KEY INSIGHTS

Health Care & Life Sciences Top Trends for 2026

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CONTENTS

Foley & Lardner's 2026 Health Care & Life Sciences Top Trends publication unpacks fast-moving developments to help your business capitalize on opportunities and navigate the potential pitfalls of an uncertain regulatory and litigation landscape.

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The health care and life sciences sector enters 2026 in a period of accelerated change. New technologies, shifting regulatory frameworks, workforce pressures, and evolving reimbursement models are reshaping how organizations deliver care, manage risk, and invest for growth. This year's Health Care & Life Sciences Top Trends report highlights where market, policy, and enforcement dynamics intersect — and where industry leaders will need clear strategy and proactive governance.

Key trends we highlight in this document include:

- Enforcement-Led Environment
- Under a Microscope: Digital Health & AI
- Public Program Pressure & Dual Enforcement Risk
- GLP-1 Market Momentum with Tighter Guardrails
- Cybersecurity Risks: Connected Devices
- Operating Model Imperatives for 2026

Enforcement will define the Health Care & Life Sciences sector for 2026. As President Trump enters the second year of his second term, federal oversight of the industry remains a clear priority. In 2024 and 2025 the government secured more than $3 billion in recoveries under the False Claims Act, marking consecutive years of record-breaking judgments. Antitrust enforcement is also expected to intensify, particularly as pharmaceutical and drug pricing issues draw heightened attention. Telemedicine and digital health companies continue to face increased scrutiny as evolving regulatory standards affect remote patient monitoring and the rapid expansion of Artificial Intelligence (AI).

As AI advances, regulatory uncertainty continues. Federal and state governments remain divided on how AI should be regulated, and the United States Patent and Trademark Office (USPTO) has yet issued guidance of AI-generated data — a growing concern as more health care & life sciences companies seek to patent their AI-generated innovations. This regulatory ambiguity comes at a time when Medicaid and Medicare Advantage face an uncertain future.

In the summer of 2025, President Trump signed H.R. 1 (One Big Beautiful Bill Act), reducing federal Medicaid spending by over $900 billion over a 10-year period. As states adjust to reduced budgets, Medicare Advantage (MA) is experiencing federal oversight. The Centers for Medicare and Medicaid Services launched its most robust enforcement initiatives yet, overhauling its Risk Adjustment Data Validation audit program. At the same time, Department of Health and Human Services Office of Inspector General has escalated its review of provider risk adjustment activities. Together, these actions signal a new era of dual enforcement risk for both Medicare Advantage Organizations and health care providers.

Amid these changes, the demand for GLP-1 drugs and medical devices remain strong. As more pharmaceutical manufacturers develop GLP-1 products, the U.S. Food and Drug Administration is keeping a close eye, issuing warning letters to companies marketing unapproved or misbranded compounded products. Additionally, we explore how medical devices, such as smart watches and wearable trackers, raise growing cybersecurity concerns.

Together, these trends reflect a system demanding both innovation and accountability. Organizations that invest in strong compliance, data governance, operational resilience, and strategic technology deployment will be best positioned to navigate uncertainty and capture opportunity in 2026 and beyond.

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Trump 2.0: Health Care Enforcement Remains a Top Priority

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In the first year of President Trump's second term, health care enforcement is not taking a back seat. The Department of Justice (DOJ) has reaffirmed that investigating and prosecuting fraud, waste, and abuse — particularly in federal health care programs — remains a top priority. This continued focus comes after two record-breaking years: in 2024, nearly $3 billion was recovered under the False Claims Act (FCA), and 2025 has seen significant judgments and settlements as well.

Recent developments underscore this commitment. In May 2025, DOJ unveiled its first-ever White-Collar Enforcement Plan, placing health care fraud at the top of its list of ten priority areas. The plan emphasizes aggressive prosecution, data-driven detection, and expanded whistleblower incentives, signaling that providers, payors, and life sciences companies will continue to face intense scrutiny. Just weeks later, the administration announced the largest health care fraud takedown in U.S. history — charging 324 defendants in schemes totaling $14.6 billion in intended losses. In its press release, DOJ also announced that the DOJ Criminal Division, Fraud Section, and Health Care Fraud Unit Data Analytics Team is working closely with the U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG), the Federal Bureau of Investigations (FBI), and other agencies to create a Health Care Fraud Data Fusion Center. The center's primary purpose is to increase efficiency, detection, and rapid prosecution of emerging health care fraud schemes by reducing duplicative data teams, increasing operational efficiency through a "whole-of-government" approach and leveraging cloud computing, artificial intelligence, and other agency resources.

In addition, in July 2025, the DOJ, in collaboration with other federal agencies, announced a new initiative, the False Claims Act Working Group, focused on increasing coordination among federal agencies affected by health care fraud and to focus on the enforcement of certain priority areas, including Medicare Advantage, drug, device or biologics pricing, network adequacy, and kickbacks related to drugs, medical devices, durable medical equipment (DME), and other products. The Working Group includes leadership from the Office of Counsel to HHS-OIG, the Center for Medicare & Medicaid Services' (CMS) Center for Program Integrity, HHS Office of General Counsel, DOJ Civil Division, with designees from various U.S. Attorneys Offices.

For health care organizations, these moves send a clear warning: compliance programs must proactively assess risk areas, keep thorough documentation, and ensure billing practices are defensible. The government's increased use of advanced data analytics, coupled with interagency collaboration, means the government can explore both tried-and-tested avenues as well as new theories of liability.

Hotspots for Enforcement Activity

Shift Towards Data-Driven UPIC Audits

Unified Program Integrity Contractors (UPICs) play a critical role in safeguarding traditional Medicare and Medicaid programs against fraud, waste, and abuse. In collaboration with states, the UPICs conduct proactive Medicaid data analysis, investigations, and audits of all types of Medicaid providers and report identified overpayments to states for recovery. CMS expects the UPICs to prioritize high dollar, high risk investigations. Particularly, during FYs 2024-2028, CMS expects that managed care, opioids, telehealth, mental health, DME, non-emergency medical transportation, hospitals, laboratories, and hospice will continue to be areas of focus for the UPICs. UPIC audit strategies evolved significantly, driven by advanced analytics, regulatory priorities, and inter-agency collaboration. Key trends for UPIC audits include:

1. data-driven audits — i.e., leveraging predictive analytics and real-time monitoring to identify high-risk claims before payment and aggressive enforcement;
2. aggressive enforcement — employing statistical sampling and extrapolation early which leads to larger recoupments; and
3. inter-agency collaboration — UPICs work closely with DOJ and CMS' Center for Program Integrity, as well as utilize AI tools to accelerate enforcement.

The potential impact of these more aggressive UPIC audit strategies on Medicare Advantage (MA) plans and providers is significant as the UPICs are authorized to initiate administrative actions including, but not limited to, payment suspensions and revocations, automatic edits to deny payments, civil monetary penalties, and referral to law enforcement where fraud is identified. Providers and managed care organizations should adopt proactive compliance strategies to navigate this evolving enforcement landscape. Further, when a provider or managed care organization receives a UPIC audit request, legal counsel should be engaged early in the process to manage appeals effectively.

Medicare Advantage – RADV Audits

Recent developments signal a new era of aggressive enforcement targeting MA risk adjustments. On May 21, 2025, CMS announced a sweeping overhaul of its Risk Adjustment Data Validation (RADV) audit program for MA plans. The initiative significantly expands audits from a limited sample of about 60 MA contracts to all eligible MA contracts annually, accelerates clearance of backlogged audits for payment years 2018 through 2024, deploys significant resources to detect overpayment vulnerabilities (i.e., enhanced technology, workforce expansion, and increased audit volume), and collaboration with HHS-OIG to recover overpayments identified in past audits. CMS intended to use statistical extrapolation to scale audit findings across entire MA contracts without applying a fee-for-service (FFS) adjuster. Using this extrapolation approach, CMS estimated potential overpayment amounts could be as high as $43 billion per year. There is currently uncertainty, however, regarding CMS' ability to execute its new plan as a recent court ruling vacated CMS's 2023 RADV Final Rule on procedural grounds, thus halting CMS' extrapolation authority for now. The court remanded the Final Rule to CMS. In the meantime, CMS can continue its audits and recover sample level overpayments.

This heightened enforcement environment reflects nearly a decade of litigation that clarified CMS' authority to conduct large-scale audits and coincides with parallel efforts by HHS-OIG, which identified risk adjustment as a high-risk area for improper payments. HHS-OIG is intensifying oversight of diagnosis coding accuracy. For example, recent OIG audits have uncovered systemic vulnerabilities and the need for improvement in policies and procedures to prevent, detect and correct noncompliance, which underscore the likelihood of corrective action plans and civil penalties for deficiencies. See e.g., June 2025 MAO audit report.

These developments increase the risk of dual exposure for MA plans and providers, as both CMS and OIG are actively scrutinizing risk. Medicare Advantage Organizations and providers should ensure they have robust compliance programs and operational readiness. For a detailed discussion of the recent developments highlighted herein and recommendations, read the next article in this series entitled "Medicare Advantage at a Crossroads: CMS RADV Audit Overhaul and OIG Risk Adjustment Enforcement Explained."

Skin Substitutes

By using Medicare Part B data, HHS OIG found Medicare Part B expenditures for skin substitutes have skyrocketed over the last several years: from $250 million in 2019 to over $10 billion in 2024, while patient volume only doubled — a red flag for regulators. In response, as part of the CY 2026 PFS final rule, CMS will now pay for skin substitutes under the Physician Fee

The government's increased use of advanced data analytics, coupled with interagency collaboration, means the government can explore both tried-and-tested avenues as well as new theories of liability.

Schedule (PFS) as incident-to supplies, a change expected to reduce Medicare spending on these products by nearly 90%. This change in payment is significant and will likely reduce profit margins for many skin substitute products. Companies and practices with providers who prescribe these products should be proactively training their team members on the proper prescription and coding of these products for 2026 and build into their compliance plans audits to ensure proper billing.

Genetic Testing & Telemedicine

Federal authorities have also intensified their crackdown on allegedly fraudulent genetic testing schemes. In one notable case, a Missouri man was sentenced to 10 years in prison for orchestrating a $174 million Medicare fraud involving medically unnecessary cancer and cardiovascular genetic tests. The scheme relied on telemarketing and telemedicine physicians who approved orders without proper patient interaction, resulting in over $55 million in wrongful reimbursements. Similarly, a Georgia physician recently pled guilty to conspiring to defraud Medicare by submitting over $24 million in false claims for allegedly medically unnecessary genetic testing and paying kickbacks through telemedicine schemes. Providers should ensure that all orders — including genetic testing — are medically necessary and follow applicable laws on patient-physician relationships.

Durable Medical Equipment

DME remains a perennial high-risk area for health care fraud, with enforcement agencies prioritizing cases involving kickbacks, false billing, and medically unnecessary equipment. In an audit report issued in October 2025, OIG found none of the $22.7 million in payments for DME items provided to enrollees during inpatient stays should have been paid by Medicare. As a result, OIG is recommended to the DME Medicare Administrative Contractors to recover from suppliers the identified overpayments. These types of reviews are likely to continue as the government finds new ways to use data to identify and recover overpayments.

As these recent enforcement actions and policy initiatives demonstrate, the government is committed to holding both organizations and individuals accountable for health care fraud, waste, and abuse. Federal agencies are leveraging advanced analytics, interagency collaboration, and creative prosecution strategies to ensure that not only companies, but also executives, providers, and other responsible parties face consequences for noncompliance. This heightened scrutiny means that robust compliance programs, thorough documentation, and proactive risk management are more critical than ever. Both corporate entities and individuals who participate in or enable alleged fraudulent schemes can and will be pursued and prosecuted.

Remote Monitoring Enforcement Trends: What Providers and Technology Vendors Need to Know

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Key Takeaways:

Remote monitoring represents a significant opportunity to enhance patient care and operational efficiency, but it also carries increased scrutiny from regulators. Recent enforcement actions as well as agency guidance documents highlight the need for robust compliance frameworks. Providers and vendors should take proactive steps to ensure proper documentation, accurate billing, and ethical enrollment practices.

Introduction

As we enter 2026, remote monitoring continues to play an increasingly significant role in patient care. At the same time, the increasing prevalence of remote monitoring has also attracted heightened scrutiny from federal regulators, including the Office of Inspector General (OIG) and the U.S. Department of Justice (DOJ). For providers, understanding recent enforcement trends is critical to maintaining compliance and protecting their organizations from significant legal and financial risk.

What is Remote Monitoring?

In general, remote monitoring enables health care providers to track and manage patients' clinical data from outside the traditional clinical office setting by leveraging medical devices and other technologies. In recent years, government health care programs and commercial payors have released a variety of reimbursable programs such as Remote Patient Monitoring (RPM), Remote Therapeutic Monitoring (RTM), Chronic Care Management (CCM), Principal Care Management (PCM), and Transitional Care Management (TCM), enabling patients to receive more connected care and attention outside of the clinic or hospital while also allowing providers to receive reimbursement for using these technologies to monitor and manage patient care needs.

Enforcement Developments

The regulatory landscape for remote monitoring has evolved rapidly, reflecting both the growth of the technology and increasing concerns about fraud, waste, and abuse. An OIG consumer fraud alert issued in November 2023 warned about schemes involving misleading remote monitoring enrollment and improper billing, underscoring the government's concern about deceptive practices in this space. Following that alert, the OIG issued a September 2024 OIG evaluation report titled Additional Oversight of Remote Patient Monitoring in Medicare Is Needed highlighting systemic compliance gaps. The report found that 43% of Medicare beneficiaries receiving RPM did not receive all the required components, indicating widespread incomplete or improper billing. OIG further noted that Centers for Medicare & Medicaid Services (CMS) lacked sufficient data to oversee RPM services effectively, particularly related to tracking device use, patient engagement, and the ordering provider. The following year, in August 2025, the OIG released a data snapshot identifying RPM billing outlier patterns based on 2024 Medicare fee-for-service and Medicare Advantage data highlighting sudden enrollment spikes, billing without a documented prior patient-provider relationship, long stretches of device supply without treatment management, multiple providers billing for the same patient, and multiple devices billed per patient per month. While these billing patterns are not proof of fraud or abuse on their own, the OIG noted that these billing patterns warrant heightened scrutiny to protect the integrity of federal health care programs.

On the heels of these OIG fraud alerts and reports, several recent enforcement actions demonstrate how these trends have played out in practice. For instance, in January 2025, LiveCare Inc. agreed to pay approximately $4.9 million to resolve allegations of violations of the Anti-Kickback Statute and the False

Claims Act. Investigators alleged that the company used call center tactics to coerce Medicare beneficiaries into enrolling in RPM programs, including misrepresenting Medicare requirements and implying patients risked losing coverage if they did not participate. Similarly, in June 2025, the DOJ alleged that Health Wealth Safe, Inc. (HWS) billed Medicare for RPM services using a device not approved by the U.S. Food and Drug Administration (FDA) that did not automatically transmit data to the provider and instead required the patients to manually enter health data through a mobile data. The DOJ also alleged that HWS did not collect data for the required minimum of 16 days per month as mandated under RPM billing requirements. HWS agreed to a settlement of $1.29 million to resolve these allegations. Additionally, in May 2025, after self-disclosing conduct to OIG, Capital Health System, Inc. agreed to pay $528,937.50 for allegedly violating the Civil Monetary Penalties Law by submitting claims to federal health care programs for RPM that did not meet the requirements for coverage and payment.

Key Compliance Considerations

Given the recent enforcement, we recommend remote monitoring providers and vendors perform self-audits to proactively identify and remediate compliance risk. We suggest paying particularly close attention to the following issues:

- **Licensure and supervision**: Confirm all clinicians are licensed in the patient's state and that supervision requirements are met for the services provided.
- **State practice standards and clinical relationships**: Ensure adherence to applicable state practice rules, including establishing and maintaining an appropriate clinician–patient relationship before initiating remote monitoring services.
- **Communication requirements**: Verify compliance with any state or payer rules that require real-time interaction as part of the remote monitoring services.
- **Time documentation**: Maintain accurate, contemporaneous time records supporting all time-based remote monitoring billing codes.
- **Appropriate coding**: Use the Current Procedural Terminology (CPT) code that best reflects the service furnished rather than selecting codes based on reimbursement differentials.
- **Fraud and abuse controls**: Evaluate remote monitoring workflows and arrangements for risks under the Anti-Kickback Statute, Stark Law, and other fraud-and-abuse laws.
- **Device-delated risks**: Confirm the supply of medical devices or wearables complies with applicable payor rules and avoids creating inducements or improperly shifting costs.
- **Marketing practices**: Ensure outreach materials and vendor activities are factual and not misleading, and do not unlawfully promise free items or inducements.

Providers and vendors should take proactive steps to ensure proper documentation, accurate billing, and ethical enrollment practices.

Trends in Antitrust Enforcement in Health Care

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This article summarizes major trends that shaped antitrust in health care over the past year, along with emerging or recurrent issues we expect to see in 2026.

Key Takeaways:

Antitrust enforcement remains a key focus in the health care industry. Health care industry leaders should seek antitrust counsel to navigate this ever-evolving landscape, but a few key takeaways to keep in mind are:

- Consult with counsel before using software that may incorporate competitors' confidential pricing information.
- Review pharmaceutical pricing, rebate and product bundling practices with the current enforcement landscape in mind.
- Consult antitrust counsel when listing drug-device patents in the Orange Book.
- Refresh or audit labor and employment policies and practices considering current antitrust risks.
- Be mindful that health care mergers may require filing obligations under state enforcement regimes in addition to filing with the FTC or DOJ.

Algorithmic Pricing Software: There is continued focus on the use of algorithmic pricing tools in the health care industry (and beyond). For example, in one case, a coalition of health care providers sued Multiplan, Inc. and several third-party payors, alleging they used algorithmic pricing in violation of antitrust laws to set prices for out-of-network health care services. The U.S. Department of Justice (DOJ) filed a statement of interest in the case, arguing that "using a common algorithmic pricing can indeed qualify as concerted action under Section 1 of the Sherman Act . . . even if the competitors do not always use the algorithm in the same way." Antitrust scrutiny of algorithmic pricing tools is certain to continue into 2026 as *Multiplan* unfolds and case law and legislation in this area continues to develop.

Pharmaceutical Pricing: PBM (pharmacy benefit managers) rebating and pharmaceutical pricing practices were under the enforcement microscope this year with no signs of a letup. For example, generic drug manufacturer Regeneron recently prevailed against rival Amgen in an antitrust case, claiming that Amgen improperly bundled PBM rebates for its drug Repatha with other "blockbuster" drugs in its portfolio, resulting in the exclusion of Regeneron's competing drug from key formularies and effectively foreclosing market access. More broadly, the Federal Trade Commission (FTC) is scrutinizing the roles of PBMs, including issuing a report in January 2025 analyzing the influence of PBMs on drug pricing, and filing a lawsuit against three PBMs and their affiliated group purchasing organizations, alleging efforts to inflate the price of insulin drugs.

U.S. Food and Drug Administration (FDA) Orange Book: The FTC has renewed its offensive against drug-device patents listed in the FDA's Orange Book. Scrutiny of improper Orange Book patent listings has been ramping up since 2023, when the FTC issued a policy statement warning that branded pharmaceutical companies could face legal action for unfair methods of competition or illegal monopolization if they improperly list patents in the Orange Book. In 2023 and 2024, the FTC challenged hundreds of patents, primarily focusing on drug-device products such as inhalers and epinephrine injectors. Recently, the FTC issued a third round of warning letters targeting manufacturers that had not delisted previously challenged patents and warning improperly listing patents in the Orange Book may harm competition and delay generic entry into the marketplace. Private plaintiffs have likewise challenged certain device patent listings, culminating in the Federal Circuit earlier this year upholding an injunction

We are likely to see continued monitoring of and challenges to Orange Book listings in the next year.

compelling a branded manufacturer to remove five inhaler patents from the Orange Book. We are likely to see continued monitoring of and challenges to Orange Book listings in the next year.

Labor Matters: In September 2025, the FTC abandoned its multi-year effort to adopt a regulation broadly prohibiting employee noncompete agreements nationwide. In doing so, however, the FTC made clear it would continue to challenge unfair noncompete agreements on a case-by-case basis, with a particular focus on noncompete agreements in the health care sector. Separately, the DOJ obtained a first-of-its kind jury conviction earlier this year in a criminal "wage-fixing" case under the Sherman Act. This DOJ win, combined with the new Labor Guidelines published by the FTC and DOJ early in 2025, demonstrate that investigations into whether restrictions on labor — including wage-fixing, non-competes, and no-poach agreements — violate the antitrust laws will likely continue into 2026 and beyond.

Private Equity: Federal and state agencies alike continue to investigate private equity's impact on health care competition, accessibility, and quality. In 2024, the DOJ, FTC, and U.S. Health and Human Services (HHS) announced a joint inquiry into private equity's control over health care. As of this writing, the agencies have yet to publish the results of this inquiry. However, earlier this year the FTC published a report regarding the effects of physician practice acquisitions, demonstrating its continued concerns over consolidation in health care. Several state legislatures are considering or have passed legislation imposing reporting requirements and restrictions on private equity consolidation in health care. The contours of future limitations on private equity investment in health care is evolving and will remain a focus of legislators and government enforcers in 2026.

Medicare Advantage at a Crossroads: CMS RADV Audit Overhaul and OIG Risk Adjustment Enforcement Explained

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The Centers for Medicare & Medicaid Services (CMS) recently launched one of its most sweeping enforcement initiatives targeting Medicare Advantage (MA) risk adjustment. On May 21, 2025, CMS announced an aggressive overhaul to its Risk Adjustment Data Validation (RADV) audit program that expands audit scope, compresses timelines, and deploys unprecedented resources. Just months later, the legal foundation underpinning one of CMS's most potent audit tools employed in these audits — statistical extrapolation — was halted. Concurrently, the Department of Health and Human Services Office of Inspector General (OIG) has intensified its scrutiny of provider risk adjustment activities for MA products, signaling a new era of dual enforcement risk for Medicare Advantage Organizations (MAOs) and providers.

RADV Audit Authority: Expansion and Legal Headwinds

Evolution of RADV and the FFS adjuster

In 2016, several MAOs sued CMS over the 2014 Overpayment Rule, which required MA plans to return payments for diagnosis codes not supported by medical records, without offsetting for similar errors in traditional Medicare fee-for-service (FFS) data.[1] The MAOs argued this violated the statutory requirement for "actuarial equivalence," claiming CMS was holding MA plans to a stricter standard than FFS. By 2018, CMS favored eliminating the adjuster entirely in its updated RADV rule. A federal district court initially sided with the MAOs observing that CMS's audit methodology failed to ensure "actuarial equivalence" because it excluded an FFS adjuster. But in 2021 the D.C. Circuit reversed, ruling that "actuarial equivalence" applies to rate-setting, not audits. The Supreme Court declined to review the case in 2022. This outcome provided CMS with a clear path to expand RADV audits and extrapolated recoveries under its 2023 RADV Final Rule[2], setting the stage for more aggressive enforcement and significant policy changes.

CMS's May 2025 Announcement: New Audit Paradigm

Against this legal backdrop and with the support of a new administration, CMS unveiled a bold reimagining of its MAO audit approach in May 2025.[3] Historically, RADV audits were limited in scope, affecting only a fraction of the market and focusing on a narrow set of patient encounters, without extrapolation to the entire MA contract.

The new strategy is transformative: CMS now plans to audit *all* eligible MA contracts annually, expanding oversight from roughly 60 to 550 contracts each year; and expand its audit workforce from approximately 40 coders to nearly 2,000. No MAO can expect to avoid scrutiny; annual medical record pulls tied to risk score validation are the new norm. Given this projected increase in contracts and coders, MAOs should anticipate corresponding increase in scrutiny and audits.

CMS also aims to clear its backlog of RADV audits for payment years 2018 through 2024 by early 2026, compressing years of potential liabilities into a short window and creating significant operational and financial exposure for MAOs. Notably, CMS intended to employ statistical extrapolation — expanding audit findings from a small sample to the entire MA contract — without using

1 *See* UnitedHealthcare Insurance Co. v. Azar, 330 F. Supp. 3d 173 (D.D.C. 2018), vacated in part, rev'd sub nom. UnitedHealthcare Ins. Co. v. Becerra, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, No. 21-1140 (U.S. June 21, 2022).

2 88 FR 6643 (February 1, 2023).

3 https://www.cms.gov/newsroom/press-releases/cms-rolls-out-aggressive-strategy-enhance-and-accelerate-medicare-advantage-audits

an FFS adjuster. Yet, for reasons explained below, there might be significant roadblocks to the use of statistical extrapolation. The Medicare Payment Advisory Commission estimates that annual recoupments from this backlog could reach $43 billion.[4]

This approach prioritizes detection of overpayment vulnerabilities and signals CMS's intent to pursue aggressive recovery where documentation does not support submitted diagnoses.

Legal Setback but the Audit Goes On

The legal landscape shifted in September 2025, when the United States District Court for the Northern District of Texas vacated CMS's 2023 RADV Final Rule[5] in response to a challenge by Humana. The court found that CMS failed to provide adequate opportunity for public comment on the legal rationale ultimately adopted, rendering the final policy not a "logical outgrowth" of the proposed rule under the Administrative Procedure Act.[6] Importantly, the court did not address whether extrapolation is substantively permissible — a question that may resurface. For now, CMS's authority to extrapolate RADV findings for 2018 and later payment years is uncertain.

Despite this setback, RADV audits continue. CMS retains the ability to review records and recover sample-level overpayments, but without contract-wide extrapolation, recoveries per audit will be significantly reduced. This development may influence CMS's plans to expand its audit workforce and underscores the agency's commitment to clearing the audit backlog while seeking avenues to restore extrapolation authority.

Dual Risk Exposure: OIG's Heightened Enforcement

Risk adjustment remains a central focus for both CMS and OIG. OIG has repeatedly identified risk adjustment as a high-risk area for improper payments, citing billions in potential overpayments tied to unsupported diagnoses. The agency's 2024 and 2025 Work Plans[7] include

multiple audits targeting risk adjustment data integrity, with recent findings highlighting systemic vulnerabilities such as inadequate documentation and weak internal controls at both MAOs and downstream providers.[8] These findings underscore OIG's commitment to heightened enforcement. MAOs and providers should expect continued and deeper probes into coding accuracy and be prepared for corrective action plans or civil monetary penalties if deficiencies are found.

At the 2025 Medicare Advantage Member Accounting and Reconciliation Summit, Ann Maxwell, Deputy Inspector General for Evaluation and Inspections at OIG, highlighted the agency's ongoing focus on Medicare Advantage reimbursement levels and compliance risks. Maxwell noted that OIG is particularly concerned with miscoded diagnosis codes, viewing them as a significant compliance issue. The agency is intensifying its review of high-risk codes and increasing audits to ensure that medical record documentation substantiates submitted diagnoses.

To mitigate these risks, Maxwell advised MAOs to strengthen compliance programs, conduct regular

4 https://www.cms.gov/newsroom/press-releases/cms-rolls-out-aggressive-strategy-enhance-and-accelerate-medicare-advantage-audits.

5 Humana Inc. and Humana Benefit Plan of Texas, Inc. v. Becerra, No. 4:23-cv-009 (N.D. Tex. Sept. 25, 2025).

6 Id.

7 *See e.g.*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000892.asp https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000940.asp https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000922.asp

8 *See e.g.*, https://oig.hhs.gov/documents/audit/10329/A-02-22-01020.pdf

self-audits for data accuracy, support coordinated care following in-home Health Risk Assessments, and engage proactively with OIG. These prophylactic compliance measures are not only best practices, but they are practical tools to minimize risk and provide robust defenses in the event of government audits or scrutiny. OIG's heightened scrutiny reinforces the need for MAOs and providers to maintain robust compliance measures and rigorous oversight, especially in areas where coding practices may result in inflated risk scores.

Strategic Takeaways for MAOs and Providers

MAOs and providers now face dual compliance challenges: the broad application of CMS RADV audits and intensified OIG enforcement, each with distinct risks:

CMS RADV Audit Risks:

- Annual audits for all MAOs, accelerated review of prior years, and increased audit resources mean more frequent and comprehensive scrutiny. The risk of significant premium recoupments and operational disruption is heightened as CMS refines its audit methods. Robust documentation and proactive audit readiness are essential.
- While risk adjustment is the current focus, CMS may expand audits to other areas, such as network adequacy and marketing.
- Providers should strengthen compliance and negotiate payor contracts to address retrospective premium adjustments.

OIG Enforcement Risks:

- OIG targets data integrity, coding accuracy, and systemic vulnerabilities. Enforcement actions may include corrective action plans or civil monetary penalties, especially where inflated risk scores or weak controls are found.
- Both MAOs and providers should expect deeper probes and ongoing oversight.
- As such, MAOs and providers would be well-served by doing prophylactic internal audits prior to government audits. Doing such internal proactive audits helps identify risks and provides opportunities for improvement and remediation prior to governmental investigations.

In this evolving regulatory environment, strong compliance programs, documentation rigor, and operational vigilance are critical to navigating audit and enforcement risks. Proactive internal audits and ongoing monitoring of CMS and OIG guidance, such as OIG Work Plans, are essential to reducing exposure and staying aligned with regulatory priorities.

OIG has repeatedly identified risk adjustment as a high-risk area for improper payments, citing billions in potential overpayments tied to unsupported diagnoses.

Health Care Patent Practice: Changes at the USPTO for 2026

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Key Takeaways:

In 2026, the U.S. Patent and Trademark Office (USPTO) is expected to push changes aimed at expanding patent eligibility and strengthen granted patents, potentially increasing patent value in the health care, life sciences, and medical device industry. In particular, the USPTO is likely to build on initial actions taken by new USPTO Director John Squires, who was confirmed in fall 2025. Eary signs point toward efforts to expand patent eligibility and limit challenges to patents.

Patent Eligibility (§ 101)

Director Squires endorsed an expansive view of patent eligibility under 35 U.S.C. § 101. Among his first acts as director were to issue a patent relating to medical diagnostics[1] and to join a panel of Patent Trial and Appeal Board (PTAB) judges to reverse a § 101 rejection for claims relating to machine learning technology[2] (a decision which has since been used by the USPTO to announce updates to the Manual of Patent Examining Procedure (MPEP)[3]. He described patent-eligibility as important for America's competitive advantage:

> "Narrow eligibility means jobs lost, industries offshored, and adversaries empowered. Expansive eligibility means jobs created, industries built, and America secured. If the United States narrows its view of what is patent-eligible, it will invite competitors to seize the initiative."[4]

The rhetoric bodes well for patent eligibility for inventions in medical diagnostics, software-enabled medical devices, artificial intelligence (AI), other health care software, and other medical technologies which may face patent eligibility challenges. The degree to which the Director's expansive view of patent eligibility will influence examination of individual patent applications remains to be seen and will be a topic of focus for patent practitioners in 2026.

Inter Partes Review (IPR)

The first proposed rulemaking issued under Director Squires proposes to modify rules for discretionary denials of Intellectual Property Rights (IRP) proceedings, in a manner "intended to promote fairness, efficiency, and predictability in patent disputes."[5] The proposed rule would provide limits on challenging patent validity at the USPTO through use of IPRs, including by (1) requiring an IPR petitioner to stipulate to not pursue invalidity challenges for obviousness or lack of novelty in other forums; and (2) providing that the USPTO will not institute an IPR when the USPTO or another forum already has adjudicated patentability or validity of the claims (the "One and Done" rule or the "One Challenge" rule). [6]

Over 10,000 comments were received during the public comment period.[7] As we move into 2026, patent practitioners will be watching for a final rule and assessing its effects on strategies for enforcing or challenging patents.

1 https://www.uspto.gov/about-us/news-updates/patent-signing-ceremony

2 https://www.uspto.gov/sites/default/files/documents/202400567-arp-rehearing-decision-20250926.pdf

3 https://www.uspto.gov/sites/default/files/documents/memo-desjardins.pdf

4 https://www.uspto.gov/about-us/news-updates/statement-director-squires-united-states-senate-subcommittee-intellectual

5 https://public-inspection.federalregister.gov/2025-19580.pdf?utm_campaign=subscriptioncenter&utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=

6 Id.; See https://www.foley.com/p/102lqj8/uspto-issues-proposed-rulemaking-on-discretionary-denials-of-ipr-proceedings/.

7 https://www.regulations.gov/document/PTO-P-2025-0025-0001

Director Squires also announced the he reclaimed the Director's direct role in determining whether to institute IPRs on the merits, i.e., with respect to whether the filings show "a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition."[8] After the announcement, the first notices from Director Squires denied institution of all listed IPRs[9], but more recently some IPRs have been instituted, including in the health care space.[10] Any trends with respect to IPR institution will come into focus as the sample size increases in 2026.

Continuation Practice

Serial filing of continuation patent applications to keep options open and adjust claim scope as markets develop has long been a valuable tool in U.S. patent practice for Medtech companies, given regulatory delays and long development timelines. 2026 could bring changes in headwinds for continuation practice which started in 2025 with: (1) a new USPTO surcharge for continuation applications introduced in 2025 that more than tripled the initial USPTO filing fees for some continuations;[11] (2) recent case law on *prosecution laches* which has left open the possibility that a patent could be unenforceable on the basis that it took too long to obtain, if such a delay was prejudicial;[12] and (3) signals that the USPTO is deprioritizing examination of continuation applications and shifting examiner time to new applications.[13] However, the USPTO's preference for new applications over continuation applications is not likely to dissuade companies from pursuing a robust continuation practice.

Pilot Programs & Other Changes

New pilot programs and changes to examination workflow may also influence patent practice in 2026. Under the "Automated Search Pilot Program," an applicant can request that the USPTO use an AI search tool to automatically provide a list of prior art references, which the applicant could then asses to adjust tactics prior to examination by a human Examiner.[14] Under the "Streamlined Claim Set Pilot Program," a new patent application (i.e., not a continuing application) can be set for expedited prosecution at an applicant's request if filed with a single independent claim and fewer than 10 total claims.[15] The USPTO has also introduced changes to the way Examiners' time is allocated which may influence application backlog, interview practice, and other nuances of patent prosecution strategy.[16]

8 https://www.uspto.gov/sites/default/files/documents/open-letter-and-memo_20251017.pdf

9 https://patentlyo.com/patent/2025/11/usptos-institution-rate.html

10 https://data.uspto.gov/ptab/trials/decisions

11 https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule; https://www.federalregister.gov/documents/2024/11/20/2024-26821/setting-and-adjusting-patent-fees-during-fiscal-year-2025

12 https://www.foley.com/insights/publications/2025/03/delaying-examination-continuing-applications-sabotage-uspto-goals/

13 See https://www.cafc.uscourts.gov/opinions-orders/18-2390.OPINION.8-29-2025_2565719.pdf; https://www.cafc.uscourts.gov/opinions-orders/24-1097.OPINION.8-28-2025_2565220.pdf;

14 https://www.federalregister.gov/documents/2025/10/08/2025-19493/automated-search-pilot-program

15 https://www.federalregister.gov/documents/2025/10/27/2025-19669/streamlined-claim-set-pilot-program

16 https://www.uspto.gov/sites/default/files/documents/USPTO-Hour-External-FY26-Examiner-PAP-Changes.pdf

Telehealth Longevity Clinics and the Legal Environment in 2026

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The rise of telehealth-based longevity clinics is among the most alluring of recent direct-to-consumer health entrepreneurial expansions. These clinics, often focused on hormone optimization and age management, offer patients access to therapies such as testosterone replacement, estrogen modulation, and peptide treatments. While the demand is clear, the regulatory landscape for 2026 warrants attention, particularly around the prescribing of controlled substances and peptides.

Testosterone is classified as a Schedule III controlled substance under federal law, rendering it subject to heightened federal and state requirements. For telehealth longevity clinics, this means complying with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Act), which requires the prescribing clinician to conduct at least one in-person medical evaluation of the patient before prescribing testosterone. The intent of the Act was to curb rogue online pharmacies, but the unintended consequence has been burdensome restrictions on legitimate telemedicine practices.

Since 2020, the Act's in-person exam requirement has been waived under a series of temporary flexibilities issued by the Drug Enforcement Administration (DEA). Those flexibilities are slated to expire at the end of 2025. As a good sign for telehealth, the DEA signaled its intent to extend the flexibilities again through the end of 2026, giving time to finalize a long-awaited "special telemedicine registration" rule. Such a rule would allow clinicians to prescribe certain controlled substances (including testosterone) via telemedicine without an in-person exam, provided the clinician meets specific requirements. The rule is expected to include a tiered registration system, distinguishing between telemedicine prescribing of Schedule II substances (e.g., opioids and stimulant medications) and other Scheduled substances. As a Schedule III controlled substance, testosterone has a lower risk of abuse and diversion, and therefore, is not subject to the same restrictions of Schedule II drugs.

However, the path to finalizing this rule has not been smooth. The 2025 federal government shutdown furloughed key staff at the Office of Management and Budget (OMB), the agency responsible for publishing new regulations. Until OMB lawyers returned to work, the DEA was unable to release the extension or finalize the special registration rule.

Fortunately, industry stakeholders, including the American Telemedicine Association (ATA) and ATA Action, have voiced strong support for the DEA's efforts to create a permanent telemedicine pathway. Congress too has weighed in its support. The SUPPORT Act of 2018 mandated the DEA issue the special registration rule by October 2019. Many years later, a final rule remains unpublished, but the industry is still hopeful.

For CEOs and founders of telehealth longevity clinics, the message is clear: regulatory compliance is not optional, and proactive engagement with policymakers is essential. Companies should prepare for multiple scenarios, including:

- **A final special telemedicine registration rule (or another proposed special registration rule) in 2026**, under which such rule would require changes in workflows, documentation, and DEA registration protocols.
- **Another extension of flexibilities through the end of 2027**, allowing telemedicine prescribing to continue as currently practiced.
- **An eventual lapse in flexibilities at the end of 2026**, a worst-case scenario that reinstates the in-person exam requirement. This seems highly unlikely to occur due

to the support from DEA, Congress, and industry leaders who have said they will not allow patients to fall off the "telehealth cliff." But said lapse would disrupt care delivery for those clinics who have not prepared and built out compliant models in anticipation.

Another novel entrant to telehealth longevity clinics is peptides. While peptides are not classified as controlled substances, their regulatory status and direct-to-consumer sales activities are not fully established. Peptides are chains of amino acids that can influence a range of physiological functions, from growth hormone stimulation to tissue repair. The U.S. Food and Drug Administration (FDA) does not treat all peptides equally: some are approved drugs, others are labeled "investigational," and many are considered unapproved substances. This ambiguity has led some websites to market peptides as "research chemicals," a tactic designed to circumvent FDA oversight by selling the products as not meant for human consumption. Such an approach poses serious safety risks. Products sold as research chemicals are often manufactured overseas, lack quality assurance, and may contain unknown or harmful ingredients. For telehealth longevity clinics, promoting or facilitating access to research chemicals — even indirectly — can trigger enforcement actions from state and federal government bodies as well as lawsuits from injured patients.

A more moderate approach taken by some telehealth longevity clinics is to have physicians prescribe peptides for clinical use in connection with a valid doctor-patient relationship. The prescription is then fulfilled by a U.S.-based compounding pharmacy. Compounded peptides are not FDA-approved, and telehealth clinics should take steps to ensure their compounding pharmacy partners are registered, follow USP Standards, and do not compound drugs that are "essentially copies" of commercially available products. Because advertising peptide therapies as anti-aging or performance-enhancing can attract scrutiny from the FDA or the Federal Trade Commission, longevity clinics should ensure their marketing practices and clinical protocols align with regulatory expectations.

The proliferation of telehealth longevity clinics reflects a broader shift in how Americans approach aging and wellness, moving from an extended lifespan to extended "healthspan." While innovation brings opportunity, it also brings responsibility. Successful entrepreneurs will be those who not only garner financial success, but do so by creating a clinically safe and legally sustainable business model in longevity medicine.

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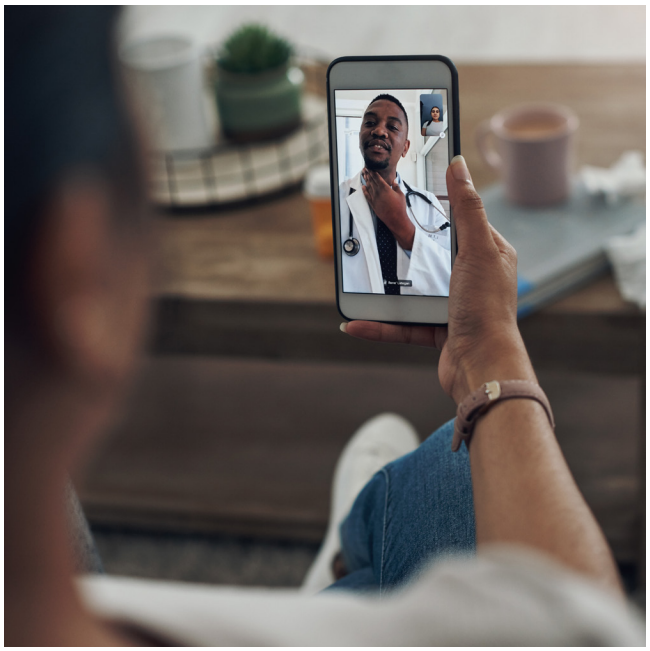

Shifting Trends in the Oncology Space

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In 2025, there were over two million new cancer cases in the United States.[1] Scientific advances are supporting enhanced early diagnosis and allowing cancer patients and survivors to live longer. Shifting demographics as well as economic, business, and regulatory pressures are forcing change in the industry in ways that will influence the experience of providers and patients alike in years to come.

Amidst general economic uncertainty in health care, oncology is facing some particularly difficult-to-navigate industry challenges in 2026, including:

- **Expansion of site neutrality.** Centers for Medicare & Medicaid Services (CMS) has continued to expand the reach of site neutrality, this year, applying a site neutral approach to reimbursement of drug administration services for certain hospital outpatient provider-based departments (OPDs). As a result, hospitals will not systematically receive higher facility payments for the same clinical service as physician offices and freestanding infusion centers.[2]
- **Increasing changes to the 340B program.** The 340B program, a critical resource for safety-net providers caring for indigent and other vulnerable patient populations, also continues to be impacted by judicial, agency, and industry actions. Congress opted to not address the controversial program through the One Big Beautiful Bill Act. In January, the Health Resources & Services Administration (HRSA), which administers the 340B program, introduced a pilot model rebate approach to 340B for certain drug manufacturers, the implementation of which has been delayed by the courts.3 Any such potential changes in reimbursement methodology, alongside other recent restrictions on pharmacy replenishment and participation, will pose a significant challenge to hospital-based oncology reimbursement and cash flow.
- **Projected physician shortages.** Demand for cancer care is growing and patients are living longer; however, the number of oncologists needed to meet that demand is not keeping pace. According to one recent study, the hematology and medical oncology workforce has been declining, with gaps in coverage especially acute among rural populations and those with high cancer burden and socioeconomic risk.[4] Physician burnout is one often cited as a contributing factor, with oncologists reporting burnout second only to emergency medicine.[5]
- **Workforce and staffing pressures.** Competition for non-physician clinical expertise has hit health care hard, and oncology practices, hospitals, and health systems are particularly challenged as they compete for talent. New market entrants in precision medicine, digital health, and big pharma are hiring critical talent such as nurses and patient navigators, driving up pay scales and squeezing smaller practices.

1 https://pmc.ncbi.nlm.nih.gov/articles/PMC11745215/

2 Calendar Year (CY) 2026 Medicare Physician Fee Schedule Final Rule (CMS-1832-F)

3 https://www.hrsa.gov/opa/340b-model-pilot-program

4 Kirkwood MK, Balogh EP, Accordino MK, et al. Where have we been and where are we going? the state of the hematology and medical oncologist workforce in America. *JCO Oncol Pract*. Published online October 7, 2025. doi:10.1200/OP-25-00144 https://www.cancernetwork.com/view/career-stage-and-location-found-to-impact-oncology-coverage-in-the-us.

5 https://www.advisory.com/daily-briefing/2024/01/31/physician-burnout (In this 2024 study, oncologists reported burnout rates of 53%, second only to emergency medicine.)

Amidst general economic uncertainty in health care, oncology is facing some particularly difficult-to-navigate industry challenges in 2026.

These headwinds are driving change in the cancer care landscape, and will ultimately require multi-faceted solutions including policy changes, technology adoption, and enhanced practice support. In the meantime, a number of strategic options are available. Health systems are looking to adopt new technologies and expand capacity, with more than $2 billion estimated to be spent by U.S. health systems on infrastructure projects in the next six years.[6] Private equity (PE) has also emerged as a powerful alternative to hospital employment,[7] with the promise of strategic exit opportunities to big pharma and others.

6 https://www.beckershospitalreview.com/oncology/6-significant-cancer-hospitals-on-the-horizon/

7 https://pubmed.ncbi.nlm.nih.gov/37126329/ The American Medical Association estimated that from 2003 to 2022, 10% of the estimated 6,919 oncology clinic locations across 45 states became affiliated with PE-backed companies.

Partnering in oncology raises numerous legal challenges, but properly structured can offer opportunities to help a practice survive and scale into new service delivery models, fast-track technology, and grow research networks. Although there are various PE platform models, the corporate practice of medicine – a legal doctrine limiting for-profit investors from influencing clinical judgment – can offer oncologists some assurance of clinical autonomy. The transaction and platform structure are also heavily influenced by federal and state fraud and abuse laws, including the Stark Law and Anti-Kickback Statute. At a threshold level, these laws will influence ownership models, purchase price, and management fee structures (they restrict, for example, the use of Earnings Before Interest, Taxes, Depreciation, and Amortization (EBITDA)-based earn-outs that are typically favored by PE), rollover terms, and compensation methodologies.

States are increasingly evaluating, and in some cases limiting, the use of physician non-competes, and implementing state filing requirements and waiting periods for transactions in the wake of recent high-profile PE-backed bankruptcies in health care.[8] An informed transaction process using counsel experienced in oncology can help navigate these issues successfully and position the affiliation for success.

Safety Net Providers Brace for Federal Medicaid Cuts

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Key Takeaways:

The number of Medicaid beneficiaries is expected to decrease materially in 2026 and beyond, and there will be a related increase in the number of patients who do not have health insurance.

Health care providers, managed care plans, and other organizations that work with Medicaid and uninsured populations should work with their community partners, trade associations, and states to develop strategies for mitigating the impact of federal Funding cuts.

In 2026, health care providers, managed care plans, states, and other entities that serve Medicaid and safety net populations will grapple with the reality of pending reductions in Federal support for the Medicaid program. The 2025 health care legislation (referred to as H.R. 1 or the One Big Beautiful Bill Act) reduced federal Medicaid spending by an estimated $911 billion over a 10-year period, with many of the reductions slated to take effect in 2027 or 2028. While these changes are pending, the impact on the budgets of each state and territory will need to be addressed in 2026. In addition, a number of other actions taken by the Trump administration — including rolling out drastic changes to permit review of health care benefits as part of public charge determinations for immigrants applying for a change of status, including a green card, or proposals to share Medicaid enrollment and utilization data with the Department of Homeland Security — are also reducing Medicaid enrollment for both eligible immigrants and citizens in mixed-status families.

Eligibility Restrictions

Changes made by H.R. 1 will exclude certain categories of lawfully present immigrants — including asylees, refugees, and victims of human trafficking — from federal health care programs, including Medicare and Medicaid. In addition, new work requirements and more frequent redeterminations of eligibility will be applied to Medicaid enrollees who are enrolled as part of the Affordable Care Act's Medicaid expansion. The work requirements are projected to reduce Medicaid enrollment by 5.3 million and reduce federal spending by $326 billion over 10 years.

Restrictions on eligibility will increase the number of patients who are no longer eligible for Medicaid or who choose not to enroll, creating an increase in uninsured patients. This increase will coincide with the planned expiration of the Affordable Care Act's enhanced subsidies, which is placing upward pressure on insurance premiums and is also expected to reduce rates of insurance coverage.

Medicaid Reimbursement Restrictions

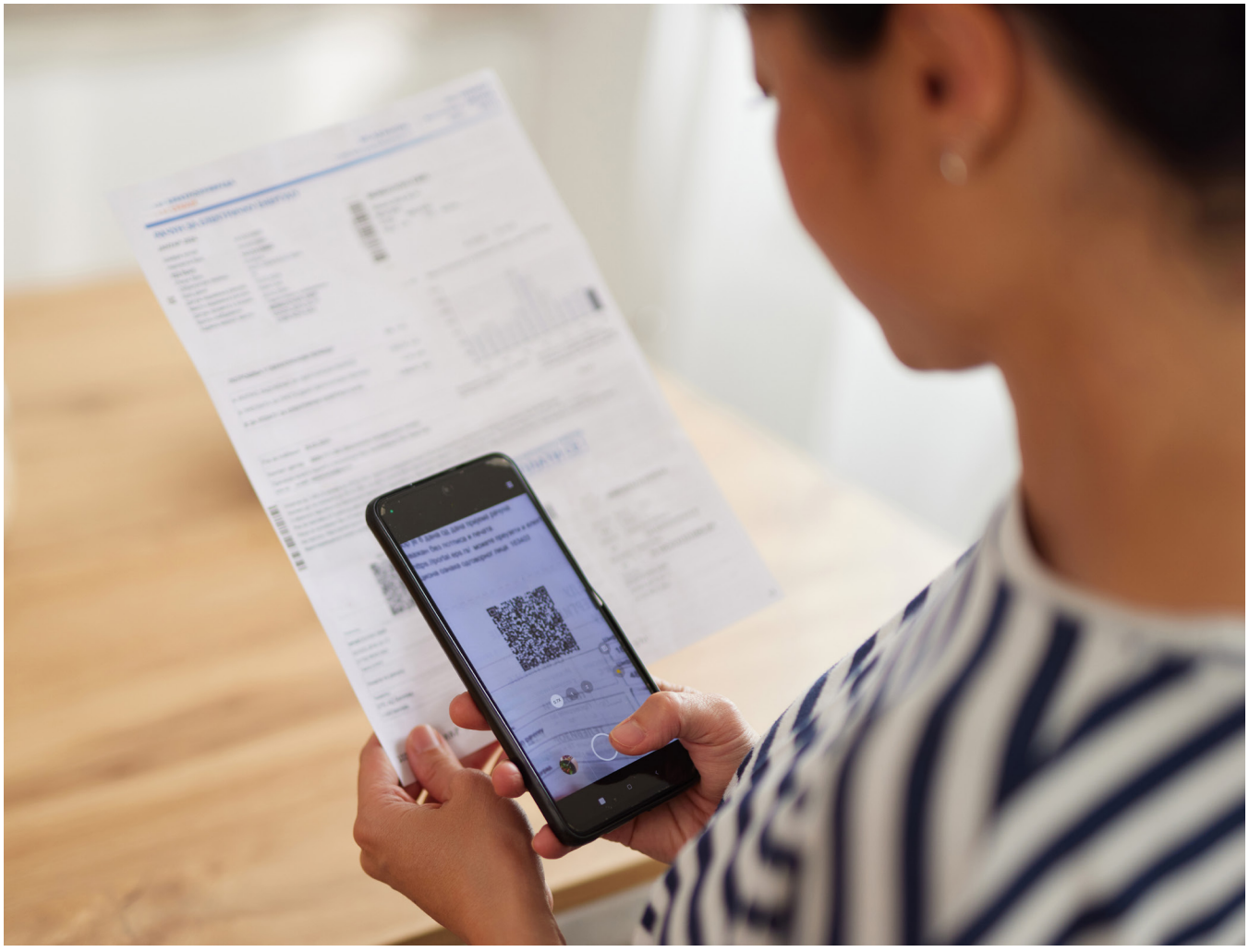
H.R. 1 also initiated major changes to Medicaid financing and supplemental payments, which are critical for maintaining state Medicaid expenditures and sustaining safety net providers. According to Centers for Medicare & Medicaid Services guidance, states may need to make changes to any taxes they impose on Medicaid managed care plans to generate revenue to support their Medicaid programs before the end of the state fiscal year that ends in calendar year 2026. Taxes imposed on other classes of health care organizations, such as hospitals and nursing facilities, will need to be modified by the end of the state fiscal year beginning in calendar year 2028. While these changes are phased in, states and affected health care organizations will need to plan to structure replacement or modified taxes to avoid steep Medicaid funding cliffs.

H.R. 1 also requires State Medicaid programs to reduce their reliance on Medicaid directed payments. Under H.R. 1, the total amount that a provider may receive if there is a Medicaid directed payment for certain classes of service — hospital, nursing facility, and professional

services in an academic medical center — will be capped at the Medicare payment rate, which typically falls well short of provider costs. In some states, the cap is 110% of the Medicare payment rate. Directed payments that were in effect at the time H.R. 1 was enacted are grandfathered, helping to avoid immediate payment reductions; however, over time the grandfathered payments must phase down until the total payment rate does not exceed the applicable Medicare rate.

Safety net providers, as well as states and managed care plans that rely on them, will need to plan prospectively in 2026 for the new Medicaid environment to avoid funding cliffs and potential lack of access for Medicaid patients. The limitations also create a tightened playing field, in which the options states have tended to rely on to address Medicaid access and funding issues will now be severely restricted.

Safety net providers, as well as states and managed care plans that rely on them, will need to plan prospectively in 2026 for the new Medicaid environment to avoid funding cliffs and potential lack of access for Medicaid patients.



Digital Health and Telehealth in 2026 and Beyond: Building the AI and Privacy Advantage

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Digital health and telehealth are entering a more optimistic and durable phase. The market is shifting from experimentation to enterprise adoption. Artificial Intelligence (AI) is becoming embedded in clinical workflows and patient engagement. Data is powering personalization, outcomes measurement, and operational efficiency. That momentum is real, as is the expectation that these platforms will be built on trust, accountability, and modern privacy engineering.

The federal and state governments are moving in opposite directions on AI regulation. In December 2025, the Department of Health and Human Services (HHS) issued a formal Request for Information (RFI) on "Accelerating the Adoption and Use of Artificial Intelligence as part of Clinical Care." The RFI asks the market how HHS can use regulation, reimbursement, and research levers to increase AI adoption while protecting patients, privacy, and civil rights. This indicates that federal policy is seeking to reduce uncertainty and create an environment where responsible AI scales faster.

State privacy law is moving toward more laws, more definitions, more enforcement pathways, and more operational friction.

At the same time, state privacy law is moving toward more laws, more definitions, more enforcement pathways, and more operational friction. That is the struggle in 2026. Federal activity is pushing toward adoption at scale. State privacy is forcing precision and restraint in data practices. The winners will be the organizations that treat AI governance and privacy architecture as core technology capabilities, not legal cleanup.

Trend 1: AI governance becomes the fastest path to adoption

The era of "AI as a feature" is ending. In 2026, AI is increasingly the system of decision support, navigation, and automation across telehealth, remote monitoring, care coordination, and utilization workflows. That is why HHS is focusing directly on how AI should be regulated, reimbursed, and supported.

In practical terms, the companies that will grow the fastest are the ones that can answer enterprise questions such as the following without hesitation:

- What does the model do, exactly, and what does it not do?
- What data trained it, and do you have defensible rights to use that data for that purpose?
- How do you monitor drift, bias, and safety issues post-deployment?

What is the human oversight and escalation path when AI influences care or clinical communications?

Action steps to implement now

1. **Create an enterprise AI inventory** that lists every model and model-enabled feature, including third-party tools. Capture purpose, data sources, validation approach, monitoring plan, and human review. Treat this as a living system.
2. **Set a tiered governance model.** If AI touches diagnosis, treatment recommendations, triage, or patient clinical communications, require heightened oversight, documentation, and change control.
3. **Contract for your AI position.** Vendor agreements should restrict secondary use of your data, address derivative learnings, and clarify ownership of fine-tuned artifacts, prompts, and outputs.

Trend 2: State AI health care laws start shaping product design

Several states are now regulating the use of AI in health care experiences, especially where AI can be confused for a licensed professional or where AI influences clinical decisions. For example:

- California is a bellwether, passing multiple laws addressing the use of AI in health care in the past few years. Assembly Bill (AB) 3030 requires disclosures when generative AI is used to communicate patient clinical information, subject to exceptions when a licensed provider reviews the communication. AB 489 targets AI systems that could misrepresent themselves as licensed health care professionals, including in advertising or functionality. Senate Bill (SB) 1120 addresses AI use in utilization review and management functions in health coverage, emphasizing physician autonomy and auditability.
- Colorado adds a broader risk-based structure through SB24-205, which imposes duties for high-risk AI systems and obligations tied to foreseeable risks of algorithmic discrimination. The compliance date for the Colorado law is June 30, 2026.
- Illinois House Bill (HB) 1806 prohibits licensed mental health professionals from using AI to make independent therapeutic decisions, directly interact with clients in any form of therapeutic communication, generate therapeutic recommendations or treatment plans without review and approval by the licensed professional, or detect emotions or mental states. It also requires patient consent to use AI for supplementary support.
- Texas is also pushing disclosure and oversight. SB 1188 requires health care practitioners using AI for diagnostic purposes to disclose that use and review AI-generated records consistent with medical record standards.

What to do in 2026

- Assume disclosure becomes the default when AI interacts with patients in clinically meaningful contexts. Build disclosure and user education into the product experience, not into the footer.
- Separate “AI communication” from “licensed provider communication.” If AI drafts, have workflows that document review and approval by appropriate clinicians where required.
- Align marketing claims with functionality. Many new rules are fundamentally anti-deception rules for health care AI. Your product, user interface materials, and sales decks must match reality.

Trend 3: State privacy laws create a compliance mosaic that rewards strong data engineering

State privacy is no longer "just a policy." It is an engineering requirement. Washington's My Health My Data Act and Nevada's SB 370 specifically regulating consumer health data both took effect in 2024. Connecticut's consumer data privacy law has specific requirements for consumer health data and many other state consumer data privacy laws regulate health data in some form as "sensitive" data.

The operational challenge is that "health data" can be defined broadly under these state laws. This is where digital health and telehealth companies feel the strain: marketing analytics, user engagement telemetry, and AI training pipelines can implicate "consumer health data" even when HIPAA does not apply.

Action steps that reduce friction and increase optionality

1. **Map your data flows like a product roadmap, not a compliance checklist.** Start at collection, trace through analytics, AI training, vendors, and disclosures. If you cannot map it, you cannot defend it.
2. **Implement a scalable process.** The point is not perfection in every state on day one. The point is having a platform capability that can adapt as new requirements emerge.
3. **Engineer data minimization for AI training and analytics.** Use purpose limitation and role-based access by default. Build audit logs that can prove what data was used, when, and why.
4. **Treat vendors as part of your privacy posture.** Update service agreements and data processing agreements to reflect consumer health data rules, restrictions on downstream use, security controls, and cooperation obligations for consumer requests.

The optimistic take

The regulatory and privacy environment is not a reason to slow down. It is a roadmap for building the kind of digital health and telehealth platforms that scale with confidence. HHS is explicitly asking how to accelerate AI adoption in clinical care. States are demanding transparency and stronger data discipline. The organizations that embrace both will move faster through enterprise contracting, reduce diligence drag in financings and merger and acquisitions (M&A), and earn durable user trust.

If you want your AI and data strategy to be a growth advantage, the playbook is consistent: build governance into the product lifecycle, architect privacy into the stack, and contract like your valuation depends on it, because it increasingly does.

The regulatory and privacy environment is not a reason to slow down.

Compounded GLP-1s: Current Status

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Uncertainty persists regarding compounded GLP-1 products and a quick internet search shows that compounded GLP-1 products remain readily available. Below is a review of key facts and considerations of these products.

Drug Shortage for Semaglutide and Tirzepatide Has Ended: In spring 2025, the U.S. Food and Drug Administration (FDA) clarified the status of compounding GLP-1 products (i.e., semaglutide/tirzepatide) after confirming that they were no longer in shortage. As a result, the FDA's enforcement discretion for state-licensed pharmacies and physicians compounding, dispensing, or distributing GLP-1 injection products under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as well as for outsourcing facilities under section 503B, has concluded.

FDA Warning Letters: In September 2025, the FDA issued Warning Letters to companies stating that their compounded, advertised, and dispensed products were unapproved new drugs and misbranded. The letters also noted that some advertisements were false and misleading, implying that compounded drugs were equivalent to FDA-approved products. While these Warning Letters demand serious attention and a response within 15 business days, the FDA has not initiated enforcement action, allowing GLP-1s to remain available from many compounding pharmacies and telehealth companies.

Important Factors Regarding Continued Compounding of GLP-1s: For compounding GLP-1 products not on the FDA's drug shortage list, key considerations include whether the product is essentially a copy of a commercially available one and if it provides significant clinical benefits to patients.

Under Section 503A of the FD&C Act, a product that has been discontinued or is on the FDA's drug shortage list may be compounded, provided it is not essentially a copy of a commercially available product and all other Section 503A conditions are met. If the compounded product shares the same active pharmaceutical ingredient (API) with similar strengths and can be administered via the same route as the commercially available product, it is likely to be deemed essentially the same.

If the compounded product is not essentially the same as a commercially available one and the change is made for a specific patient, as determined by the prescriber to offer significant benefits, then it may be compounded.

Current Status of GLP-1 Drug Compounding: Compounded GLP-1 products remain widely available online. Telehealth companies and compounding pharmacies continue to prescribe, compound, and dispense GLP-1s, likely concluding that these compounded products are not essentially copies of commercially available ones and provide significant benefits to individual patients.

Compounding continues through microdosing of GLP-1s or by combining ingredients to differentiate the compounded product from the commercially available versions. Microdosing, a popular method, allows for more frequent administration — often daily — rather than a weekly injection. Combinations such as GLP-1 with Vitamin B-12 or mixtures of semaglutide and tirzepatide are also being prepared.

Telehealth companies and compounding pharmacies are modifying dosage and administration methods, as well as combining ingredients, to distinguish compounded GLP-1 products from commercial options.

To date, the FDA has not taken action against compounded GLP-1 drugs. However, the FDA may still enforce violations of other statutory or regulatory requirements, especially concerning product quality, safety, or the categorization of unapproved new drugs.

Medicare Advantage Supplemental Benefits: Recent Developments in SSBCIs and Speculation on the Future of Supplementals

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On June 3, 2025, the Centers for Medicare & Medicaid Services (CMS) narrowed what Medicare Advantage Organizations (MAOs) can offer as Special Supplemental Benefits for the Chronically Ill (SSBCIs).[1] CMS published a non-exhaustive list of services that it views as outside the scope of improving or maintaining health or overall function, drawing clearer boundaries around what qualifies as "program-related benefits" under Medicare Advantage. With virtual reality, wearables, and AI enabled therapies rapidly advancing, MAOs face both opportunity and constraint in fitting these tools within CMS's evolving benefit framework. The following discussion surveys some of the regulatory, clinical, and financial pressures for emerging technologies as program-related benefits.

CMS's Framework for Supplemental Benefits

MAOs can provide certain supplemental benefits to their members, subject to 42 U.S.C. § 1395w-22(a)(3), which authorizes supplemental benefits approved by the Secretary of Health and Human Services (HHS). CMS regulations 42 C.F.R. §§ 422.100 and 422.102 outline the distinctions between basic and supplemental benefits, as well as mandatory versus optional supplemental benefits. Mandatory supplemental benefits are included in the plan and funded through enrollee premiums or cost sharing, while optional benefits are available for purchase at the enrollee's discretion.

MAOs typically fund mandatory supplemental benefits through rebates generated when their bids for Part A and B services fall below local benchmarks. CMS strictly controls how these savings are converted into enrollee benefits and imposes guardrails to prevent supplemental benefits from becoming marketing tools or risk-selection incentives.[2]

CMS imposes three core requirements on supplemental benefits:

1. Benefits must be primarily health-related (diagnosing, treating, or preventing illness; compensating for impairments; or reducing avoidable utilization).
2. MAOs must incur a real, non-zero medical cost.
3. Benefits cannot duplicate coverage under traditional Medicare.

SSBCIs: Expanded Flexibility and New Boundaries

In 2018, effective for plan years 2020 and subsequent, Congress relaxed the requirement that all supplemental benefits be primarily health-related for benefits provided to a certain segment of chronically ill enrollees and introduced the concept of "special supplemental benefit for the chronically ill" via amendment to 42 U.S.C. § 1395w-22, at Subsection (a)(3)(D). Under 42 C.F.R. § 422.102(f)(1)(ii), CMS states that SSBCIs include any benefit reasonably expected to improve or maintain health or overall function — even if not primarily health-related.

CMS defines a chronically ill enrollee as having "one or more comorbid and medically complex chronic conditions that meet all of the following: (1) Is life threatening or significantly limits the overall health or function of the enrollee, (2) Has a high risk of

1 Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Final Rule; 90 FR 15792-01 (April 15, 2025).

2 This is with the exception of SSBCIs, which are a discussed subsequently.

hospitalization or other adverse health outcomes, and (3) Requires intensive care coordination." This targeted expansion enables MAOs to use social and functional benefits to improve outcomes for a high-impact Medicare Advantage population. However, the lack of clear boundaries around what benefits have "a reasonable expectation of improving or maintaining health or overall function" led to both creativity and uncertainty in plan design.

For 2026, CMS tightened SSBCI eligibility by publishing a non-exhaustive list of excluded services, including cosmetic procedures; hospital indemnity insurance; funeral expenses; life insurance; alcohol, tobacco, and cannabis products; broad membership programs; and non-healthy food. See 42 C.F.R. 422.102(f)(1)(iii).[3] [3]These exclusions clarify CMS's interpretation of services that do not meet the standard of improving or maintaining health or overall function for chronically ill enrollees.

Several exclusions stand out as especially interesting:

- Cannabis products are excluded not based on health rationale, but because they remain illegal under federal law.
- Broad membership programs (e.g., Amazon Prime, Costco) are excluded because they are not limited to items or services with a reasonable expectation of improving or maintaining health or function.
- Life insurance and funeral services are excluded as they are provided after the death of the beneficiary and cannot be tied to improving or maintaining health or function.

3 42 C.F.R. 422.102(f)(1)(iii) excluding as follows: "(A) procedures that are solely cosmetic in nature and do not extend upon Traditional Medicare coverage (for example, cosmetic surgery, such as facelifts, or cosmetic treatments for facial lines, atrophy of collagen and fat, and bone loss due to aging); (B) hospital indemnity insurance; (C) funeral planning and expenses; (D) life insurance; (E) alcohol; (F) tobacco; (G) cannabis products; (H) broad membership programs inclusive of multiple unrelated services and discounts; [and] (I) non-healthy food."

MAOs must carefully evaluate the cost effectiveness and competitive value of supplemental offerings, balancing innovation with compliance and sustainability.

Looking Ahead: Opportunities and Constraints

The regulatory landscape for supplemental benefits is defined by two main prongs:

1. Mandatory and Optional Supplemental Benefits

- Must be primarily health-related (diagnose, prevent, or treat illness or injury; compensate for physical impairments; ameliorate functional/psychological impact; or reduce avoidable utilization).
- Must involve a non-zero direct medical cost (MAO must spend real money for care).
- Must not duplicate coverage under traditional Medicare.

2. SSBCIs

- Need not be primarily health-related.
- Must have a reasonable expectation of improving or maintaining health or overall function.
- Must be provided to a chronically ill enrollee (as defined above).
- Must not be excluded by the new list of prohibitions.

Emerging technologies — such as virtual reality therapies, wearables, and AI-driven drug tools — may fit within these regulatory frameworks, offering new opportunities for MAOs to innovate. For example, therapeutic techniques utilizing virtual reality, wearable device integration, and AI-driven prescription management could be positioned as either primarily health-related or as SSBCIs, provided they meet regulatory standards.

However, longevity-focused experimental technologies raise questions about regulatory alignment and economic viability, given CMS exclusions for investigational or unproven treatments. While such technologies might be considered to compensate for physical impairments or reduce avoidable emergency and health care utilization under general supplemental benefits, their inclusion is limited by the overarching exclusionary principles for experimental, investigational, or research-oriented services. For example, if these technologies are proven medically effective, they may become covered by traditional Medicare, thereby excluding them from supplemental benefit categorization. This creates a narrow window for MAOs to identify, justify, and market emerging longevity technologies as supplemental benefits before they are either adopted as covered services or excluded due to lack of proven benefit.

Further, the economic proposition of offering such supplemental benefits could undermine the financial viability of an MAO's overall benefit package, conflicting with CMS's regulatory rationale for program-related benefits. MAOs must carefully evaluate the cost effectiveness and competitive value of supplemental offerings, balancing innovation with compliance and sustainability.

Medical Devices: A Ripe Target for Cybercriminals?

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Key Takeaways:

There is an increasing risk to sponsors for not developing and maintaining robust cybersecurity protections for medical devices.

The interconnectivity of everyday consumer products has been increasing at a rapid pace – from home security systems to smart connected appliances. This trend holds true for many medical devices as well, with wearables such as glucose monitors and remote patient-monitoring telemedicine platforms connecting to and integrating with new and existing medical systems.

At the same time, cyberattacks overall in general have increased. Among the most coveted information to cybercriminals is health care data due to its high monetary and intelligence value. Health care organizations typically possess personally identifiable and protected health information as well as patients' financial information such as credit card and bank account numbers. One estimate suggests that stolen health information may sell for up to 10 times more than non-health information on the dark web, and that the cost to companies to remediate a breach of health care information is nearly three times greater than the cost associated with breaches involving non-health data.[1]

Over the past decade, cyberattacks on medical systems and devices have been severe but relatively infrequent, with ransomware and other software vulnerabilities greatly disrupting patient care. However, the low frequency of serious cyberattacks serves as a reminder to avoid complacency and underscores the ongoing need to prevent vulnerabilities in the systems through which medical devices are connected. Regulated industry and regulators would be well-advised to take seriously the threat of a cyberattack on medical devices in advance of a particularly catastrophic event.

The U.S. Food and Drug Administration (FDA), for its part, has recently reissued its medical device cybersecurity guidance.[2] In it, FDA defines medical device cybersecurity as:

"*the process of preventing unauthorized access, modification, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient.*"[3]

Due to the rapid evolution of technology and the inherent one-upmanship nature between cybersecurity threats and prevention, FDA guidance on considerations relevant to cybersecurity will likely need to be continuously updated to stay current. Indeed, the current guidance was reissued less than two years after its prior version.

The main takeaway for the device industry from FDA's recent guidance is that cybersecurity is a critical component of device safety and the Quality System Regulation, and that in turn, responsible cybersecurity practices are expected to have a positive impact on both safety and effectiveness of the device. Ensuring that all components operating within interconnected systems have appropriate cybersecurity measures in place reduces the likelihood that any single component's vulnerability could compromise the device's overall safety or performance.

1 American Hospital Association Center for Health Innovation, The Importance of Cybersecurity in Protecting Patient Safety.

2 Guidance for Industry and Food and Drug Administration Staff, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (June 2025).

3 Id. at 55.

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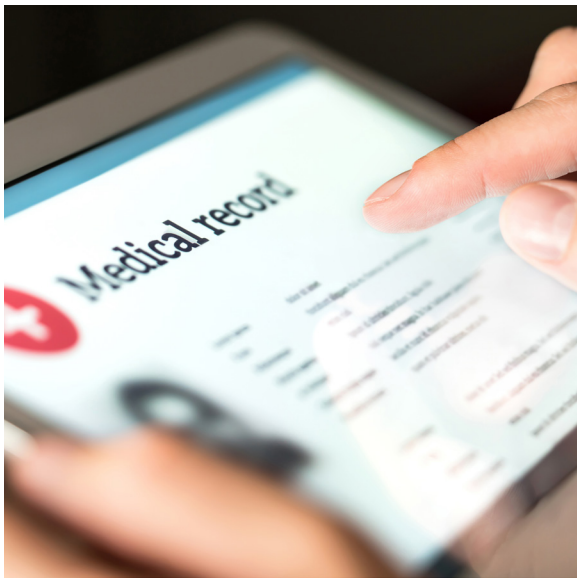

"Risk management for device manufacturers is the essential systematic practice of identifying, analyzing, evaluating, controlling, and monitoring risk throughout the product lifecycle to ensure that the devices they manufacture are safe and effective."[4]

This means that device developers need to consider and implement cybersecurity from the earliest stages of development. Appropriate systems and documented procedures need to ensure that cybersecurity safeguards remain current throughout the entire product lifecycle, regardless of whether the device meets the definition of a "cyber device"[5] or a premarket submission to FDA is required.

The increased risk to device sponsors for cybersecurity compliance is not hypothetical. In July 2025, the Department of Justice entered into a settlement agreement in which Illumina Inc. agreed to pay $9.8 million to resolve allegations of cybersecurity vulnerabilities for their genomic sequencing systems.[6] The claims were raised under the False Claims Act alleging that Illumina was aware of the vulnerabilities but nevertheless sold the systems to federal agencies.

Medical device companies should be aware of the combination of increasing cybersecurity vulnerabilities and heightened regulatory scrutiny to prepare for, and be ready to respond to, a cybersecurity incident. Having a plan in place in advance of a cyberattack or accusation of vulnerability is essential to addressing this emerging area of risk.

4 Id. at 4.

5 In 2022, section 3305 of the Food and Drug Omnibus Reform Act (FDORA) added new cybersecurity requirements for "cyber devices," defined as a device that includes software validated, installed, or authorized by the sponsor as a device or in a device; has the ability to connect to the internet; and contains any such technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats.

6 Press Release, Illumina Inc. to Pay $9.8M to Resolve False Claims Act Allegations Arising from Cybersecurity Vulnerabilities in Genomic Sequencing Systems, July 21, 2025.

Patent Protection in the Age of Artificial Intelligence: An Examination of the Potential Role of AI-Generated Data in Diagnostics and Therapeutics Inventions

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Key Takeaways:

Artificial intelligence (AI)-generated data is increasingly valuable in biomedical innovation. To seek patent protection for new diagnostics and therapeutics, stakeholders should consider leveraging this AI-generated data to augment the strength and robustness of their patents. Although the United States Patent and Trademark Office (USPTO) has yet to comment on this issue, the ever-growing use of AI makes it likely that this issue will be faced sometime in the future. Practitioners in this space should continue to monitor developments.

The advent of AI has ushered in a new wave of research and development in biomedical technology. With the launch of DeepMind's AlphaFold in 2020, protein structures that once required months or years of experimental work and specialized equipment could now be predicted in hours with high accuracy. The emergence of ChatGPT just two years later brought the capability to process voluminous amounts of information to output human-like responses providing valuable and novel insights.

The biomedical industry now continues to seek ways to integrate AI tools in all stages of developing diagnostics (e.g., biomarker assays, imaging methods, or medical devices) and therapeutics (e.g., drugs, biologics, cell and gene therapies, or dosing regimens). The adoption of AI tools arrives at a time when the industry faces mounting pressures: the cost and complexity of developing new diagnostics and therapeutics continue to rise, while the demand for precision treatments grows.

Earlystage projects often have strong theoretical underpinnings and promising *in silico* data generated using AI tools. Procuring *in vitro* or *in vivo* clinical data, however, can be lengthy and expensive, if not almost impossible for rare diseases. AI-generated data offers a compelling way to supplement conventional clinical data. Indeed, data derived from such AI tools is already being used by the U.S. Food and Drug Administration (FDA) to evaluate the safety and efficacy of drugs and medical devices.[1]

Patenting such diagnostic and therapeutic innovations, however, has always posed special challenges, as these types of inventions involve unpredictable, complex biological systems. For diagnostic inventions, there should be an explanation of how the invention is non-conventional compared to previous techniques, not just a bare correlation or abstract idea. For therapeutic inventions, a credible demonstration of the effect has to be shown with evidence.

The use of generative AI raises new questions in patenting inventions in the biomedical field. Although the USPTO has commented on the patentability of AI inventions[2] and directed that AI agents cannot be named as inventors[3], it has yet to wade in on the acceptability of *in silico* data. This article explores to what extent data generated by AI models can potentially support patentability of diagnostic and therapeutic inventions.

1 https://www.fda.gov/science-research/about-science-research-fda/modeling-simulation-fda (Modeling & Simulation at FDA - *FDA scientists routinely use M&S approaches for scientific research and regulatory decision-making*)

2 *2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence*, 89 Fed. Reg. 58128, July 17, 2024 (https://www.federalregister.gov/documents/2024/07/17/2024-15377/2024-guidance-update-on-patent-subject-matter-eligibility-including-on-artificial-intelligence)

3 *Revised Inventorship Guidance for AI-Assisted Inventions*, 90 Fed. Reg. 54636, November 28, 2025 (https://www.federalregister.gov/documents/2025/11/28/2025-21457/revised-inventorship-guidance-for-ai-assisted-inventions)

1. Types of AI-Generated Data

There are several types of AIgenerated data that can be relevant to diagnostic and therapeutic inventions. This section highlights three examples:

- **Structure/Sequence Outputs**: Tools such as AlphaFold can be used to generate detailed structure and sequence information, including predicted three-dimensional structures, likely binding sites on target molecules, activity or function, variant sequences.
- **Simulations**: Digital twins can virtually replicate physical systems or processes for an individual subject and can be used to provide insights on disease state, predicted responses to treatments, and medical device performance. Physiologically based pharmacokinetic (PBPK) models can simulate how a drug behaves within the body; predict absorption, distribution, metabolism, and excretion; and conduct virtual clinical studies to test the effects of a drug on a virtual target population.
- **Generative Outputs**: Generative models, such as large language models and generative adversarial networks, can be used to create synthetic clinical data that mimics actual clinical data and to process large volumes of data (e.g., electronic medical records) to extract relevant pieces of information.

2. Implications of AI-Generated Data on Patent Strategy

To obtain patent protection, an invention must be directed to patentable subject matter, be novel and non-obvious, and meet the written support and enablement requirements. Inventions related to diagnostics and therapeutics often face challenges with respect to patentability, written matter, and enablement.

A. Patent Subject Matter Eligibility and Diagnostic Inventions

One acute challenge in patenting diagnostic inventions is patent subject matter eligibility under 35 U.S.C. § 101. Under this requirement, a claimed invention that is deemed as an abstract idea, laws of nature, or natural phenomena is excluded from patent-eligible subject matter. [4] Under the USPTO's examination guidelines, when the invention is deemed to fall under one of these excluded categories, examiners are to evaluate whether the claims recite additional elements that integrate the judicial exception into a practical application, such as with technical improvements to an existing technology.[5] If there is no integration, examiners are to assess whether the claimed features amount to something "significantly more," such as by showing that the features are *not* well understood, routine, conventional.

Diagnostic inventions are often challenged as directed to one of these categories of exclusion.[6] With the increasing incorporation of AI, diagnostic inventions are often an amalgamation of AI models with biomedical data to provide output used for clinical applications.

The USPTO's 2024 guidance on AI inventions provided a specific example relating to the use of an AI model to assist in personalized medical treatment.[7] In this example, a claim that recited a step of "administering an appropriate treatment" was found ineligible because it did not particularly recite a *specific* treatment for the patient's condition.[8] On the other hand, a claim that specified the particular treatment for a specific patient population was found eligible.

4 35 U.S.C. § 101

5 MPEP § 2106.04(d)

6 *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012)

7 July 2024 Subject Matter Eligibility Examples, Example 49

8 See also *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018).

The incorporation of an administration step with a particularized treatment to a specific patient population can help to resolve the patent eligibility issues. But including this step in a patent claim may not be desirable due to the issue of split infringement: one actor could be running the diagnostic, while another actor could be performing the administration.

Notably, one Federal Circuit case found a diagnostic invention eligible in part because of documentation in the patent regarding technical improvements, including reducing false negatives and positives in cardiac monitoring.[9] AI-generated data could be potentially used to show that the invention provides a technical improvement and is non-conventional relative to the prior techniques. For example, using a virtual patient population, comparative data could be used to illustrate that the new diagnostic technique has higher accuracy and robustness, relative to conventional methods. Applicants should collaborate with inventors to articulate how their inventions achieve these improvements and identify which steps are non-conventional.

B. Written Description and Enablement and Therapeutic Inventions

Another major difficulty in obtaining patents is in calibrating the scope of the claims with the written description and enablement requirements under 35 U.S.C. § 112. Under this section, a patent application must describe the invention with adequate detail such that a person skilled in the art can recognize the boundaries of the invention (i.e., the "written description" requirement) and can be enabled to practice the invention (i.e., the "enablement" requirement).[10]

Therapeutic inventions often involve unpredictable and complex biological systems. This unpredictability means that applications claiming a therapeutic effect are scrutinized to assess whether there is a credible showing of those effects. In practice, obtaining such evidence can be a significant hurdle, especially during the early stage when clinical data may be limited or unavailable.

Given the speed of research and development in the biomedical field, patent applicants should consider incorporation of AI-generated data. For example, if there is already experimental data demonstrating therapeutic activity for a few antibody or small-molecule examples, AI-generated data could be used to support broader genus claims by showing numerous related variants that are predicted to have similar activity. Furthermore, *in silico* data from PBPK simulations could lend support to a credible therapeutic effect of a drug or a medical device. Applicants should include an explanation of the reliability of the model and data and descriptions of the training method and validation cohorts.

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Since the USPTO has yet to comment on the acceptability of *in silico* data, applicants should take a "belt-and-suspenders" approach by also including prophetic examples to accompany preliminary AI-generated data. Prophetic examples describe expected future or anticipated results, without actual, past experimental data.[11] Should there be pushback during prosecution on the use of AI-generated data, post-filing submissions of clinical data that fit within the scope of the prophetic examples could be used to support the claimed therapeutic effect. It should be noted, however, that the acceptance of prophetic examples and post-filing submissions varies by jurisdiction, with many jurisdictions outside the United States and Europe not accepting them as evidence of enablement.

To provide additional time to gather clinical data, applicants should consider filing provisional applications as opposed to starting with non-provisional applications. Provisional patent applications can establish an early priority date while allowing applicants up to 12 months to refine their inventions before filing a non-provisional application.

9 *CardioNet LLC. V. InfoBionic, Inc.*, 955 F. 3d 1358, 1368–69 (Fed. Cir. 2020)

10 35 U.S.C. § 112(a)

11 *Properly Presenting Prophetic and Working Examples in a Patent Application*, 86 Fed. Reg. 35074, July 1, 2021 (https://www.federalregister.gov/documents/2021/07/01/2021-14034/properly-presenting-prophetic-and-working-examples-in-a-patent-application)

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