





# 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

			
<b>Shifts in Healthcare Policy &amp; Regulation</b>	<b>Emphasis on Regulatory Transparency/Oversight</b>	<b>Changes in Funding &amp; Financial Models</b>	<b>Regulatory Coordination &amp; Global Divergence</b>
Significant changes in healthcare policies and regulations, including drug pricing, and mergers activity.	Desired transparency in healthcare, including research and drug approval processes, but with diminished federal agency capacity.	Changes in funding models and impacts of tariffs for healthcare initiatives, including grant modifications, user fee reassessment and potential supply chain shortages.	Increased coordination among U.S. regulatory bodies and divergence from international entities.

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

- 1**  
Regulatory Divergence
- 2**  
Trusted AI & Systems
- 3**  
Cybersecurity & Information Protection
- 4**  
Financial Crime
- 5**  
Fraud & Scams
- 6**  
Fairness & Protection
- 7**  
Financial & Operational Resilience
- 8**  
Parties & Providers
- 9**  
Governance & Controls
- 10**  
Markets & Competition



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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 well-being 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 Sector Lead



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