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FOR IMMEDIATE RELEASE

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East Providence, RI

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## **Your Doctor May Be Using a Secret Score to Deny You Care—FDA Petition Demands Transparency and Oversight of NarxCare**

The Doctor Patient Forum Calls on the FDA to Regulate Hidden Risk-Scoring Algorithm Used in Prescription Drug Monitoring Programs.

EAST PROVIDENCE, RI – A powerful FDA Citizen Petition has been filed calling for immediate regulation of NarxCare, a secretive risk-scoring algorithm that is being used to flag patients as “high risk” and deny them access to medications—often without their knowledge.

The petition, now posted on the FDA docket under Docket No. FDA-2025-P-0701, urges the agency to classify NarxCare as a Software as a Medical Device (SaMD) and impose transparency, oversight, and accountability to ensure patient safety and fairness.

The FDA docket opened for public comment on March 12, 2025, and will remain open for 60 days.

“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. “We are calling on the FDA to step in and regulate NarxCare before more people are harmed.”

### **Key Requests of the Petition:**

- Determine if NarxCare qualifies as a medical device under FDA regulations.
- Require clinical validation and transparency to ensure accuracy and fairness.
- Establish regulatory guidelines for risk-scoring software to prevent patient harm.
- Mandate companies disclose algorithms, data sources, and validation methods.



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The petition documents multiple cases of patients being denied medications, forced off life-saving treatments, or even turned away from medical care due to NarxCare scores—without ever being told why.

### **Why This Matters:**

NarxCare and similar PDMP risk-scoring systems operate without federal oversight, using undisclosed algorithms to flag patients as “high risk” without clinical context. These scores are being used by pharmacies, insurers, and healthcare providers to justify opioid prescription denials, creating barriers to care for chronic pain patients, individuals on stable opioid therapy, and even those receiving medications for opioid use disorder (MOUD).

### **Patients Have No Way to Check for Errors or Fix Them**

Unlike a credit score, which consumers can dispute, NarxCare operates in complete secrecy. Patients do not have access to their score, cannot check it for accuracy, and have no formal process to challenge or correct errors.

### **Errors in NarxCare’s system have led to:**

- Medication denials—even for long-term stable patients
- Doctors refusing treatment due to an undisclosed "high risk" score
- Patients losing access to surgery or emergency care because their prescriptions raised "red flags"

“The consequences of unregulated risk-scoring systems are devastating,” said Claudia A. Merandi, President of The Doctor Patient Forum. “Patients are being denied pain relief, forced off stable medications, and even abandoned by their doctors—while the companies behind these algorithms profit from their suffering. There is no appeals process, no transparency, and no accountability.”

### **How the Public Can Help:**

- **Submit a Public Comment:** Patients, healthcare professionals, and advocates are encouraged to submit comments supporting the petition.  
Direct Link to FDA Docket: [FDA-2025-P-0701](https://www.fda.gov/oc/2025/p-0701)
- **Spread Awareness:** Share this issue on social media using #RegulateNarxCare.



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- Contact Lawmakers: Urge Congress to investigate PDMP algorithms and their impact on patient care.

### **About The Doctor Patient Forum**

The Doctor Patient Forum (DPF) is a nationally recognized nonprofit dedicated to educating and empowering patients to advocate for themselves while challenging bias, conflicts of interest, and the harmful consequences of the opioid reduction movement. Through education, awareness, and policy advocacy, DPF works to expose the systemic barriers preventing access to proper medical care and to protect the rights of chronic pain patients and healthcare providers.

✦ For more information or media inquiries, contact:

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