FDA Proposes Phased Approach to Regulating Laboratory Developed Tests

On September 29, 2023, the U.S. Food and Drug Administration (FDA) posted and scheduled for publication its long-awaited **proposed rule** concerning FDA regulation of laboratory developed tests (LDTs). If enacted, the proposed rule would amend the Agency's regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act; and this includes when the manufacturer of the IVD is a laboratory.

Upon finalization of the rule, FDA proposes to phase out its general "enforcement discretion" approach for LDTs so that tests manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs.

Comments to the proposed rule are due 60 days after the date of publication of the proposed rule in the Federal Register. We will provide our full analysis of the proposed rule in the coming days. Contact the authors or a member of the Goodwin **Life Sciences Regulatory & Compliance** team for any questions.

LDT Proposed Rule Remains Under OIRA Review

 Throughout August 2023, the Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President ("OIRA") has **held stakeholder meetings** regarding a proposed rule which, if enacted, would amend the U.S. Food and Drug Administration's ("FDA's") regulations to make explicit that laboratory developed tests ("LDTs") are devices under the Federal Food, Drug, and Cosmetic Act. The next stakeholder meeting on the proposed rule is scheduled for September 6, 2023.

Per its **website**, OIRA received the proposed rule from FDA on July 26, 2023. The proposed rule was initially **published** this past spring on the Biden Administration's Unified Agenda of Regulatory and Deregulatory Actions with a target publication date of August 2023. The forthcoming stakeholder meeting on September 6th suggests that OIRA may continue its review process well into September, if not later.

The publication of the proposed rule would mark the first significant FDA action on LDTs since its two 2014 draft guidances (available **here** and **here**) and 2017 **discussion paper**. The proposed rule is also expected to be controversial after prior U.S. Department of Health & Human Services statements concerning regulation of LDTs and legislative attempts to further define the LDT regulatory framework. Once cleared by OIRA, the proposed rule will be published in the Federal Register and subject to public comment.

We will continue to monitor for updates on the LDT proposed rule. Contact Goodwin Life Sciences Regulatory & Compliance team members for any questions.

First Drugs Selected for Price Negotiations Under The Inflation Reduction Act

The Inflation Reduction Act's Medicare Drug Price Negotiation Program has now officially kicked off. Earlier today (August 29, 2023), **the White House announced the list of the first 10 selected drugs** under the program, prior to the statutory deadline of September 1.

The first 10 drugs selected are as follows:

- Eliquis
- Jardiance
- Xarelto
- Januvia
- Farxiga

- Entresto
- Enbrel
- Imbruvica
- Stelara
- Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill

The government notes that these selected drugs accounted for $50.5 billion in total Part D drug costs – or about 20% of the Part D spend for June 1, 2022 through May 31, 2023. For next steps, manufacturers of these drugs must enter an agreement with the government to agree to the negotiation program. The government will publish the agreed-upon negotiated prices for these selected drugs by September 1, 2024, with the prices going into effect January 1, 2026.

For those interested in more detail about the IRA, please visit our **Goodwin IRA webpage**, where you can view and download material from our previous webinars covering additional detail and background on the IRA, including guidance from the Centers for Medicare & Medicaid Services (CMS) on implementation of the Program, presented by Goodwin Life Sciences Regulatory & Compliance partner **Matt Wetzel**.

We will be monitoring pending legal challenges to the IRA and tracking updates on **Goodwin's IRA resource page**.

Seven Tips for Healthcare & Life Sciences Companies Engaging Independent Monitors and Compliance Experts

For a healthcare or life sciences company settling a government enforcement action, the prospect of being subject to an independent monitor, independent review organization (IRO), or other government-mandated compliance expert may become a reality. (We collectively refer to all of these individuals and entities as monitors throughout this update.) Hiring an independent monitor is a sensitive topic, as a company subject to a monitorship is required to open up its records and files, financial information, proprietary and confidential materials, IT assets, and employees to a third party — often at frequent and regular intervals, and often for a period of five years — not to mention the potential multimillion-dollar expense associated with the engagement.

Read the client alert **here**.

HHS to Create New Potential Medicare Pricing Models for Cell and Gene Therapy, Drugs Subject to Accelerated FDA Approval, and "High-Value" Generics

On February 14, 2023, the U.S. Department of Health and Human Services (HHS) published a **report** identifying three models that the Center for Medicare & Medicaid Services' (CMS) Center for Medicare & Medicaid Innovation (CMMI) will test to try to improve the affordability and accessibility of prescription drugs. The report responds to the state of prescription drug costs and access in America, as well as the widespread changes introduced by the Inflation Reduction Act of 2022 and President Biden's **Executive Order 14087** (October 2022), both intended to help lower prescription drug costs for Americans. The three selected models will test the feasibility of methods to: (i) offer generic prescription drugs at $2 or less for Medicare patients; (ii) reduce Medicaid costs for novel cell and gene therapies through outcomes-based agreements with manufacturers on a multistate level; and (iii) improve the safety and efficacy of drugs approved through the FDA's Accelerated Approval Program by aligning payment methods with stakeholders' incentives. More detail on these three models is expected, and Goodwin attorneys will continue to monitor for additional guidance and any opportunities for public comment.

Read the client alert **here**.

New OIG Advisory Opinion Impacts Pharmaceutical & Medical Device Company Funding of Continuing Education Programs

OIG Advisory Opinion 22-14 (June 29, 2022) could have significant implications for how life sciences companies (pharmaceutical, medical device, and diagnostics test makers) contribute towards continuing education ("**CE**") programs for healthcare providers ("**HCPs**"). Specifically, in AO 22-14, the U.S. Department of Health & Human Services Office of Inspector General ("**OIG**") rejects a Requestor's proposal to permit pharmaceutical and medical device industry sponsorship of a CE program for HCPs, noting that it could generate prohibited remuneration under the Federal Anti-Kickback Statute.

Read the full Washington legal Foundation's Legal pulse blog post **here**.

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.

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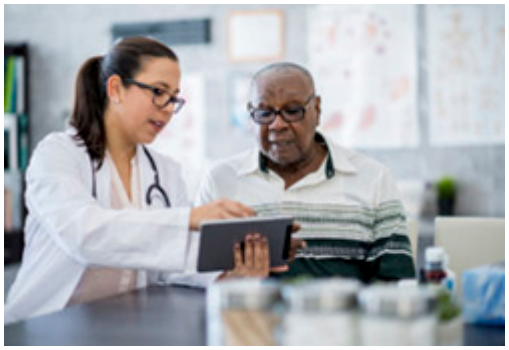
[1] The PHE determination was recently renewed by Xavier Becerra, Secretary of the U.S. Department of Health and Human Services on January 16, 2022. A public health emergency declaration expires 90 days after the declaration or renewal or renewal is made, unless terminated prior. It is unclear whether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

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.

Senate Judiciary Committee Advances False Claims Act Amendment to Full Senate

On October 28, a majority of members on the Senate Judiciary Committee voted 15-7 to advance to the full Senate a bipartisan bill that would make a number of amendments to the False Claims Act ("FCA"), including one that would make significant changes to the FCA's definition of "materiality." Senator Chuck Grassley of Iowa, who serves as the ranking member of the Judiciary Committee, argued for the materiality amendment, stating that it is intended to correct the "misinterpretations" of the FCA "created by the *Escobar* court."

Under the FCA, only a material violation – one that has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property by the government" – can form the basis for liability. The Supreme Court in *Universal Health Services v. United States ex rel. Escobar* stated that the FCA's materiality standard is "rigorous" and "demanding," and held that a violation of a particular requirement would likely not be considered material if (for example) the government had actual knowledge of the violation and chose to pay the claim anyway.

The materiality amendment advanced to the full Senate would undo the protections offered by the *Escobar* ruling, and instead states that "in determining materiality, the decision of the government to forego a refund or pay a claim despite actual knowledge of fraud or falsity shall not be considered dispositive if other reasons exist for the decision of the government with respect to such refund or payment."

The number of suits filed under the *qui tam* provisions of the FCA are steadily increasing over the years, with **672 *qui tam* actions filed in 2020** alone. Should this FCA amendment be enacted, its lowered materiality standard will make it significantly more difficult for defendants in *qui tam* actions to win motions to dismiss on materiality grounds, or to obtain summary judgment; as a result, many more of these cases will move forward to more expensive and time-consuming stages of litigation.

Health care providers and other health care companies who are the potential defendants in FCA cases already often spend significant resources defending against these claims. While the proposed amendment advanced by the Judiciary Committee last week is intended to reduce fraud and abuse – for example, the amended materiality standard would be particularly important in situations in which the government is aware of fraudulent claims but is unable or unwilling to stop paying for the provision of critical healthcare services***; but, it may also have an effect on the overall costs of defending a claim, whether or not meritorious. We will continue to monitor updates with respect to the FCA and related legislation.***