Key Legal Trends For Healthcare And Life Sciences In 2024

By **Xin Tao and Lois Liu** (January 8, 2024)

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As we look back at 2023, we reflect on a year marked by significant developments in the legal framework governing the life sciences and healthcare industries in the U.S.

These developments include the implementation of the Medicare Drug Price Negotiation Program under the Inflation Reduction Act; the rise of artificial intelligence in drug development and manufacturing; the evolving landscape of U.S. Food and Drug Administration regulation and enforcement of laboratory-developed tests; and the new general compliance program guidance issued by the U.S. Department of Health and Human Services Office of Inspector General.

We anticipate these topics will continue to dominate the headlines throughout 2024.

Between the contentious legal battles over drug pricing negotiations, the growing integration of AI in drug development and manufacturing, the government's ambitious plan to regulate lab-developed tests as medical devices and the publication of industry segment-specific healthcare compliance guidance, the year ahead promises to be a dynamic period of changes and challenges for both the industry and government regulators.

Below, we briefly discuss these key legal trends, followed by our take on their implications and proactive measures that the industry should consider in response.

Medicare Drug Price Negotiation in 2024

Under the Inflation Reduction Act, the U.S. federal government now has the legal authority to negotiate the prices of certain drugs directly with pharmaceutical companies for Medicare.

The negotiated maximum drug prices for the 10 drugs selected for the first round of negotiations are expected to be disclosed by the Centers for Medicare and Medicaid Services by Sept. 1, with the new price effective beginning in 2026.[1] Other expected 2024 milestones for the first round of Medicare drug price negotiation include:[2]

- By Feb. 1, CMS is to send an initial offer of a maximum fair price.

- By March 2, participating drug companies are to either accept the initial offer or propose a counteroffer.

- In the spring and summer of this year, CMS is to provide up to three negotiation meetings if a counteroffer is proposed and not accepted.

- On Aug. 1, the negotiation period will conclude.

However, the implementation of the Inflation Reduction Act is currently facing constitutional challenges through several separate lawsuits filed by pharmaceutical manufacturers and trade associations in federal district courts in Washington, D.C., New Jersey, Connecticut, Texas, Ohio and Illinois.[3]

The plaintiffs argue that the Inflation Reduction Act violates the First Amendment because the proposed pricing agreement to be signed with the U.S. Department of Health and Human Services amounts to compelled speech.

The plaintiffs also contest that the Inflation Reduction Act violates the due process clause and the takings clause under the Fifth Amendment. While we anticipate more headlines on Medicare drug price negotiation as these cases continue evolving in 2024, a single decision issued by one court is unlikely to be final, and the matter could eventually land before the U.S. Supreme Court.

Notably, the drug price negotiation program applies only to a selected few high-expenditure, single-source Medicare drugs lacking generic or biosimilar competition. CMS has further specified several exemptions and exclusions, and the first 10 drugs selected must meet the following criteria:

- Single-source drugs with no generic or biosimilar competition;[4]

- Exclusion of orphan drugs, low-spend Medicare drugs, and plasma-derived products;

- Exception for small biotech drugs; and

- Exclusion of delayed biologics due to a high likelihood of biosimilar market entry.

Companies should carefully, and realistically, evaluate the likelihood that their Medicare drugs or drug candidates may become subject to the drug price negotiation program. It is worth highlighting that the initial 10 selected drugs accounted for $50.5 billion in total Medicare Part D gross covered prescription drug costs during 2022-2023, ranging from approximately $2.5 billion to $16.5 billion in costs for each drug during that time period.

As the program is still in its early phase, CMS is willing to engage the industry stakeholders to provide further clarifications when warranted.

For example, under the orphan drug exclusion, a drug that is designated and approved as a drug for only one rare disease or condition under Section 526 of the Federal Food, Drug, and Cosmetic Act is not subject to the drug price negotiation program. As such, a drug will not qualify for orphan drug exclusion if it has designations for multiple rare diseases or conditions, even if the drug has been approved only for one indication.

In response to comments from the industry, CMS has clarified in its guidance that it will only consider active designations and active approvals when evaluating a drug for the orphan drug exclusion.[5] In other words, CMS will not consider withdrawn orphan designations or withdrawn approvals as disqualifying a drug from the orphan drug exclusion.

The Use of AI in Drug Development and Manufacturing in 2024

We also anticipate more use of AI in drug development and manufacturing in 2024.

AI is broadly characterized as the application of algorithms or models to execute tasks relying on training data. The integration of AI into drug development and manufacturing is no longer a futuristic concept.

According to the FDA, the inclusion of AI in new drug and biologic submissions has surged, exceeding 100 submissions in 2021 alone.[6] In 2023, the FDA was vigilant of the rapid technology advancement and published two discussion papers on AI, including "Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products," and "Artificial Intelligence in Drug Manufacturing."

The FDA outlined the following current and potential uses of AI in the drug development and manufacturing process.

Current and Potential Uses of AI in Drug Development and Manufacturing

- Drug discovery: drug target identification, selection and prioritization, and compound screening and design;

- Nonclinical research;

- Clinical research: recruitment selection and stratification of trial participants, dose and dosing regimen optimization, retention, site selection, clinical trial data collection, management and analysis, and clinical endpoint assessment;

- Post-marketing safety surveillance: case processing, case evaluation and case submission;

- Advanced pharmaceutical manufacturing: optimization of process design, advanced process control, smart monitoring and maintenance and trend monitoring

Because AI has been used or can be potentially used in a broad range of drug development and manufacturing activities, it is crucial for the pharmaceutical industry to evaluate whether integrating AI presents unique risks for their specific applications, and how these risks can be addressed within the current legal and regulatory framework.

For instance, AI algorithms have the potential to amplify errors and inherent biases present in the underlying data sources. This can pose a particular challenge in drug development, where the margin of error is usually slim.

Moreover, the intricate and proprietary nature of AI systems can lead to the apparent nontransparency in submissions, which can make it difficult for the regulators to fully assess the safety and effectiveness of the drug products developed or manufactured with the involvement of AI.

In an effort to address these concerns, the FDA developed very general principles for AI use:

- Human-led governance, accountability and transparency;

- Quality, reliability and representativeness of data; and

- Model development, performance, monitoring and validation.

As the role of AI in drug development and manufacturing is in its nascent phase, the FDA is actively soliciting comments and willing to engage the industry stakeholders on this topic.

We also note the specific scenarios of AI may be unfamiliar to certain regulators, and it falls upon the industry to proactively consider potential issues using the general principles outlined by the FDA. Often regulation lags behind innovation, and AI will inevitably complicate the matrix by introducing uncertainties to regulatory compliance.

Companies using AI in drug development and manufacturing are encouraged to collaborate with regulatory agencies to continue developing an open and flexible framework that can foster its development in 2024.

FDA Regulations on Lab-Developed Tests in 2024 and Beyond

Historically, lab-developed tests are defined as in vitro diagnostic products that are intended for clinical use and are designed, manufactured and used within a single clinical laboratory.

Such labs must be certified under the Clinical Laboratory Improvement Amendments of 1988 and meet the CLIA's regulatory standards to perform high-complexity testing.

On Sept. 29, 2023, the FDA issued a proposed ruleseeking to expand its authority to regulate lab-developed tests as medical devices. Since then, the FDA has received more than 6,700 public comments from laboratories, academic medical centers, hospitals, professional and trade organizations, individuals citizens, and other industry stakeholders.

Despite requests for an extension of the comment period, the FDA publicly declined to extend the 60-day comment period, and has announced that it intends to publish a final rule by April, leaving the industry limited time to prepare for compliance.

In addition to bringing lab-developed tests under the FDA's oversight, the proposed rule also includes a gradual, four-year phase-out policy of enforcement discretion from the FDCA compliance historically provided to LDTs.

While the FDA is proposing a broad scope of the phase-out policy, the agency has made clear that it does not intend to apply the policy to certain lab-developed tests that were already excluded from the FDA's general enforcement discretion approach. These tests are:

- Tests that are intended as blood donor screening or human cells, tissues, and cellular and tissue-based products donor screening tests required for infectious disease testing;

- Tests intended for emergencies, potential emergencies or material threats such as an emergency use authorization; and

- Direct-to-consumer tests.

Despite the FDA's determination to move the proposed rule expeditiously, its efforts to finalize and implement the phase-out policy will likely face obstacles from industry.

Among the thousands of comments from interested stakeholders, many argue that the FDA does not have the legal authority to regulate lab-developed tests. As such, the FDA proposed rule may also get litigated in the courtroom this year, which would delay the FDA's timeline and implementation.

Although we may be years away from the FDA's complete oversight of lab-developed tests, it is unclear whether the phase-out policy would provide sufficient time for industry to transition.

Additionally, as the FDA recognizes in the proposed rule, implementation of the proposed rule and the phase-out policy may result in some tests coming off the market, if the product cannot meet the applicable requirements or if the laboratory chooses not to invest resources to meet those requirements.

It would be prudent for laboratories and companies that manufacture or offer lab-developed tests — including advertising or marketing — to review their portfolio and perform regulatory diligence to determine the potential product classification and the relevant premarket submission requirements in order to ensure continued operation in

manufacturing and offering these tests after the new FDA rule takes effect.

HHS-OIG to Publish Industry-Specific Compliance Program Guidance in 2024

On Nov. 6, 2023, the OIG published the general compliance program guidance, or GCPG. This is the most comprehensive and practical general compliance guidance document that the OIG has released in decades.

The GCPG is a 91-page document consisting of summaries of the relevant federal laws, generally applicable compliance basics, key resources and tools, and enforcement action summaries. The GCPG also discusses the seven updated elements of an effective compliance program:

- Written policies and procedures;
- Compliance leadership and oversight;
- Training and education;
- Effective lines of communication and disclosure program;
- Enforcing standards;
- Risk assessment, auditing and monitoring; and
- Responding to detected offenses and developing corrective action initiatives.

The GCPG is the first step of a series of compliance guidance documents anticipated to be issued by the OIG. Prior to the GCPG, the OIG developed compliance guidance documents directed at 11 types of providers and industry participants, including:

- Hospitals;
- Home health agencies;
- Clinical laboratories;
- Third-party medical billing companies;
- The durable medical equipment, prosthetics, orthotics and supply industry;
- Hospices;
- Medicare Advantage organizations;
- Nursing facilities;
- Individual and small group physician practices;
- Ambulance suppliers; and
- Pharmaceutical manufacturers.

While the GCPG is meant to be applicable to all individuals and entities involved in the healthcare industry, the OIG has announced that starting in 2024, it will be publishing industry segment-specific compliance program guidances for different types of providers, suppliers and other participants in healthcare industry subsectors or ancillary industry sectors relating to federal health care programs, which will likely cover the eleven types of providers and participants.

These guidances will be tailored to fraud and abuse risk areas for each industry subsector and will address compliance measures that the industry subsector participants can take to reduce these risks.

Further, the OIG intends to update these guidances periodically to address newly identified risk areas and compliance measures for the applicable participants.

In addition to the GCPG and the forthcoming industry segment-specific compliance program guidances, the OIG has been releasing compliance guidance information through different formats, including advisory opinions, such as the OIG's favorable Advisory Opinion No. 23-11 regarding the proposed subsidization of certain Medicare cost-sharing obligations in a medical device clinical trial, and its unfavorable Advisory Opinion 23-08 against a manufacturer's proposal to provide free hearing aids to certain patients.

There are also special fraud alerts, such as the OIG special fraud alert regarding speaker programs by pharmaceutical and medical device companies.

The GCPG serves as a practical reference tool for providers and industry participants of all sizes and types to reassess their compliance capabilities and determine what measures are needed to keep up with OIG standards.

As we progress into the new year, individuals and companies in the healthcare industry should anticipate the upcoming industry segment-specific compliance program guidances, as they may provide compliance specifics relevant to the company itself as well as other parties with whom the company maintains a financial arrangement, such as a third-party vendor of a pharmaceutical company.

While the OIG notes that the GCPG is a voluntary, nonbinding document, and likely the same note for industry segment-specific compliance program guidances, companies with existing compliance programs should closely review these guidance documents and implement updates as needed and appropriate.

Conclusion

In conclusion, we note it is dangerous to make predictions, especially about the future.

At the dawn of 2024, as we briefly walk through these key legal trends, we want to emphasize it is imperative for the industry to not only stay abreast of the evolving laws and regulations, but also proactively engage in assessing the implications and invest in strategic, responsive measures.

If history is any guide, we look forward to witnessing how the life science and healthcare industries will continue to progress and thrive in 2024.

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[1] The complete list of the ten drugs subject to the first round of negotiation is available at: https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf.

[2] Of course, this is based on the assumption the legal challenges against the IRA implementation will be unsuccessful in 2024.

[3] See, e.g., Merck & Co. v. Becerra, No. 23-1616 (D.D.C. Jun. 6, 2023); U.S. Chamber of Commerce, et al. v. Becerra, No. 23-0156 (S.D. Ohio, Jun. 9, 2023); Bristol Myers Squibb Company v. Becerra, No. 23-3335 (D.N.J. Jun. 16, 2023); Pharmaceutical Research and Manufacturers of America (PhRMA) et al. v. Becerra, No. 23-0707 (W.D. Tex. Jun. 21, 2023); Janssen Pharmaceuticals Inc. v. Becerra, No 23-3818 (D.N.J. July 18, 2023); Astellas Pharma U.S., Inc. v. Becerra, No. 23-4578 (N.D. Ill. July 14, 2023); Boehringer Ingelheim Pharmaceuticals, Inc., v. Becerra, No. 23-01103 (D. Conn. Aug. 18, 2023); AstraZeneca Pharmaceuticals LP v. Becerra, No. 23-0931 (D. Del. Aug. 25, 2023).

[4] Single source drugs are drugs for which at least 7 years, or biologics for which at least 11 years, have elapsed between the FDA approval or licensure of the drug or biologic, and for which there is no generic or biosimilar competition.

[5] A copy of the CMS revised guidance is available at: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (cms.gov).

[6] See FDA's website: Artificial Intelligence and Machine Learning (AI/ML) for Drug Development | FDA.