

Regulatory Alert

Regulatory Insights



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First 100 Days: Upcoming Regulatory Signals for Healthcare/Life Sciences

KPMG Insights

- **Quick Actions/Long Tail:** Expect new leadership, including the 'Make America Healthy Again' Commission, to focus on a broad array of areas such as child health, vaccines, additives (e.g., food, chemical), nutrition, pricing/funding, transparency and conflicts of interest.
- **Leadership Shifts:** Expect new leadership at HHS, FDA, CMS and DOJ to quickly re-prioritize their agency objectives, regulatory focus and enforcement activities, in line with Administration priorities/Executive Orders.
- **Regulatory Shifts:** Anticipate initial pullback of select guidance and funding policies and shifts in the issuance of net-new rules (e.g., food additives, state-directed Medicaid).

Under a mantra of "Make American Healthy Again", the healthcare and life sciences sectors anticipate a flurry of regulatory changes to come. Incoming and acting agency leadership under initial Executive Orders (including de-regulatory and the Make America Healthy Again Commission) provide preliminary signals for potential regulatory shifts, including:

- Agency Objectives, including Regulatory Pullback/Shifts, Funding Pullback, Investigation & Enforcement Shifts, Global Divergence, and State Activity
- Regulatory Focus, including Research "Transparency", Food Additives, Labeling, Technology & AI

1. Agency Objectives

Across agencies, current, incoming and acting agency leadership is setting parameters for regulatory activity going forward, including initial support for:

Signals	Description/Examples	Source
Regulatory Shifts	Recission of previous Executive Orders (e.g., EO 14009, "Strengthening Medicaid and the Affordable Care Act", EO 14070, "Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage")	White House
	Implementation of the Executive Actions "Regulatory Freeze Pending Review" and "Unleashing Prosperity Through Deregulation"	White House here and here
	Potential changes to guidance, procedures (e.g., Section 1557 of the Affordable Care Act regarding nondiscrimination in health programs that receive federal funding, Section 504 of the Rehabilitation Act of 1973 regarding nondiscrimination on the basis of disability in federally-assisted programs	
	Shifts in policy/regulation may include the potential: <ul style="list-style-type: none"> — Decreasing of regulatory focus on Medicare Advantage plans — Increased flexibility for healthcare mergers and acquisitions — A focus on lowering prescription drug costs, with the potential for new policies anticipated for price negotiation — New regulations in specific agency/Administration priority areas (e.g., bans on food additives, state-directed Medicaid, Medicaid/CHIP Expansion Program) 	
Funding Pullback	Modification of grant policies (e.g., NIH capping indirect cost reimbursements, spillover cuts to research grants based on changes in Medicare drug price policies)	NIH guidance
	Potential reassessment of user fee programs Uncertainty around extensions of ACA subsidies	
Investigation & Enforcement Shift	Implementation of Executive Order pausing investigations and enforcement of the FCPA and directing review/revision of the related guidelines and policies	White House
	Implementation of DOJ Memo re-prioritizing enforcement focus of FCPA to foreign bribery that facilitates the criminal operations of Cartels and Transnational Criminal Organizations	DOJ Memo
	Potential shift in False Claims Act enforcement	
Interagency coordination	Implementation of the Executive Order establishing the "Make America Healthy Again Committee", to be chaired by HHS and comprised of leadership from various departments and agencies (including USDA, VA, EPA, OMB, CDC, NIH), and its initial mission to advise the President on how to address childhood chronic disease through an assessment and related strategy	White House

	<p>Coordination and assessment of potential consolidation/standards with respect to food safety (including FDA and USDA (e.g., WIC and SNAP coverage))</p> <p>Coordination between HHS, CMS, and other regulatory bodies regarding healthcare policy implementation.</p>	
Global Divergence	Implementation of Executive Order on "Withdrawing the United States from the World Health Organization (WHO)	White House
	Implementation of Executive Order on "Revaluating and Realigning United States Foreign Aid", including pullback on foreign health aid (e.g., USAID) and reevaluation of all foreign aid programs by OMB within first 90 days	White House
	<p>Reassessment of trade agreements including the:</p> <ul style="list-style-type: none"> — United States-Mexico-Canada Agreement (USMCA) — World Trade Organization Agreement on Government Procurement — Execution of tariffs/duties for select countries and/or sectors 	White House White House Actions, here , here , and here
State Activity	Potential for increasing divergence between federal government and patchwork of state laws (e.g., food date labeling - potential for federal standard via USDA/FDA and state laws (e.g., California, Massachusetts))	

2. Regulatory Focus

In addition to statements regarding agency objectives, current, incoming and acting agency leadership is also noting potential changes in key regulatory areas, including:

Signals	Description/Examples	Source
Research "Transparency"	<p>Greater scrutiny of federally funded health research for perceived conflicts of interest, including "ethics review"; increased focus on "transparency" of current data and open-source data</p> <p>Potential for higher barriers to vaccine use, including study design, approval, manufacturing and controls, as well as public meetings / dockets, transparency of data regarding related risks and mitigation measures, and consumer choice</p>	White House here and here
	Potential for policy changes, including possible regulation and/or legislative actions related to "psychedelics, peptides, stem cells, raw milk, hyperbaric therapies, chelating compounds, ivermectin, hydroxychloroquine... [and] nutraceuticals"	HHS secretary statement

Food Additives	<p>Establishment of the Make America Healthy Again Commission to address chronic diseases, emphasizing "transparency" with increased skepticism toward medications</p> <ul style="list-style-type: none"> — Comprehensive review of health factors including diet, "toxins", food production techniques, corporate influence, and government policies, with an initial focus on childhood chronic disease — Commission to deliver a detailed assessment and strategic plan for restructuring federal health responses within specified timeframes, ensuring ethical transparency and expert input <p>Potential changes to standards for the Generally Recognized as Safe process</p>	White House
In-vitro fertilization	Implementation of the Executive Order to seek policy recommendation for reducing statutory or regulatory burdens in effort to make IVF treatment more affordable and accessible	White House
Labeling	Potential shift in focus on specific set of products within incoming leadership including HHS, FDA, USDA (e.g., dietary supplements, ultra-processed foods, front-of-package (FOP) nutrition labeling, date labeling)	White House
Technology & AI	<p>Implementation of Executive Order on Removing Barriers to American Leadership in AI</p> <p>Naming of Special Advisor for AI and Crypto with responsibilities for overseeing regulatory frameworks, collaboration with officials and stakeholders, including PCAST, and alignment of AI priorities with administration policies</p>	White House Actions here and here
	Rescission of select previous Administration Executive Orders, including EO 14110, "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence", regulating AI synthesis of nucleic acids and requiring guidance for AI deployment and risk monitoring in healthcare	White House

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