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Hidden Formulas, High Stakes: The Fight to Regulate Clinical Decision Support Tools

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This article is the second in a series on prescription drug monitoring programs and analysis tools designed to give clinicians a view of how likely their patient is to abuse or overdose on a prescribed controlled substance. The

first part examines one such tool, NarxCare scores, and the scientific evidence backing their use.

This story focuses on the lack of government oversight of such tools and a recent effort to prompt a regulatory agency to set standards for these products.

A group representing clinicians and pain patients is seeking a formal review from the US Food and Drug Administration (FDA) of a controversial product that uses proprietary algorithms in judging the risk for opioid overdose.

Their petition is part of a broader debate on how and if algorithm-based clinical decision support tools should be

overseen by regulators, just like medical devices are, in an effort to minimize potential patient harm.

The platform, called NarxCare, was developed by Bamboo Health, a Louisville, Kentucky–based behavioral health company that is the nation's largest provider to states of technical services for prescription drug monitoring programs (PDMPs). Half of these states — at least 20 — use the company's NarxCare platform, which contains several scores, including one that indicates the past use of prescribed scheduled drugs.

"Patients are judged by an undisclosed algorithm that can determine whether they receive medical care or not —

without any way to see, challenge, or correct errors in their score," said Beverly C. Schechtman, vice president of The Doctor Patient Forum, a nonprofit focused on patients with pain based in Rhode Island. "We are calling on the FDA to step in and regulate NarxCare before more people are harmed."

Earlier this spring, the group asked the FDA to conduct a formal review to determine if NarxCare qualifies as a medical device subject to regulation. Their letter asked the agency to create clear guidelines for risk-scoring software used in clinical decision-making and to mandate companies to disclose their algorithms and methodologies for independent review. Critics say Bamboo

Health has not published the algorithms that generate the scores nor have the tools been extensively validated.

While some clinicians see the NarxCare product as a tool to aid in patient care, many also say health clinicians may not provide appropriate pain treatment because of the scores.

“We’d definitely like to see it regulated because it is so vastly used,” said Kate Nicholson, executive director of the National Pain Advocacy Center, which represents researchers and patients.

She cited concerns that patients with higher NarxCare scores might be flagged simply because they are treated in group practices, which can make it

appear as though they have multiple prescribers. She also said NarxCare scores put people who see several specialists for complex chronic conditions at a disadvantage.

Bamboo Health declined requests for interviews and referred *Medscape Medical News* to an outside spokesperson, who said the company "won't speculate on ongoing legal matters."

On its website, Bamboo Health stated that it makes information about their algorithms available to clients.

The company previously told *Medscape Medical News* that NarxCare "falls within the exclusion from FDA oversight for

non-device medical software established by Congress."

The FDA is currently taking comments in response to the citizen petition, of which more than 1000 have been made.

A Gray Area

The implementation of PDMPs and risk scores could be considered a success, with queries by clinicians and other authorized users like pharmacists doubling from 61.5 million in 2014 to 1.4 billion in 2023, according to the American Medical Association (AMA).

Federal funding for electronic PDMPs ramped up in the early 2000s in response to the opioid epidemic, which

began in the previous decade. Overdose deaths, including those from opioids, nearly quadrupled from 8.2 deaths per 100,000 people in 2002 to 32.6 per 100,000 in 2022. But prescriptions for these drugs have dropped by nearly half since 2012, and deaths linked to the substances are declining.

A driver of the crisis has been the practice of "doctor shopping," whereby patients seek multiple prescriptions for opioids from different clinicians to avoid raising suspicion about their abuse of the drugs.

The NarxCare scores were developed in part to help prevent this problem. One of the components of the scores is

information on controlled substances prescribed to a patient, including opioids and sedatives. Scores range from 000 to 999.

"Pharmacists and physicians can use the thresholds as calls-to-action to further review details in the patient's prescription history in conjunction with other relevant patient health information as they attend to the patients," said Rob Cohen, then-president of Appriss Health, which has since been rebranded as Bamboo Health, in a 2021 press release.

At least three other companies provide services for PDMPs in the 10 states where Bamboo Health does not have a foothold, including LogiCoy in Illinois;

Leap Orbit in Utah, Maryland, and Nebraska; and Tyler Technologies in Wisconsin. Two states, Kentucky and New York, collect their own PDMP data.

Of the states that use Bamboo Health to run various parts of their PDMPs, more than 20 states use the NarxCare platform, according to the company.

The AMA told *Medscape Medical News* it has encouraged Bamboo Health to make its algorithms subject to peer review, such as through publication of a paper in a journal.

“There’s a lot of people that give it much more emphasis than it should have, which is as one tool, but not something that should define whether somebody is

inappropriately getting prescribed something," said Bobby Mukkamala, the president-elect of the AMA and chair of the group's AMA Substance Use and Pain Care Task Force.

Previous Efforts at Regulation

The FDA for many years has regulated some software products used in medicine. But agency leaders and lawmakers have wrestled with questions about the FDA's role in overseeing rapid advances in the field of clinician decision support.

In 2016, Congress established broad rules about regulation of these tools as part of the 21st Century Cures Act. But the law did not resolve all the questions

about which kinds of decision support products the FDA should regulate and which it should leave alone.

The FDA itself concedes that the distinction between software products it can and cannot regulate is difficult to understand.

“Because a wide variety of software can be described as ‘decision support,’ understanding the regulatory requirements that may apply to such software can be challenging,” the agency says on its website.

In 2022, the FDA issued a guidance document to help companies understand which clinical decision support products might trigger further

scrutiny. This drew criticism from Sen. Bill Cassidy (R-LA), who said the FDA was seeking to expand its authority of the software without identifying safety concerns for justification.

The FDA in 2023 declined to act on another citizen petition filed by the nonprofit Center for US Policy, which sought to have the agencyinitiate a recall of the NarxCare platform. The center focuses on removing barriers to the treatment of pain and opioid use disorder.

In explaining that denial, the FDA said requests for the agency to initiate enforcement actions and related regulatory activity are beyond the scope of agency responses to citizen petitions.

Medscape Medical News reviewed petition decisions by the FDA's Center for Devices and Radiological Health since July 2024 and found most were denied.

An Uncertain Future in Artificial Intelligence (AI)

Whether the FDA will grant the petition on NarxCare or otherwise seek to expand its current regulation of AI-driven products is unclear.

President Donald Trump has signaled a preference for a more open-market for AI-driven products than for increased regulation. His administration in January revoked a 2023 executive order in which President Joe Biden encouraged

the development of AI products, while also seeking safeguards against discrimination and bias. Trump's January 2025 executive order on AI directs agencies to seek ways to remove barriers to innovation in the field.

FDA Commissioner Marty Makary, MD, MPH, will likely face challenges regarding the agency's stance on clinical decision support products.

Makary last year retweeted a *JAMA Health Forum* article in which former FDA Commissioner Scott Gottlieb, MD, said companies working on AI tools for clinical care may limit their product capabilities to avoid having their software tools classified as medical devices. Gottlieb argued for Congress to

take more steps to create a more modern approach to regulation of AI devices.

"The FDA's traditional regulatory approach, which depends on the agency's capacity to meticulously examine a product's construction, might prove infeasible in this context," Gottlieb wrote.

Makary repeated this line in a retweet of Gottlieb post on the article, which the now FDA commissioner described as a great take on how "the FDA needs to change" how it evaluates AI.

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