

# [US Artificial Intelligence Regulations: Watch List for 2023](#)



Companies are developing, deploying, and interacting with artificial intelligence (AI) technologies more than ever. At Goodwin, we are keeping a close eye on any regulations that may affect companies operating in this cutting-edge space.

For companies operating in Europe, the landscape is governed by a number of in force and pending EU legislative acts, most notably the EU AI Act, which is expected to be passed later this year; it was covered in our prior client alert here: [EU Technology Regulation: Watch List for 2023 and Beyond](#). The United Kingdom has recently indicated that it may take a different approach, as discussed in our client alert on the proposed framework for AI regulation in the United Kingdom here: [Overview of the UK Government's AI White Paper](#).

For companies operating in the United States, the landscape of AI regulation remains less clear. To date, there has been no serious consideration of a US analog to the EU AI Act or any sweeping federal legislation to govern the use of AI, nor is there any substantial state legislation in force (although there are state privacy laws that may extend to AI systems that process certain types of personal data).

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](#)

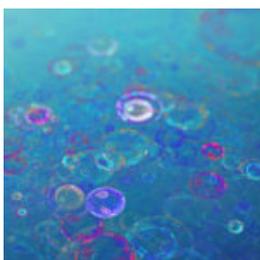


On February 14, 2023, the U.S. Department of Health and Human Services (HHS) published a [report](#) identifying three models that the Center for Medicare & Medicaid Services' (CMS) Center for Medicare & Medicaid Innovation (CMMI) will test to try to improve the affordability and accessibility of prescription 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](#).

---

## [FDA Announces Total Product Life Cycle Advisory Program \(TAP\) Pilot](#)



The U.S. Food and Drug Administration's ("FDA" or "the Agency") Center for Devices and Radiological Health ("CDRH") recently announced the launch of its Total Product Life Cycle Advisory Program ("TAP") Pilot. The first phase of this voluntary initiative, called TAP Pilot Soft Launch, will be conducted during fiscal year ("FY") 2023 with enrollment beginning on January 1, 2023.

The Agency committed to establishing the TAP Pilot as part of the MDUFA V reauthorization, and the Agency's long-term vision for TAP is "to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance." As part of the TAP Pilot, the FDA will provide strategic engagement for such devices by:

- Improving participants' experiences with the FDA by providing for more timely premarket interactions
- Enhancing the experience of all participants throughout the device development and review

process, including FDA staff

- Facilitating improved strategic decision-making during device development, including earlier identification, assessment, and mitigation of device development risk
- Facilitating regular and solutions-focused engagement early in device development between FDA review teams, participants, and other stakeholders, such as patients, providers, and payers
- Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process

Read client alert [here](#).

---

## [FDA Issues Final Clinical Decision Support Software Guidance](#)



On September 28, 2022, the U.S. Food and Drug Administration (“FDA” or “the Agency”) issued its long-awaited final guidance, “Clinical Decision Support Software” (the “CDS Guidance”). The CDS Guidance follows the Agency’s September 2019 draft guidance of the same name (the “Draft Guidance”) and seeks to clarify several key concepts for determining whether clinical decision support (“CDS”) software is a medical device.

Specifically, the CDS Guidance provides the Agency’s interpretation of the four criteria established by the 21st Century Cures Act for determining whether a decision support software function is excluded from the definition of a device (i.e., is considered “Non-Device CDS”). A software function must meet all of the following four criteria to be considered Non-Device CDS:

1. Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device (“IVD”) or a pattern or signal from a signal acquisition system
2. Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
3. Intended for the purpose of supporting or providing recommendations to a health care professional (“HCP”) about prevention, diagnosis, or treatment of a disease or condition
4. Intended for the purpose of enabling such HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

Software functions that *do not* meet all four criteria are considered device functions subject to FDA oversight. Notable updates to FDA’s interpretation of the four criteria include the following.

Read the Goodwin insight [here](#).

Visit the [Goodwin on Medtech hub](#) to stay informed on important developments affecting medtech innovators and investors.

---

## [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](#)

---

## [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.

---

## [It's Starting to Register: FDA Draft Guidance Addresses Use of Registries to Support Regulatory Decision-Making for Drugs & Biological Products](#)



Showing no signs of food coma, the FDA issued [draft guidance](#) on the Monday following the Thanksgiving holiday weekend that outlines considerations for sponsors proposing to design a registry or use an existing registry to support regulatory decision-making about a drug’s effectiveness or safety. This draft guidance represents the Agency’s latest response to the mandate in the 21<sup>st</sup> Century Cures Act to issue guidance on the use of real world evidence in regulatory decision-making, and expands on the [Framework for FDA’s Real-World Evidence Program](#) from December 2018.

The draft guidance, [Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products](#), defines a registry as “an organized system that collects clinical and other data in a standardized format for a population defined by a particular

disease, condition, or exposure,” and identifies three general categories of registries: disease registries, health service registries, and product registries.

Given the range of registry types, FDA notes that registry data can have varying degrees of suitability for use in a regulatory context depending on several factors, including how the data are intended to be used for regulatory purposes, the patient population enrolled, the data collected, and how registry datasets are created, maintained, curated, and analyzed. FDA advises sponsors to be mindful of both the strengths and limitations of using registries as a source of data to support regulatory decision-making. In general, the draft guidance advises that (i) a registry that captures objective endpoints, such as death or hospitalization, is more likely to be suitable to support regulatory decision-making than a registry that collects subjective endpoints, such as pain; and (ii) a registry that is specifically designed to answer a particular research question is more likely to be useful to support regulatory decision-making than a registry that was designed for a different purpose.

At the same time, the Agency acknowledges that an existing registry can be used to collect data for purposes other than those originally intended, and that leveraging an existing registry’s infrastructure to support multiple purposes can be efficient. Therefore, the draft guidance describes factors sponsors can use to assess the **relevance** and **reliability** of a registry’s data to determine whether the registry data may be fit-for-use.

When determining **relevance** of registry data, the draft guidance advises sponsors to consider, among other things, whether the data elements captured by the registry are sufficient given the intended use or uses of the registry (e.g., external control arm vs. a tool to enroll participants in an interventional study) and whether the methods involved in patient selection may have impacted the representativeness of the population in the registry.

When assessing the **reliability** of registry data, the draft guidance advises sponsors to assure the registry has appropriate governance measures in place to help ensure the registry can meet its objectives, such as processes and procedures governing the operation of the registry, adequate training of staff, and other recommended practices including:

- Defined processes and procedures for data collection, management and storage;
- A data dictionary and rules for validation of queries and edit checks of registry data;
- Conformance with [21 CFR part 11](#), as applicable, including access controls and audit trails; and
- Adherence to applicable human subject protection requirements, including safeguarding the privacy of patient health information.

The draft guidance specifically recommends that sponsors interested in using a registry to support a regulatory decision should meet with the relevant FDA review division (e.g., through a Type C meeting), *before* conducting a study that will include registry data. Sponsors also should be prepared to submit protocols and statistical analysis plans for FDA feedback prior to conducting a study that includes data from registries.

**Comments on the guidance should be submitted to the [docket](#) by February 28, 2022.**

---

# Things for Pharma and Biotech Companies to Watch in the Cures 2.0 Proposed Legislation



Last week, Diana DeGette (D-CO) and Fred Upton (R-MI) introduced in the House highly anticipated bill language for “Cures 2.0”, a follow-up to the transformational 21<sup>st</sup> Century Cures Act enacted in 2016. For full text of the bill, click [here](#). The 21<sup>st</sup> Century Cures Act included a variety of measures seeking to accelerate medical product development and bring advancements and innovations to patients more efficiently. Cures 2.0 seeks to improve and expand on those strides, as well as address pressing public health priorities that became apparent through the COVID-19 pandemic.

The Cures 2.0 bill is structured around five main topics:

- Title I—Public Health
- Title II—Patients and Caregivers
- Title III—Food and Drug Administration
- Title IV—Centers for Medicare & Medicaid Services
- Title V—Research

While all of these sections are ripe for further analysis, we selected a few provisions to highlight here that may be of particular interest for the pharmaceutical and biotechnology companies out there. We’ll keep tracking these as the bill moves through the legislative process:

## **Section 204:** Patient Experience Data

- Would require sponsors developing a drug under an IND to collect standardized patient experience data during clinical trials and include that patient experience data “and such related data” in an NDA or BLA; and
- Would direct FDA to consider this patient experience data and “related information” in its approval decision for the NDA or BLA.
- These proposals to standardize and require patient experience data collection could be significant, and they underscore lawmakers’ continued interest in elevating the relevance of clinical outcomes that are meaningful to patients living with a disease or condition.

## **Section 302:** Grants for Novel Trial Designs and Other Innovations in Drug Development & **Section 310:** Recommendations to Decentralize Clinical Trials

- Section 302 would appropriate \$25 million annually, for 3 years, for the FDA to award grants to clinical trials conducted under an IND with protocols incorporating complex adaptive or other novel trial designs and that collect patient experience data. The section further specifies that grant awards should prioritize the incorporation of digital health technologies and real world evidence.
- Section 310 proposes a multi-stakeholder meeting, including industry representatives and patient advocacy groups, to discuss incentives to adopt decentralized clinical trials. The

section also would adopt a definition of decentralized trials: “a clinical trial method that includes the use of telemedicine or digital technologies to allow for the remote collection of clinical trial data from subjects, including in the home or office setting.”

- These provisions reflect a sustained emphasis on fostering clinical trial innovation, including building on the experience with remote clinical trials during the COVID-19 pandemic.

#### **Section 304:** Increasing Use of Real World Evidence (RWE) & **Section 309:** Post-Approval Study Requirements for Accelerated Approval

- Section 304 would call for new guidance on the use of RWE in post-market review of drugs that were designated as a breakthrough therapy or fast track product, or considered for accelerated approval. Section 309 would further specify that the post-approval study requirements to verify and describe the clinical benefit for products granted accelerated approval could be satisfied through RWE, including analyses of data in clinical care repositories or patient registries.
- Section 304 also would establish a permanent Real World Evidence Task Force to coordinate programs and activities within the Department of Health and Human Services related to the collection and use of RWE.
- These and other sections of Cures 2.0 share a common theme of enhancing the use of RWE in regulatory decision-making. Although the inherent variability in RWE likely will continue to present challenges to doing so, the signal is clear that legislators would like to see FDA and HHS continue to move forward in this area.

Last week’s introduction of Cures 2.0 and President Biden’s announcement that he will nominate Robert Califf for FDA Commissioner contributed to a newsworthy week for those of us who follow the FDA. We look forward to seeing how Cures 2.0 develops and how the Agency’s policy priorities unfold in the coming months.

---

## **Pharmaceutical Manufacturers Beware: New State Drug Transparency Laws and Enforcement Mechanisms Are Coming In 2022**



In 2016, states began passing pharmaceutical price reporting laws. These laws are designed to bring transparency to a pharmaceutical manufacturer’s drug pricing process by requiring drug manufacturers to report pricing and other information related to the cost, development, and sale of

drugs. By October 2021, approximately twenty states have passed or are implementing transparency laws. While many of these laws are applicable to drug manufacturers, pharmacy benefit managers, and health carriers, recent enforcement of these laws has focused only on drug manufacturers.

Each state has its own set of unique requirements that drug manufacturers must meet in order to distribute drugs within each individual state. Reporting is often completed via an online portal administered by the state's implementing agency. Some states will use this submitted data to produce public reports about the cost of prescription drugs with a goal of educating the state legislature and the public about the cost of drugs and to provide accountability for increased prices.

Enforcement of these state reporting laws is beginning to take shape as states pass legislation and implement administrative guidance - the majority of which provide for civil or administrative penalties. Enforcement authorities typically assess fines for each day a manufacturer is in violation and may increase penalties the longer the violation persists. Additionally, the appeals process for any enforcement action typically follows either a prescribed process codified by the state law or defaults to the appeals process under the state's administrative procedure act.

Accordingly, pharmaceutical manufacturers will need to be vigilant as more states pass and implement drug transparency laws. These laws require different reporting deadlines, the reporting of different information, disclosures based on different dollar thresholds, and have different requirements and processes for protecting confidential information and trade secrets. For the latest developments in this area, please see Goodwin's recent [client alert](#). For an in-depth analysis of these laws, please see our publication, [State Drug Transparency Laws: Considerations for Pharmaceutical Manufacturers](#), in Chapter 8 of the American Health Law Association's 2021 edition of *Health Law Watch*.