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 The CDS Guidance follows the Agency's September 2019 draft guidance of the same name (the "Draft Guidance") and seeks to clarify several key concepts for determining whether clinical decision support ("CDS") software is a medical device.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**.

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.

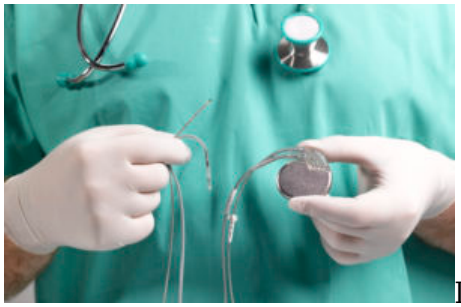
Aduhelm has been approved by FDA for the treatment of Alzheimer's since June 2021. This is the first drug approved by FDA for the treatment of Alzheimer's in almost 20 years. In 2019, two clinical trials for Aduhelm were **paused** due to data showing the drug was of no benefit to patients' cognitive 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 21st 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.

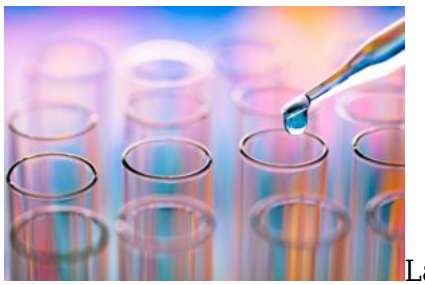
When assessing the **reliability** of registry data, the draft guidance advises sponsors to assure the registry has appropriate governance measures in place to help ensure the registry can meet its objectives, such as processes and procedures governing the operation of the registry, adequate training 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 21st Century Cures Act enacted in 2016. For full text of the bill, click **here**. The 21st 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 sates 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*.

Don't Forget about the States! Understanding the Maze of State Billing Laws for Physicians and Laboratories Providing Anatomic Pathology Services

Laboratory tests play a critical part of the healthcare system. Ordering and billing for these tests, however, is not always cut-and-dry. Compliance with federal laws and rules (like the Clinical Laboratory Improvement Amendments (CLIA), the Anti-Kickback Statute (AKS), and the Eliminating Kickbacks in Recovery Act (EKRA) – not to mention Medicare billing requirements is essential. but, laboratory testing companies and physician practice groups must also pay attention to an array of state laws and regulations that place restrictions on which parties can bill for laboratory tests and for how much, among other requirements. These laws are important, as they can dictate significantly how, where, and with which entities laboratory testing companies do business. These laws can also have a significant impact on how physicians can order critical tests for their patients.

As laboratories and medical groups continue expand nationally, and the trend in mail-order laboratory testing, spurred by the COVID-19 pandemic, continues, it is important for both laboratories and practice groups not to overlook compliance with applicable state laws and regulations, including states' direct billing, anti-mark-up, and disclosure laws.

What tests are at issue?

State laws regarding laboratory billing practices are focused on "anatomic pathology services." This could include, for example, cytology, molecular pathology, hematopathology, histopathology, surgical pathology, and blood banking services performed by a pathologist. Put another way, state laws focused on billing for laboratory tests are concerned with those procedures that diagnose disease based on the macroscopic, microscopic, biochemical, and immunologic and molecular

examination of organs and tissues.

> **Hypothetical Example:** Patient Smith visits Dr. Jorgensen, a dermatologist. Dr. Jorgensen seeks to biopsy a suspicious mole that she spots when Patient Smith visits. Dr. Jorgensen's practice group does not have an in-house laboratory with the capabilities needed to run the relevant pathology test. Dr. Jorgensen regularly sends tissue samples for processing to Oncology Lab LLC, a nationwide provider of pathology testing services for dermatologists and other specialists. Oncology Lab receives the tissue sample, conducts the relevant testing, and returns the test results to Dr. Jorgensen's office to deliver to the patient. Oncology Lab charges $100 per test.

In the hypothetical above, for example, the referring physician and the lab that runs the test are both subject to a series of laws and about who can bill for these tests, who can pay for the tests, and how much can be charged, all depending upon where Dr. Jorgensen, Patient Smith, and Oncology Lab LLC are located. These state direct billing laws, anti-markup laws, and disclosure laws, apply regardless of whether the test is paid or covered by government insurance, commercial insurance, or the patient directly on a cash pay basis.

Direct Bill Laws

Many states have so-called "direct billing" laws that require the laboratory that performed the anatomic pathology services must bill the patient (or the patient's payor, or a limited set of other individuals or entities) for the test. According to the College of American Pathologists ("CAP"), the idea is that "payment for anatomic and clinical pathology services should be made only to the person or entity who performed or supervised the service." The purpose of these laws is to prohibit so-called "pass-through billing" or "client billing," under which a laboratory bills the practice group that ordered the test, and the practice group then in turn bills the patient.

Under a direct billing model, the treating physician is not incentivized to order additional or unnecessary testing or to refer patients to one specific laboratory over another, simply on the basis of the amount of profit the treating physician might earn. Rather, the physician orders the tests that the patient needs, the laboratory runs the tests, and the laboratory bills the patient or payor for the tests. Direct billing, according to CAP, helps make certain that quality – as opposed to financial considerations – influence the physician's selection of a pathology services laboratory.

Under a pass-through or client billing model, the treating physician can score an extra profit by charging the patient for the full price of the laboratory service that the physician received at a discount. This practice **may also incentivize health care providers** to choose certain laboratories (i.e., lower quality laboratories charging lower fees) or order certain laboratory tests (i.e., to increase profits) – both of which are not in the best interest of the patient.

Because of the perverse incentives, and the potential effect on quality of care, many states prohibit pass-through or client billing and mandate direct billing as the only acceptable pathology services billing practice. In fact, the **pass-though billing prohibition under California law** was spurred by a September 2005 Wall Street Journal article, titled *How Some Doctors Turn a $79 Profit from a $30 Test*. The article describes startling studies indicating that "physicians are more likely to order services for patients if they have a financial incentive." An author of one such study by the Center for Health Policy, described in the article, stated that pass-through laboratory testing "appears to be done exclusively to earn more revenue and increase profits."

For example, California law states, "A [licensed health care provider] shall not charge, bill, or otherwise solicit payment, directly or indirectly, for anatomic pathology services if those services were not actually rendered by that person or under his or her direct supervision." [Cal. Bus. & Prof. Code § 655.7(a)(1).] New York law similarly restricts billing of clinical laboratory services to the "recipient of the services, such recipient being the person upon whom the clinical services have been or will be rendered." [N.Y.P.H.L. § Sec. 586(1).]

Why Care?

First, state laws vary – while some states are only focused on tests that require the use of a pathologist to read the results, many other tests are not. Most states indicate that a laboratory can bill a patient, the patient's payor, a patient's representative, a patient's employer or health plan, a patient's union, or a relevant government agency; some states permit a laboratory to bill a health care facility or hospital for a pathology test; other states (like Maryland) appear to prohibit it. Similarly, some states' laws apply where the patient is located, some apply where the provider who ordered the test is located, and others could even apply where the lab is located. Put another way, laboratories that operate in multiple states need to clearly understand the rules in all of their states of operation and may need to adjust and modify their practices accordingly. There is a potential lack of consistency across states that can create disruption and require complicated and administratively burdensome internal policies and practices.

Second, not all physicians may understand how direct billing works, especially when they order expensive laboratory tests for their patients. Some practice groups include billing for lab tests as part of their financial projections; however, direct bill laws may prohibit this practice and mandate that the laboratory that performed the test bills the patient directly. By failing to account for whether an entity is in a direct bill state or not, their financial projections may fall flat.

At the federal level, **Medicare rules** clearly require direct billing for outpatient hospital laboratory services – i.e., in order to receive Medicare reimbursement for a laboratory test, the laboratory must bill the patient or the payor directly – and pass-through billing is prohibited. However, physicians may be reimbursed for clinical laboratories services performed by third party laboratories so long as certain disclosures are made to Medicare. [45 C.F.R. § 405.515.] This adds yet another layer of complication for laboratory testing companies and for practice groups, as a patient's status as a Medicare beneficiary must be factored into account.

> **Hypothetical Example:** In a state with a direct billing requirement, Oncology Lab must bill Patient Smith (or Patient Smith's insurance company or other relevant payor) the $100 for the cost of the mole biopsy test.

Anti-Markup Laws

A second type of law that applies to pathology testing services is the so-called "anti-markup" law. Anti-markup laws might technically permit a lab to bill a physician practice group for a test performed. But, these laws also prohibit the physician practice group from charging a patient or the patient's payor any more than the amount the group paid to the lab.

At a national level, Medicare has a similar anti-markup rule, prohibiting physicians and practice groups from marking up the cost of purchased laboratory tests. The idea is "that allowing physician group practices or other suppliers to purchase or otherwise contract for the provision of diagnostic tests and then to realize a profit when billing Medicare may lead to patient and program abuse in the form of over utilization of services and result in higher costs to the Medicare program." [71 Fed.Reg. 69624, 69688.]

Why Care?

First, and again, state laws vary. Therefore, laboratory companies' business plans must vary by state and **may not be subject only to the federal Anti-Markup Rule**. Second, physician practice groups seeking to turn a profit on laboratory tests ordered from outside labs could easily run afoul of these state requirements. States that prohibit marking up laboratory services include like California, Michigan, and Oregon, as follows:

- Bus. & Prof. Code § 655.5(c). "It is also unlawful for any person licensed under this division or under any initiative act referred to in this division to charge additional charges for any clinical laboratory service that is not actually rendered by the licensee to the patient and itemized in the charge, bill, or other solicitation of payment…"
- Michigan, Comp. Laws Ann. § 445.161(1). "A person licensed to practice medicine by an agency of the department of licensing and regulation, a hospital, agency or any other entity billing patients or third parties for laboratory work, shall not bill a patient for laboratory work performed by a clinical laboratory for any amount in excess of the amount billed by the clinical laboratory to the licensed person for such services."
- R.S. § 676.310(1). "…However, a practitioner shall not mark up, or charge a commission or make a profit on services rendered by an independent person or laboratory."

Penalties for violation of state anti-markup rules include imprisonment for up to one year and/or fines ranging from $500 up to $10,000 – and may include reprimand by the state medical board.

Failing to comply with Anti-Markup Rule may also mean a violation of the federal Anti-Kickback Statute (AKS) and/or the Stark Law. Penalties for violating AKS include incarceration, exclusion from federal health care programs, and civil monetary penalties of $11,803 to $23,607 per claim, plus three times the amount of damages.

> **Hypothetical Example:** In a state with an anti-markup rule and no direct bill rule, Oncology Lab may be able to bill Dr. Jorgensen for the $100 cost of the mole biopsy test. Dr. Jorgensen can then pass the test's charge through to the patient; however, Dr. Jorgensen cannot charge the patient more than $100.

Disclosure Laws

A third type of state law governs the ordering of pathology testing services: disclosure laws. Disclosure laws do not technically prohibit labs from billing physician practice groups, and they also do not technically prohibit practice groups from marking up laboratory test prices. Instead, these laws require that a physician practice that purchases a test from a laboratory (and passes the cost of such test along to the patient) must disclose the price that the physician paid for the test to the patient and the applicable non-federal third-party payors. These laws do not ban markups for laboratory services, so long as the markup is disclosed. States with disclosure laws include but are not limited to, Arizona, Pennsylvania, and Texas, as follows:

- Stat. Sec. 36-472(B). "The bill to the patient shall specify the actual charge by the reference laboratory together with the reasonable specimen collection charge by the referring laboratory or physician."
- Admin. Code § 5.48. "A notification of charges for laboratory tests performed for the patient shall be sent to the patient by the clinical laboratory unless the patient has been billed directly or otherwise notified of the charges by the laboratory."
- Health & Saf. Code § 161.061. "(a) A person licensed in this state to practice medicine,

dentistry, podiatry, veterinary medicine, or chiropractic may not agree with a clinical, bioanalytical, or hospital laboratory to make payments to the laboratory for individual tests, combinations of tests, or test series for a patient unless:

1. the person discloses on the bill or statement to the patient or to a third party payor the name and address of the laboratory and the net amount paid to or to be paid to the laboratory; or
2. discloses in writing on request to the patient or third party payor the net amount.

(b)The disclosure permitted by Subsection (a)(2) must show the charge for the laboratory test or test series and may include an explanation, in net dollar amounts or percentages, of the charge from the laboratory, the charge for handling, and an interpretation charge."

Why Care?

Importantly, physician practice groups need to be aware when they are operating in a disclosure state so that their billing and invoicing systems are appropriately calibrated to include any lab testing costs.

In addition, we often think of the federal ban on pass-through billing and the federal anti-markup rule, but laboratories, hospitals, and physician practice groups that order lab tests from outside labs should be aware of and make sure their practices comply with this complicated web of state requirements. Providers may be using one compliance model to comply with federal laws in connection with federal health care programs, but such model may violate applicable state laws.

> **Hypothetical Example:** In a state with a simple disclosure requirement, Oncology Lab could submit a bill to Dr. Jorgensen (instead of Patient Smith); however, when Dr. Jorgensen bills Patient Smith for the test, the physician must also disclose that she paid Oncology Lab $100 for the test.

Nationwide telehealth groups and digital health providers ordering tests for patients located in different states or hospitals, laboratories, or physician groups ordering laboratory tests from outside their home state, may also prefer a one-size fits all model; however, this might require tailoring all operations to fit the strictest regime of no pass-through billing or markups across the board. Other providers – particularly those that are more local or regional in nature – might find it more feasible to have a state-by-state model with laboratory billing policies and procedures tailored to each state. Further, Medicare providers may find it easiest and most efficient to implement Medicare markup restrictions for all laboratory billing, including cash pay and commercial patients.

* * * * *

As depicted above, states vary widely on their regulation of laboratories and violations of state law may trigger not only civil penalties but criminal prosecution as well. Laboratory testing companies and physician practice groups should pay particular attention to their policies and compliance programs, which must be crafted to account for these additional complexities. In addition, existing laboratories and physician practice groups should analyze and update their compliance policies to ensure that they are aligned with existing state and federal requirements.

For questions regarding current laboratory compliance with federal and state laws or for questions related to expansion and compliance concerns, please reach out to Anne Brendel at **abrendel@goodwinlaw.com** or Matt Wetzel at **mwetzel@goodwinlaw.com**.

Biden Executive Order Targets Competition in Healthcare, Life Sciences to Spur Economic Activity

On July 9, 2021, President Joe Biden issued an **Executive Order** (the "Order") designed to promote competition in the American economy. The Order describes the administration's concerns with competition in several markets, including healthcare, noting that industry consolidation has exacerbated racial, income and wealth inequality and emphasizing that robust competition is critical to the United States economy.

In this Order, to combat these concerns, the Biden administration affirms (i) its policy to support legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices and by imposing inflation caps; and (ii) its policy to support the enactment of a public health insurance option.

Read the **client alert**.

Disrupt + Innovate + Transform: Key Regulatory Issues for Digital Health Companies Webinar

Goodwin Life Sciences and Healthcare partner **Roger Cohen** and associate **Anne Brendel** along with Life Sciences and FDA associate **Steven Tjoe** kicked off

Goodwin's multi-part webinar series "Disrupt + Innovate + Transform: A Healthcare Webinar Series" with "Key Regulatory Issues for Digital Health Companies" discussing the key regulatory issues affecting digital health, telemedicine and healthcare IT companies. The webinar series will be presented by a cross-disciplinary team of Goodwin lawyers exploring the topics that are most relevant for the healthcare industry today. From ever-changing regulatory guidelines to digital health, women's health and privacy, Goodwin will take attendees through these topics and more and provide guidance to help you navigate the current healthcare landscape.

View the Video:

For information on upcoming webinars in the Disrupt + Innovate + Transform: A Healthcare Webinar Series, visit our **mini site**.