by dry weight remain Schedule I controlled substances under the Controlled Substances Act ("Schedule I Cannabis") and the Drug Enforcement Administration ("DEA") is the lead federal agency for regulating such controlled substances. As such, the FDA encourages sponsors and investigators involved in clinical research to contact the DEA regarding Schedule I Cannabis.

Throughout the development and investigation of a new drug, sponsors are expected to show that a quality product can be consistently manufactured. Accordingly, sponsors must be prepared to submit sufficient information ensuring the identity, quality, purity, and potency or strength of the investigational drug. The FDA cautions that, even if the starting materials qualify as Hemp, the manufacturing process may alter the composition of the materials or by-products that are no longer Hemp but qualify as Schedule I Cannabis. The Guidance identifies relevant resources for quality considerations in the research and development of drugs containing cannabis or cannabis derived compounds and notes that, whether or not the material meets the definition of Hemp, reliable laboratories for analytical testing and related reporting should be used by sponsors.

In light of the regulatory importance placed on the calculation of THC content when distinguishing between Hemp and Schedule I Cannabis, the Guidance notably provides the FDA's recommendations for calculating the percent delta-9 THC by dry weight for both solution based material and solid oral dosage form. Information regarding such calculations will need to be furnished in the applicable investigational new drug (IND) application. Though the FDA cautions against using the calculation recommendations for other purposes such as chemistry, manufacturing, or controls, they do provide an insight into at least one federal agency's thoughts on establishing a standard federal method for determining whether a product is Hemp or Schedule I Cannabis (i.e., a controlled substance).

Those interested in submitting comments on the draft Guidance to the FDA must do so by September 21, 2020.

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42 CFR Part 2

SAMHSA Adopts Historic Part 2 Rule Changes

By Deborah A. Cmielewski, Esq.

In a significant effort toward expanding coordination and quality of care, the Substance Abuse and Mental Health Services Administration ("SAMHSA") has adopted changes

to the rules governing the confidentiality of substance use disorder ("SUD") records codified at 42 C.F.R. Part 2 ("Part 2"). The adoption marks an important step in the nation's efforts to combat the opioid crisis and the United States Department of Health & Human Services ("HHS") Regulatory Sprint to Coordinated Care.

The basic framework of the Part 2 rules, which provides robust privacy protections to sensitive SUD records, remains unchanged. According to HHS Secretary Alex Azar, however, the final rules "will help make it easier for Americans to discuss substance use disorders with their doctors, seek treatment, and find the road to recovery." A complete copy of the adopted changes to the Part 2 rules is available online.

Some of the key modifications and clarifications contained in the adoption include the following:

Treatment Records of Non-Part 2 Providers: The recording of patient information about a SUD by a non-Part 2 provider does not render the non-Part 2 provider's records subject to Part 2, provided that the non-Part 2 provider segregates any SUD records received from a Part 2 program or lawful holder.

Consent Requirements: A SUD patient may consent to disclose the patient's own SUD information to an organization without a treating provider relationship to the patient. The patient need not identify a specific individual in the organization on the consent form.

Disclosures to Central Registries and PDMPs: Non-opioid treatment programs and non-central registry treating providers are permitted to access central registries in order to investigate whether their patients are enrolled in an opioid treatment program.

Medical Emergencies: The meaning of a "bona fide medical emergency" is expanded to include a temporary state of emergency declared by a state or federal authority and resulting from a natural disaster. Accordingly, SUD records may be disclosed by a Part 2 program without patient consent in order to facilitate a patient's access to treatment if a natural disaster prohibits the Part 2 program from rendering services.

Undercover Agents and Informants: A court may order an undercover agent or informant to be placed in a Part 2 program under criminal investigation for up to 12 months, unless a new court order extends that time frame.

SAMHSA has left intact the prohibition against law enforcement use of SUD records in criminal prosecutions against SUD patients, without a valid court order. Moreover, SAMHSA made no changes to the prohibition against using SUD records without patient consent, absent a bona fide medical emergency; for the purpose of scientific research, audit or program evaluation; or based on a valid court order.

For more information regarding these or the balance of the changes to the Part 2 rules, contact Deborah A. Cmielewski, Esq. at dac@spsk.com or 973-540-7327.

Out-of-Network Billing

ERISA Does Not Preempt Out-of-Network Provider's Breach of Contract and Promissory Estoppel Claims

By Divya Srivastav-Seth, Esq.

Out-of-network ("OON") providers have long waged an increasingly futile "battle royal" with insurers and third-party administrators to obtain reimbursement for services rendered to beneficiaries of employer-sponsored group health plans. By definition, an OON provider does not have a direct contractual relationship with the insurer or the plan, and so is unable to sue for payment in its own right. In the past, OON providers were able to rely on the remedies afforded to them as assignees of the plan participants under the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001, et seq. ("ERISA"). Federal courts had consistently recognized that an OON provider standing in the shoes of the beneficiary pursuant to a valid assignment of benefits is better situated to champion the interests of the beneficiary, the protection of whom is the legislation's primary goal. In response, carriers and plans have incorporated anti-assignment clauses into their plan documents designed to stymie such efforts and the same courts that had sought to vest the provider with the power to act on behalf of the patient are now constrained to recognize the validity of the anti-assignment clauses. As a consequence, the risks and costs are shifted back to the beneficiary, who often lacks the resources to commence

a legal action against the insurer or the plan. The OON provider is left without any recourse, other than to sue the patient or deny care.

In this context, the Third Circuit Court of Appeals recently reversed the district court's ruling that ERISA preempted an OON provider's state claims for breach of contract and promissory estoppel and concluded that such preemption would have the opposite effect than that intended by ERISA's comprehensive remedial scheme. See Plastic Surgery Ctr., P.A. v. Aetna Life Ins. Co., Nos. 18-3381, 2020 U.S. App. LEXIS 22274, at 35-36 (3d Cir. July 17, 2020). The Court of Appeals found persuasive the OON provider's argument that it had a separate standalone, albeit oral, agreement with Aetna that failed to have a connection or relate to the ERISA plan, other than in a cursory manner to determine the methodology for the amount due. Id. at 23. In contrast, the Court of Appeals upheld the dismissal of the OON provider's unjust enrichment case because such a claim necessarily implicated the actual benefits due under the plan. Id. at 36.

In Plastic Surgery Ctr., the plan beneficiaries required highly specialized plastic reconstructive services that were not available through Aetna's network but that the OON provider was able to supply. The OON provider obtained Aetna's verbal approval of the procedures via telephone for payment to be calculated later at a reasonable amount according to the terms of the plan or at the highest in-network level. Despite this verbal agreement, Aetna denied payment of the claim. The OON provider filed suit claiming breach of contract, promissory estoppel and unjust enrichment. Aetna moved to dismiss the matter based on ERISA preemption because the claims impermissibly related to or had a connection with an employee benefit plan. See 29 U.S.C. § 1144(a).

The Court of Appeals held that the breach of contract and promissory estoppel claims did not relate to ERISA plans because they were based on a separate agreement between the OON provider and Aetna, with only the amount of payment to be resolved by looking at the methodology of the plan. See Plastic Surgery Ctr. at 19-20. The Court of Appeals also found the following factors persuasive indicators of the independence of the state law claims from the ERISA governed plans: (i) the OON provider's services were not covered services under the plan; (ii) the claims did not arise out of a relationship ERISA intended to govern (i.e., the employer, the plan and its fiduciaries, and the participants and beneficiaries); (iii) the claims did not interfere with plan administration; and (iv) the claims did not undercut ERISA's primary stated purpose of protecting the interests of the beneficiary. Id. at 28. The Court stated that ERISA's goals would actually be undermined by ERISA preemption due to the operation of the anti-assignment clause by creating consequences, such as for providers to require up-front payments from patients or to "deny care or raise fees to protect themselves against the risk of noncoverage." Id. at 36.

The Court further noted that while OON providers migrate from accepting assignment of benefits forms, many have yet to develop an alternate standard form of contract and default back to an ad hoc arrangement, which depending on the facts and circumstances, may so intertwine with the plan as to "relate to" an ERISA plan, and not survive ERISA preemption.

OON providers are encouraged to review their daily operations processes in order to avail themselves of the additional remedies afforded by this decision.

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

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