AI Chatbot's Medical Claims Highlight Enforcement Risks

By **Sonia Nath, Sean Quinn and Auguste Humphries** (August 18, 2026)

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The Pennsylvania State Board of Medicine is currently suing Character Technologies, the corporate entity operating the Character.ai generative artificial intelligence platform, in the Commonwealth Court of Pennsylvania.[1]

The complaint, **filed** on May 1, raises immediate questions about state licensing board enforcement, but the regulatory picture it reveals extends further — to U.S. Food and Drug Administration oversight and an accelerating wave of state legislation targeting AI in healthcare.

Character Technologies also faces a separate lawsuit brought by the Kentucky attorney general — Commonwealth of Kentucky ex rel. Coleman v. Character Technologies Inc., filed in the Franklin Circuit Court in January — which alleges that the company preys on children and leads them to self-harm.[2]

Background

The complaint arose from a state investigator's interaction with a user-created chatbot that held itself out as a licensed psychiatrist and engaged in the unauthorized practice of medicine. That a regulator initiated the investigation based on a keyword search, not a patient complaint or reported harm, underscores that AI-related violations are a primary enforcement target that regulators are actively pursuing.

For attorneys advising clients in this space, the case is a good reminder that AI products built on general-purpose models are capable of saying or doing virtually anything, including, as here, holding themselves out as licensed professionals.

Also, the range of functionality requiring guardrails may be far broader than anyone initially anticipates. Counsel should check in with clients on applicable state laws, product design and intended use, including any updates or introduction of AI software that could expand the product's capabilities into regulated territory.

Legal issues

State Licensing

In Pennsylvania, medicine and surgery is defined as "[t]he art and science of which the objectives are the cure of diseases and the preservation of the health of man, including the practice of the healing art with or without drugs, except healing by spiritual means or prayer."[3] Medical doctors, including psychiatrists, as with most distinct healthcare professions, e.g., nurses, physician assistants, etc., are licensed at the state level.

Further, Pennsylvania, like other states, prohibits the unauthorized practice of medicine, which includes:

- Practicing medicine;
- Purporting to practice medicine;
- Holding forth as authorized to practice medicine through use of a title; and
- Otherwise holding forth as authorized to practice medicine.[4]

Given the breadth of these statutory prohibitions, the bar for demonstrating the unauthorized practice of medicine appears low.

For example, a platform need not deliver clinical care in the traditional sense to run afoul of the statute; merely holding itself forth as authorized to practice medicine, whether through the use of a title, the assertion of credentials or other representations of licensure, may be sufficient.

In this case, the complaint expressly alleges that the Emilie character represented that it was a medical doctor, claimed to have attended medical school at Imperial College London and to have been practicing psychiatry for seven years, asserted that it was licensed to practice medicine in Pennsylvania, and provided a fabricated Pennsylvania license number.

Each of these allegations, standing alone or in combination, may be used as evidence that the chatbot held itself out as authorized to practice medicine.

Intended Use and the FDA's Medical Device Regulatory Framework

The Character.ai matter also raises significant questions under federal law — specifically, whether a chatbot that performs diagnostic or treatment-related functions could be classified as a medical device subject to FDA oversight.[5]

Counsel advising clients in this space should not assume that the absence of FDA enforcement to date reflects a settled regulatory position; to the contrary, the agency's existing statutory and regulatory framework is more than sufficient to reach AI chatbot platforms with these types of functions, and the Pennsylvania complaint may accelerate federal attention to this space.

Under the Federal Food, Drug and Cosmetic Act, a product qualifies as a device if it is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or is "intended to affect the structure or any function of the body" — provided that, unlike a drug, it does not achieve its primary intended purposes through chemical action within or on the body and does not depend on being metabolized to achieve such purposes.[6]

Critically, the FDA does not simply accept a company's characterization of what its product is intended to do. Under Title 21 of the Code of Federal Regulations, Section 801.4, a product's intended use can be established by, among other things, its design, the circumstances surrounding its distribution, website claims, advertising, and oral and written statements.

The FDA evaluates the totality of the circumstances — how a product is actually used, what it actually communicates and what the objective evidence shows about the manufacturer's intent.

Importantly, the FDA regulates software as a medical device in the same manner as other products, unless the software is subject to one of the statutory carveouts from the 21st Century Cures Act, such as software intended for general wellness purposes.[7] Thus, software that is intended for use in the diagnosis or treatment of a disease or condition is subject to regulation as a medical device under the FDCA.

While the FDCA may already provide a basis for reaching chatbot operators, enforcement to date has largely been driven by state attorneys general rather than FDA. That gap likely reflects issues of timing and resource constraints rather than any meaningful limitation in

federal authority.

In the current environment, states like Pennsylvania also appear more willing to devote their limited resources to enforcement in this space. For practitioners advising clients in this area, that combination of latent federal authority and active state enforcement means the question is not whether regulatory scrutiny is coming, but whether clients are positioned to meet it when it does.

Practical Guidance for Counsel

So, what should counsel be advising platform clients to do now, before a regulator comes knocking? Because a general-purpose AI model can end up doing things no one planned for at launch, the compliance challenge goes beyond keeping up with the law.

It means figuring out what the product can actually do and making sure it does not wander into regulated territory. The starting point is a multijurisdictional regulatory risk assessment helping clients identify the full landscape of applicable state laws across every jurisdiction in which their platform operates before health AI features are deployed.

From there, counsel can help clients determine applicable standards. That means calibrating compliance practices to either the highest applicable state standards or to emerging national frameworks, whichever is more protective.

The Federation of State Medical Boards, for example, announced in May the formation of a new work group charged with developing recommendations and model guidelines for state medical boards on the regulation of AI tools used in the practice of medicine. At the federal level, and as discussed further below, the Trump administration has also signaled its desire to establish a uniform federal framework for AI.[8]

What's Next

It is too early to say whether the Character.ai lawsuit will open the floodgates for state enforcement actions, but the conditions are there. State licensing boards now have a live case that hands them a road map for going after AI platforms whose responses stray into regulated territory.

And they are not the only ones: Nearly every state has regulated, or is in the process of passing laws to regulate, AI and chatbots in some manner. States like California, Texas,

New York and Illinois are leading the way, but the wave is building.

These developments suggest a regulatory landscape that may become both broader and more varied over time — though federal pressure on state AI regulation is mounting. On Dec. 11, 2025, President Donald Trump signed an executive order directing federal agencies to establish "a minimally burdensome national policy framework for AI."

While the order does not preempt existing state AI laws, it identifies several mechanisms for challenging state AI laws inconsistent with that policy, including U.S. Department of Justice litigation, U.S. Department of Commerce review of onerous state laws and a White House mandate to prepare a legislative recommendation establishing a uniform federal framework that would preempt state laws conflicting with the administration's policy of sustaining and enhancing U.S. global AI dominance through a minimally burdensome national framework.[9]

For now, state AI compliance obligations remain in effect. The scope of these regulations varies considerably from state to state, ranging from disclosure requirements mandating that users be informed they are interacting with an AI agent to data privacy obligations, advertising restrictions and other consumer protection measures.

Of particular relevance to the issues raised by the Character.ai matter, Delaware recently enacted legislation that expressly prohibits a "nonhuman entity," including an "agent powered by artificial intelligence," from using professional titles or abbreviations associated with licensed healthcare professions, including, but not limited to, "advanced practice registered nurse," "registered nurse," "doctor" and similar designations.[10]

The Delaware law further prohibits the licensure of a nonhuman entity to practice medicine, nursing or related healthcare professions, and bars any such entity from engaging in the practice of medicine within the state.

Legislation of this nature may reflect a growing desire among state legislatures to expressly address this practice in an attempt to rein in AI platforms that offer medical advice without state oversight — though their durability will depend on whether federal legal challenges to these laws materialize and succeed, or whether Congress moves to preempt them through a federal AI framework.

What makes the Pennsylvania case especially notable is how it started — not with a purpose-built health app, but with a single chatbot on a general-purpose platform that a

state investigator found by searching "psychiatry."

For attorneys advising clients in this space, the practical takeaway is that regulators are looking at what the AI actually says, and if those responses look like the practice of a licensed profession or the function of a regulated device, disclaimers may not be enough.

That said, enforcement is not the only model, and counsel should be aware of the alternatives. Some states have signaled a preference for regulatory partnership over litigation. Utah, for example, has entered into a regulatory mitigation agreement with mental health chat app ElizaChat, under a framework created by Utah law that allows companies to operate under agreed terms in exchange for regulatory flexibility.[11]

Whether other states follow Utah's lead remains to be seen, but the gap between a regulatory partnership and an enforcement action may come down to whether the platform drew the lines itself before a regulator had to or, where a regulator has already drawn them, whether the platform engaged constructively with those boundaries rather than ignoring them.

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[1] The Pennsylvania State Board of Medicine operates under the Pennsylvania Department of State, Bureau of Professional and Occupational Affairs.

[2] Commonwealth of Kentucky ex rel. Coleman v. Character Technologies, Inc., No. 26-CI-00029 (Ky. Franklin Cir. Ct. filed Jan. 8, 2026).

[3] 63 Pa. Stat. Ann. § 422.2.

[4] 63 Pa. Stat. Ann. § 422.10.

[5] 21 USC § 321(h)(1).

[6] Id.

[7] 21 USC § 360j(o). See also, Cooley, "FDA Opens Aperture for Wearables in Latest General Wellness Guidance," January 20, 2026.

[8] "Ensuring a National Policy Framework for Artificial Intelligence," Exec. Order No. 14365, 90 FR 58499, December 11, 2025).

[9] "Ensuring a National Policy Framework for Artificial Intelligence," Exec. Order No. 14365, 90 FR 58499, December 11, 2025. See also, Cooley, "Showdown: New Executive Order Puts Federal Government and States on a Collision Course Over AI Regulation," December 12, 2025.

[10] Del. H.B. 191, 153d Gen. Assemb. (2026).

[11] UT Code § 13-72-302.