President Biden Signs Into Law Medicare Telehealth Coverage Extension Post-Public Health Emergency

 On March 15, 2022, President Biden signed into law the $1.5 trillion Consolidated Appropriations Act of 2022 (the "Omnibus Bill"). Included in the 2,700+ page Omnibus Bill is an extension of Medicare coverage of professional consultations, office visits, and office psychiatry services conducted via telemedicine for 151 days after the end of the designated public health emergency ("PHE").[1]

Prior to the PHE, in order to qualify for Medicare coverage:

- A patient receiving telehealth services had to be physically located at a physician's office, hospital, or other healthcare facility that is located in a geographical health professional shortage area (HPSA) that met certain requirements, a county that was not included in a Metropolitan Statistical Area as of December 31st of the preceding year, or an entity participating in a Federal telemedicine demonstration project in order for telehealth services to be covered by Medicare.
- Further, the patient had to obtain telehealth services furnished through technology that enabled real-time audio visual communication, with limited recent exceptions, as discussed in our Client Alert titled ***CMS Continues to Modernize by Expanding Reimbursement for Digital Health Services***.

Administrative and legislative changes made in March 2020 as part of the government's response to the COVID-19 pandemic waived these location and technology requirements for the duration of the PHE. These waivers of location and technology requirements are now extended further under the Omnibus Bill.

Additionally, the Omnibus Bill expands the types of practitioners eligible to provide telehealth services to patients. Prior to the PHE, Medicare covered telehealth services only if offered by physicians, physician assistants, nurse practitioners, clinical nurse specialists, nurse-midwives, clinical psychologists, clinical social workers, registered dieticians or certified registered nurse anesthetists. Under the Omnibus Bill, qualifying practitioners now include occupational therapists, physical therapists, speech-language pathologists and audiologists. Other changes include delaying in-person requirements for the provision of mental health services and extending coverage of telehealth services rendered by federally qualified health centers to provide telehealth services for the same 151 day post-PHE period.

While these changes are welcomed by many in the healthcare industry as a necessary resource and buffer for telehealth patients and providers, it remains to be seen whether additional coverage flexibilities, beyond certain limited opioid treatment program expansion and counseling therapy telehealth coverage expansion under **CY 2022 Medicare Physician Fee Schedule Final Rule**,

established during the PHE will become permanent moving forward. The Omnibus Bill requires the Medicare Payment Advisory Commission to provide Congress with a report by June 15, 2023 on the expansion of telehealth services as a result of the PHE. The Department of Health and Human Services, Office of Inspector General is similarly required to provider Congress with a report by June 15, 2023 on program integrity risks associates with Medicare telehealth services. In addition, the Department of Health and Human Services must post quarterly data, starting July 1, 2022, on Medicare claims for telemedicine services.

We will continue to monitor these and other legislative and regulatory changes impacting telehealth industry stakeholders.

---

[1] The PHE determination was recently renewed by Xavier Becerra, Secretary of the U.S. Department of Health and Human Services on January 16, 2022. A public health emergency declaration expires 90 days after the declaration or renewal or renewal is made, unless terminated prior. It is unclear whether the latest PHE declaration will be renewed or not or whether the PHE declaration will be terminated prior to the 90-day deadline.

CMS Continues to Modernize by Expanding Reimbursement for Digital Health Services

The COVID-19 Public Health Emergency ("PHE") fundamentally changed the healthcare industry, forcing healthcare providers and patients onto their computers and phones to enable continuation of care when patients were mandated to stay home across the country. Prior to the COVID-19 PHE, approximately 12,5000 Medicare beneficiaries received telehealth services and only 106 telehealth services were reimbursable. By October 2020, over 24.5 million (of 63 million) Medicare beneficiaries received telehealth services.

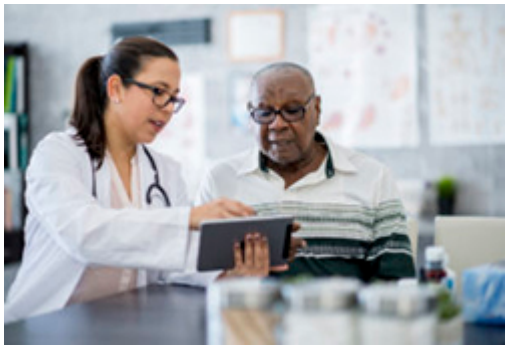
Read the **client alert**.

For Clinical Trial Recruiting, Words Matter

In a recent publication we helped co-author, we examined ClinicalTrials.gov entries and their possible impact on informing potential subjects of their eligibility to participate in clinical trials. In particular, we analyzed certain clinical trials focused on HIV treatment or prevention that allowed entry of pregnant women to assess the use of pregnancy-related terms in each trial's description and inclusion/exclusion criteria, such as those relating to gestational age and trimester. The assessment focused on evaluating the potential utility of ClinicalTrials.gov for pregnant women and their healthcare providers in identifying potential clinical research in which they may be eligible to participate. In brief, we found that descriptors and terminology can play an important role in communicating with providers and prospective subjects about eligibility for participation. While our findings are in the context of HIV research and pregnant women, our takeaways could apply to other disease areas and populations where specific terminology may play a role in successful identification and recruitment of eligible patients, particularly where competition for patients presents an ongoing challenge, such as rare diseases.

Read the full **article** in *Contemporary Clinical Trials Communications*.

California Physicians Allege PE-Backed Provider Violates Corporate Practice Law



On December 20, 2021, a group of emergency medicine physicians in California filed suit against a private equity-backed health care services company, claiming that (among other things), the company has run afoul of the state's prohibition on the corporate practice of medicine ("CPOM") since it took over an emergency department at a California hospital. The plaintiff is the **American Academy of Emergency Medicine Physician Group**, or "AAEM"; and the defendant is Envision Healthcare ("Envision"), which is owned by the private-equity firm Kohlberg Kravis Roberts.

Generally, CPOM laws, which can be found in almost every state, are designed to prohibit

corporations, lay entities, or any non-licensed persons from practicing medicine, employing physicians, or owning physician practices or health care facilities. California's **CPOM law** is fairly strict and is more regularly enforced compared to other states that rarely enforce their statutory prohibition.

In the California matter, Envision contracts with health systems to provide practice management services, such as billing and collection, communication with vendors and financial reporting. In its **complaint**, AAEM provides several examples of how it believes Envision exercises "profound and pervasive direct and indirect control over the physicians' practice of medicine." For example, according to the plaintiffs, Envision appoints medical directors, who are employed directly by Envision, for each entity that Envision controls. AAEM alleges that, because Envision exercises control over the medical directors, it is actually *Envision* making medical decisions, not the licensed professionals. AAEM further claims that because Envision controls physician employment, physician scheduling, staffing levels, and number of patient encounters and denies physicians the right to appeal via traditional medical staffing mechanisms, it is again Envision – not the medical directors – that make decisions for contracted health systems, thereby violating the CPOM laws.

AAEM also claims that Envision is participating in illegal fee-sharing since Envision codes and bills on a physician's behalf, without physicians seeing what is billed in remitted in their names. Finally, AAEM takes issue with Envision's requirement of physician's executing restrictive covenants, prohibited the physician from assisting or joining any other emergency medicine group.

The AAEM lawsuit does not seek monetary damages; rather, the emergency medicine doctors are seeking an injunction to prevent Envision from operating the emergency department at Placentia-Linda Hospital and at least a dozen other emergency departments in the state. We will continue to monitor this case and its outcome, which could have a bearing on how the CPOM laws (at least in California) are applied to private equity-backed health care arrangements.

Medicare Agrees to Limited Payment for New Alzheimer's Drug

On January 11, 2022, the Centers for Medicare and Medicaid Services (CMS) **released** a proposed National Coverage Determination (NCD) decision memo limiting Medicare coverage for Biogen's new Alzheimer's drug, Aduhelm. Under the terms of the NCD – despite FDA's 2021 approval of the drug – CMS will only pay for Aduhelm for Medicare beneficiaries who are enrolled in a qualifying clinical trial to assess the drug's safety and its effectiveness in slowing the progression of Alzheimer's. CMS **stated**, "[B]ased on the public comments submitted previously and evidence CMS

reviewed, the potential for harm, and important questions that remain, we have determined that coverage with evidence development through clinical trials is the right decision for Medicare patients, clinicians, and caregivers, and we look forward to receiving feedback on the proposal." The proposed NCD is **open** to public comment for thirty (30) days, and a final decision from CMS is expected **on April 11**. If the proposed NCD is finalized, CMS must evaluate each submitted clinical trial to verify that it meets the qualifying criteria specified in the proposed NCD.

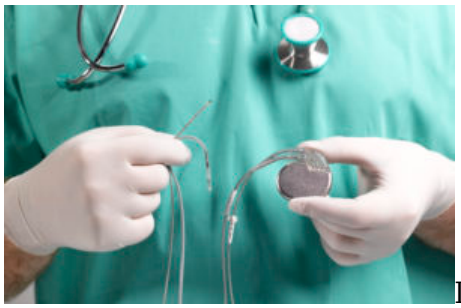
Aduhelm has been approved by FDA for the treatment of Alzheimer's since June 2021. This is the first drug approved by FDA for the treatment of Alzheimer's in almost 20 years. In 2019, two clinical trials for Aduhelm were **paused** due to data showing the drug was of no benefit to patients' cognitive function. However, after Biogen re-analyzed one of its trials, it decided to apply to the FDA for approval. The FDA used the accelerated approval process but can withdraw Aduhelm from the market if Biogen's new clinical trial demonstrates that the drug is ineffective. The FDA **pivoted** on the approval itself, later **recommending** Aduhelm only in patients with mild cognitive impairment or mild dementia. Patient advocacy groups such as the Alzheimer's Association **played** an important role in pressuring FDA to approve Aduhelm, given the minimal advancements in drug treatment in the space.

Since receiving FDA approval, Biogen has faced tough scrutiny about Aduhelm's efficacy and cost. Aduhelm's initial annual price of $56,000 elicited widespread criticism. In December 2021, Biogen **announced** that it would reduce the drug's price to $28,200 for some patients. Biogen most likely reduced the price in response to slower than anticipated sales and CMS's announcement it would increase Medicare's monthly Part B premium for outpatient care in anticipation of the Aduhelm's price impact. Adding to Biogen's challenges, an FDA advisory committee agreed almost **unanimously** that the clinical trials did not provide strong enough evidence to corroborate Aduhelm's efficacy data. However, based on the clinical trials it did review, FDA **claimed** that Aduhelm could reduce clumps of plaque in the brain, which is likely to slow dementia. The discrepancy between the advisory committee's and FDA's findings coupled with broad criticism of the FDA led the Department of Health and Human Services Office of Inspector General to conduct a **probe** into the FDA's approval process for Aduhelm.

Adding to the complexity, State Medicaid programs have also been vocal in protesting CMS's decision. Unlike Medicare, Medicaid is required to cover all FDA-approved drugs regardless of a drug's clinical efficacy. Therefore, had Medicare determined not to cover Aduhelm, all costs would **shift** to the state Medicaid programs. Though some states and insurers have already **declined** to cover Aduhelm, CMS's ruling is likely to influence other payors to refuse coverage.

While some commenters and industry observers have questioned whether CMS's decision with respect to Aduhelm somehow creates a new, default secondary clinical testing and approval threshold for drug makers, it is more likely that the Medicare agency's decision on Aduhelm reflects the unique circumstances posed by the drug (*i.e.* unclear efficacy concerns, conflicting FDA guidance, and an unusually high price point). Whether CMS will make a habit of limiting coverage for innovative drugs only to beneficiaries participating in additional clinical trials remains to be seen, but is not likely. We will continue to monitor trends and developments at CMS with respect to coverage and payment decisions on new therapeutics and treatments, including additional research and testing requirements that the agency may impose.

Planning For The End: Goodwin FDA attorneys Steve Tjoe and Susan Lee highlight key takeaways From FDA's draft guidances proposing transition plans for medical devices marketed under EUAs or enforcement policies during the COVID-19 Public Health Emergency

 During the COVID-19 public health emergency, the United States Food and Drug Administration (FDA) has issued hundreds of Emergency Use Authorizations (EUAs) and numerous enforcement policies to facilitate the availability of important medical devices. On December 23, 2021, FDA published two draft guidances setting forth the Agency's proposed process for transitioning the multitude of devices brought to market under these circumstances to full compliance with FDA requirements:

- Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "EUA Transition Draft Guidance"); and
- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "Enforcement Policies Transition Draft Guidance").

In our **recent Alert**, we summarize some key takeaways from FDA's proposed transition plan for manufacturers of devices marketed under a COVID-19 EUA ("EUA Devices") and devices marketed under one of more than 15 COVID-19 enforcement policies listed in the guidance ("Enforcement Policy Devices"). **Read More**

Review of FDA's 2021 Drug Approvals – Small Molecules Dominate

 The FDA's Center for Drug Evaluation and Research (CDER) approved 50 new drugs and biological products in 2021 (not including the vaccines, cellular and gene therapy products, or other products approved in 2021 by the Center for Biologics Evaluation and Research). As in past years, small molecule drug approvals dominated the list.

Of the 50 approved new drugs and biological products, 33 were small molecule drugs and 17 were monoclonal antibodies and other big molecules drugs. A new ADC (antibody drug conjugate) was approved, Tivdak®, and a bispecific antibody was also approved, Rybrevant®. Notably, a small interfering RNA drug was approved, Leqvio®, for the treatment of atherosclerotic cardiovascular disease.

As small and big molecule drugs enter the clinic, Goodwin's patent attorneys focus on securing not only composition of matter patent protection, but additional patent protection derived from clinical data. Learn more about additional patent protection secured from the clinic in **Goodwin's Patent Savvy Executive video**.

Each new drug and biological product can be found in the FDA's **Orange Book** or the FDA's **Purple Book**. To learn more about the Orange Book and how to determine patent terms on approved drugs, visit **Goodwin's Patent Savvy Executive video**.

See the full list **here**.

On Remote Control: FDA Issues Draft Guidance to Facilitate Use of Digital Health Technologies for Remote Data Acquisition in Clinical Trials

 During the COVID-19 pandemic, decentralized clinical trials

and remote patient monitoring and data acquisition became a necessity, accelerating the use of digital health technologies in clinical trials. Acknowledging that technological advances "have revolutionized the ability to remotely obtain and analyze clinically relevant information from individuals" and that "DHTs [ ] are playing a growing role in health care and offer important opportunities in clinical research," the FDA issued during the last week of December 2021 a draft guidance, ***Digital Health Technologies for Remote Data Acquisition in Clinical Investigations***, which provides recommendations for sponsors, investigators and other stakeholders to facilitate the use of DHTs for remote data acquisition in clinical trials, including clinical trials that will be submitted to the FDA in a marketing application for a medical product.

The draft guidance defines a digital health technology (DHT) as a system that uses computing platforms (such as a mobile phone, tablet, or smart watch), connectivity, software, and/or sensors for healthcare and related uses. Some DHTs may meet the definition of "device" under the Federal Food, Drug and Cosmetic Act, but the draft guidance specifically does not address the circumstances under which a DHT would meet the statutory definition of a device and notes that DHTs used in clinical investigations generally are exempt from premarket clearance or approval requirements, as long as the clinical investigation is compliant with 21 CFR Part 812.

The draft guidance explains that sponsors must foremost ensure that a DHT is "**fit-for-purpose**" for its proposed use in a specific clinical investigation. In essence, the level of verification and validation associated with the DHT must be sufficient to support its use and interpretability in the clinical investigation. This may require sponsors to work with the developer or manufacturer of the DHT, patients, caregivers, and other technical and clinical experts to assure that the DHT is suitable for its intended purpose in the clinical investigation. The draft guidance advises sponsors to select a DHT that corresponds to the clinical outcome to be assessed, and that considers the clinical trial population and the design/operating characteristics of the DHT that may affect trial participants' use of the DHT.

Sponsors should also be prepared to describe how they will analyze data collected from DHTs in their statistical analysis plan, including prespecifying "**intercurrent events**" (defined as events that occur after treatment initiation that result in missing or erroneous data associated with the clinical outcome of interest) that may be related to the DHT and/or the general purpose computing platform, and how these events will be accounted for in the analysis. To maintain data integrity, FDA recommends that the output of the DHT and associated metadata be transmitted to a **durable electronic data repository** that is protected from alterations and maintained until the end of the record retention period. FDA generally will consider data in such a repository to constitute the source data and should be made available for inspection and to reconstruct and evaluate the clinical investigation.

FDA further notes that "unique privacy risks" may arise when DHTs are used in a clinical trial. Sponsors are advised to evaluate the risk of potential disclosures of personally identifiable information through breaches of the DHT, the general computing platform on which the DHT runs, and/or the durable electronic repository, assure appropriate security safeguards are in place, and consider including such information in the informed consent documents for the clinical trial.

The draft guidance recommends that sponsors:

- train trial participants and trial personnel on the use of DHTs and develop a plan to provide technical assistance to trial participants and study personnel;

- develop a risk management plan to address potential problems with the DHT (e.g.,

interference between mobile applications, or loss, damage and replacement);

- develop a safety monitoring plan that addresses how abnormal measurements related to participants' safety measured by DHTs will be reviewed and managed; and
- develop a contingency plan for any changes to the DHT (e.g., discontinuation of a specific model, operating system updates)

The draft guidance includes appendices with specific examples of how different types of DHTs could be incorporated into a clinical investigation. Given the particular circumstances of each DHT and clinical investigation, the draft guidance encourages sponsors to engage early with the appropriate FDA Center responsible for the medical product under development to discuss the proposed use of DHT(s) in a clinical investigation and, for DHTs or DHT-collected endpoints that require qualification, engage with an appropriate FDA qualification program, such as the **Medical Device Development Tool Qualification Program**.

Comments on the draft guidance are due March 23, 2022.

Changes to Stark Law Special Compensation Rules for Group Practices Go into Effect on January 1, 2022

The final rules regarding special compensation under **42 U.S.C. § 1395nn**, the Physician Self-Referral or Stark Law, go into effect on January 1, 2022 and will require many physician group practices to modify their compensation methodologies, specifically the pooling and distribution of profits for the provision **designated health services** ("DHS").

Under the **current regulations**, a physician in a group practice that relies on the in-office ancillary services exception can be paid a share of overall group profits, so long as that share is determined in a way that is not "directly related to the volume or value of referrals of DHS by the physician." The same is true of productivity bonuses based on services that a physician has performed. "A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services 'incident to' such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services 'incident to' the physician's

personally performed services)."

This provision had previously been interpreted to allow "split pool" profit-sharing plans that create pools of DHS-derived profits for different services, in which only certain physicians benefit from certain profit pools.

Effective January 1, 2022, split pooling is no longer permitted. In the **final regulation**, which modifies the special compensation rules under 42 C.F.R. §411.352(i), CMS clarifies that "if a group practice wishes to pay shares of overall profits to any of its physicians, it must first aggregate: (1) The entire profits from the entire group; or (2) the entire profits from any component of the group that consists of at least five physicians. Once aggregated, the group practice may choose to retain some of the profits or distribute all of the profits through shares of overall profits paid to its physicians." Therefore, although a group practice may employ different profit distribution methods for the provision of DHS for each component of the group practice that consists of five or more physicians, the group practice must employ the same method for distributing overall profits to every physician within such a component. It is important to note that although CMS limited the general definition of DHS to "only DHS payable in whole or in part by Medicare" in § 411.351, "overall profits" for the purpose of the special compensation rules for group practices continues to include "the group's entire profits derived from DHS payable to Medicare or Medicaid."

Group practices that currently employ the split pool compensation structure for physicians and rely on the in-office ancillary services exception will need to modify their compensation structures to comply with this clarification.

Reality Check: FDA Draft Guidance Outlines Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drugs and Biological Products

Last week the FDA issued another draft guidance in its series of recent guidance documents setting forth the agency's views regarding the generation and use of Real-World Data (RWD) and Real-World Evidence (RWE) for prescription drugs and biological products. (see our **recent post** on FDA's draft guidance relating to registries).

This latest draft guidance, **Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products**, clarifies the agency's expectations for sponsors submitting new drug applications (NDAs) or biologics license

applications (BLAs) with studies using Real-World Data (RWD) to support the safety or effectiveness of drugs or biological products, when such studies are not subject to FDA's investigational new drug (IND) application requirements under **21 CFR Part 312**. The draft guidance focuses on non-interventional (*a.k.a.* observational) studies, in which patients receive a drug during routine medical practice, according to a medical provider's clinical judgment and based on patient characteristics, rather than via assignment to a study arm and according to a clinical trial protocol.

Key considerations outlined in the guidance:

- *Sponsors designing a non-interventional study to support a marketing application should engage early with the relevant FDA review division* (e.g., through a Type C meeting) and be prepared to submit draft protocols and SAPs for FDA feedback *before* conducting the study analyses.

- *To assure the FDA that the results of a non-interventional study were not skewed to favor a particular conclusion,* sponsors should provide evidence that the non-interventional study protocol and statistical analysis plan were finalized *prior* to reviewing outcome data and *before* performing prespecified analyses. Sponsors should provide a justification for selecting relevant data sources and generate audit trails in their datasets. FDA also recommends that sponsors post their non-interventional study protocols on a publicly available website, such as **ClinicalTrials.gov**.

- *Sponsors must be able to submit patient-level data from the RWD.* Where a third party owns or controls the RWD, sponsors should have agreements with such parties to ensure that patient-level data and source data to verify the RWD can be provided to the FDA for inspection, as applicable. Sponsors should have well-documented programming codes and algorithms that would allow the FDA to replicate the study analysis using the same dataset and analytic approach.

- *Non-interventional studies should be monitored*. The FDA advises sponsors to use a risk-based quality management approach, with a focus on preventing or mitigating important and/or likely risks to study quality. If a non-interventional study does not include any activities or procedures involving patients, monitoring can focus on assuring the data integrity of the RWD, from extraction to analysis to reporting of results. When a non-interventional study protocol includes ancillary activities or procedures, sponsors should exercise appropriate oversight of processes critical to human subject protection.

- *Adverse events that a sponsor becomes aware of through a non-interventional study must be submitted in accordance with postmarketing safety reporting regulations*. However, the agency acknowledges that if a sponsor is conducting a non-interventional study that appropriately utilizes only a subset of a larger dataset, the sponsor will not have to search the entirety of the dataset for adverse events.

- *Sponsors should take responsibility for all activities related to the design, conduct and oversight of a non-interventional study that is being submitted for regulatory review*. This includes selecting qualified researchers, ensuring the study is conducted in accordance with the protocol, maintaining and retaining adequate study records, and maintaining an electronic system to manage RWD that complies with **21 CFR Part 11**. Where a sponsor engages third parties to perform certain study-related tasks, the responsibilities of each organization should be documented and made readily available to the FDA upon request.

Comments on the guidance should be submitted to the docket by March 9, 2022.