# Key 10 Regulatory Challenges: 2025 Midyear

A reshaping of regulations around public health, health insurance and agriculture—including the potential for legal challenges, limitations to availability of data/data sharing, and extended regulatory timelines. Increased state rulemaking.

### **Key Regulatory Signals**



### Shifts in Healthcare Policy & Regulation

Significant changes in healthcare policies and regulations, including drug pricing, and mergers activity.



#### **Emphasis on Regulatory Transparency/Oversight**

Desired transparency in healthcare, including research and drug approval processes, but with diminished federal agency capacity.



#### Changes in Funding & Financial Models

Changes in funding models and impacts of tariffs for healthcare initiatives, including grant modifications, user fee reassessment and potential supply chain shortages.



#### Regulatory Coordination & Global Divergence

Increased coordination among U.S. regulatory bodies and divergence from international entities.

Healthcare and Life Sciences companies should expect regulatory focus and change across:



Regulatory Divergence



Trusted Al & Systems



Cybersecurity & Information Protection



Financial Crime



Fraud & Scams



Fairness & Protection



Financial & Operational Resilience



Parties & Providers



Governance & Controls



Markets & Competition



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e.g., Direct/Secondary impacts e.g., Enhanced scrutiny on to materials and products. federally funded research, Adapting business models and operations to comply Increased scrutiny in approval processes and potential including data sources. with applicable EOs/agency policies. for delays. e.g., Greater focus on e.g., Agency actions to Signals managing conflicts of implement EO 14273 on Additional reporting requirements and higher Navigating changes in drug pricing and interest, conducting "ethics lowering drug prices; potential operational costs. reimbursement models. reviews." revisions to price negotiation. e.g., Focus on, and e.g., DOJ/FTC Merger increased transparency Navigating new transparency regulations while Managing potential market dynamics due to changes Guidelines. regarding, Food Additives maintaining a competitive edge. in merger policies/regulations. and Labeling. **Emphasis on Regulatory Transparency &** Shifts in Healthcare Policy & Regulation -1/~ **Oversight** What's coming... Regulatory Coordination & Global Divergence **Changes in Funding & Financial Models** e.g., Modifications to NIH grant e.g., "Make America Healthy policies, such as caps on Again" Committee: Activities Adjusting to potential reductions in grant funding and Harmonizing compliance with domestic regulatory indirect cost reimbursements to address childhood chronic indirect cost reimbursements. bodies. disease and food safety. e.g., Reassessment of user fee e.g., Withdrawal from WHO; Signals Signals execution of tariffs/duties. programs Managing financial implications of changing user fee Managing impacts of global divergence, especially for programs. multinational companies. e.g., EO "Reevaluating and e.g., Uncertainty on extension of



Ensuring sustainability amid funding pullbacks and

subsidy uncertainty.

ACA subsidies

Realigning US Foreign Aid."

Staying abreast of changing regulations across

jurisdictions.

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"Growing regulatory divergence and fragmentation add another layer of complexity to establishing a clear path from strategy and operations to effective risk and compliance. Will a deregulatory policy really equate to deregulation?"

Amy Matsuo, Principal & Leader KPMG Regulatory Insights

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"In the dynamic healthcare ecosystem, the fusion of increased regulatory change, stringent compliance, and shifting financial landscape necessitates a resilient approach to safeguard patient wellbeing and drive meaningful innovation."

Ash Shehata, Principal Healthcare Sector Lead

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"U.S. Life Sciences is still fighting for the regulatory clarity and balanced oversight needed to protect patients and drive innovation. At the same time, companies are contending with federal policy shifts and tariff threats that hit the industry at its core. It's a high-stakes environment that demands we stay not just informed, but several steps ahead."

Kristin Pothier, Principal Life Sciences SectorLead





Amy Matsuo
Principal & Leader
Regulatory Insights



Ash Shehata

Principal

Healthcare Sector Lead



Kristin Pothier
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