US Perspective | Regulating LLMs: New Challenges for Oversight

LLMs differ from already-regulated, software-as-a-medical-device and introduce new challenges for regulatory bodies

Patient Data Privacy	Ensuring that patient data used for training LLMs are fully anonymized and protected from potential breaches.
Intellectual Property	If an LLM generates content similar to proprietary medical research or literature, it could lead to issues regarding intellectual property rights
Medical Malpractice Liability	Determining who is responsible when an AI's recommendations lead to patient harm.
Quality Control & Standardization	Regulation is required to ensure the reliability and consistency of AI-generated medical advice
Informed Consent	Patients need to be informed and give consent when AI tools are used in the healthcare management.
Interpretability & Transparency	Regulations need to ensure transparency about how decisions are made by AI.
Fairness and Bias	Regulation is needed to prevent biases in AI models
Data Ownership	It can be challenging to define and regulate who owns the data that LLMs learn from, especially when it comes to patient data.
Over-reliance on AI Models	Over-reliance on AI could lead to decreased human expertise and potential errors
Continuous Monitoring & Validation	Ensuring the continuous performance, accuracy, and validity of AI tools over time and across different populations is a critical regulatory challenge.

Source: Nature