THE DOCTOR PATIENT FORUM
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The Doctor Patient Forum
March 11, 2025

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Submitted to the U.S. Food and Drug Administration (FDA)
Under **21 C.F.R. § 10.30**

Petitioner Information

This petition is submitted on behalf of **The Doctor Patient Forum (DPF)**, a nonprofit organization advocating for chronic pain patients and healthcare providers. The following individuals have authorized me to sign and submit it on their behalf:

- **Claudia A. Merandi, President, The Doctor Patient Forum**
- **Chad D. Kollas, MD, FACP, FAAHPM, Chair, AMA Pain & Palliative Medicine Section**
- **Jennifer D. Oliva, JD, Professor of Law**
- **Dan Laird, MD, Board-Certified Pain Management Specialist**

A full list of additional co-signers is provided at the end of this petition.

I, **Beverly C. Schechtman** as **Vice President** of The Doctor Patient Forum, am the authorized representative submitting this petition. My signature is provided at the end of this document, in accordance with FDA submission requirements.

I. Action Requested

Pursuant to 21 C.F.R. § 10.30, we, the undersigned, respectfully request that the Food and Drug Administration (FDA) classify and regulate NarxCare, a proprietary risk-scoring algorithm used in Prescription Drug Monitoring Programs (PDMPs), as a Software as a Medical Device (SaMD). Specifically, we request the FDA to:

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- Conduct a formal review to determine whether NarxCare qualifies as a medical device under FDA regulations.
- Require that NarxCare undergo clinical validation and transparency assessments to ensure accuracy, fairness, and reliability.
- Establish clear regulatory guidelines for risk-scoring software used in clinical decision-making to ensure oversight and prevent undue harm to patients.
- Mandate that companies producing such software disclose their algorithms, data sources, and validation methodologies for independent review.

II. Relevant FDA Departments for Petition Review

The regulation of medical software falls primarily under the Center for Devices and Radiological Health (CDRH), which oversees the classification and regulation of Software as a Medical Device (SaMD). However, because opioids and other controlled substances are directly impacted by NarxCare's risk-scoring system, it is also critical to involve the Center for Drug Evaluation and Research (CDER), which regulates prescription medications and ensures their safe and effective use.

Additionally, because this petition addresses issues that span multiple regulatory areas—including medical software, clinical decision support tools, and controlled substances—it may also be beneficial for the Office of the Chief Scientist (OCS) to be involved in this review.

III. Ensuring Compliance with FDA Procedures

We recognize that the FDA's Citizen Petition process does not cover enforcement actions under **21 CFR 10.30(k)**. This petition does not request enforcement action, such as a recall or warning letter. Instead, it calls for classification, regulation, and transparency of NarxCare as a medical device, ensuring that the software meets FDA safety, accuracy, and fairness standards.

IV. Statement of Grounds

NarxCare is an Unregulated Medical Device That Requires FDA Oversight

NarxCare and similar risk-scoring systems function as clinical decision support tools, influencing prescribing practices, access to necessary medications, and patient treatment pathways. Given that NarxCare utilizes algorithmic risk calculations to influence medical decisions, it meets the

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definition of a Software as a Medical Device (SaMD) and should therefore fall under FDA regulatory authority as a medical device.

NarxCare Fails to Qualify for Exemption Under the Cures Act

Bamboo Health asserts that NarxCare is exempt from FDA regulation under Section 520(o)(1)(E) of the FD&C Act, claiming it 'does not make clinical recommendations' and 'is expressly exempt from FDA regulation' (Owens, 2023) [1]. However, the 21st Century Cures Act explicitly states that software must meet ALL FOUR exemption criteria to avoid FDA regulation. NarxCare fails multiple conditions, making FDA oversight not just necessary, but legally required (21st Century Cures Act, 2016) [2]. The following points outline why NarxCare does not meet the exemption criteria:

1. **NarxCare is not merely intended to display, analyze, or print medical information** (Section 520(o)(1)(E)(i)).
    - As noted in the paper *"Dosing Discrimination: Regulating PDMP Risk Scores"* by Jennifer D. Oliva, NarxCare aggregates and analyzes data from electronic health records, criminal justice databases, and other sources to generate proprietary risk scores (Oliva, 2021) [3].
    - This function goes beyond passive data display and qualifies NarxCare as a medical device under FDA definitions because it actively processes and interprets data in a way that influences medical decision-making.
2. **NarxCare does not merely support clinical decision-making—it interferes with treatment outcomes** (Section 520(o)(1)(E)(ii)).
    - PDMP risk scores coerce healthcare providers into making clinical decisions based on undisclosed algorithms rather than individualized patient assessments.
    - Bamboo Health cites decreased prescribing rates as evidence of NarxCare's success. An Ochsner Health case study attributes reduced opioid prescriptions to NarxCare's integration into electronic health records (EHR) (Bamboo Health, 2022) [4]. This demonstrates that NarxCare's predictive risk scores and alerts actively shape prescriber decisions rather than merely supporting them. FDA exclusion criteria require CDS software to inform, not dictate clinical choices. By promoting its role in reducing prescribing, NarxCare clearly influences medical

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decision-making, failing to meet exemption criteria and necessitating FDA oversight as a medical device.

- Patients flagged as "high-risk" face medication tapers, prescription denials, and even forced discontinuation of care, which directly affects patient treatment pathways rather than serving as an optional decision-support tool.

3. **NarxCare does not enable independent review by healthcare professionals, as required for exemption** (Section 520(o)(1)(E)(iii)).

   - Bamboo Health refuses to disclose how NarxCare's risk scores are calculated or provide external validation of their accuracy.
   - According to Oliva, no independent studies exist demonstrating that NarxCare accurately predicts overdose risk or improves patient outcomes.
   - The lack of transparency prevents healthcare professionals from making independent clinical decisions, as they are forced to rely on black-box scoring mechanisms with no ability to verify their validity.
   - According to the FDA's 2019 Final Guidance on Clinical Decision Support Software, any software that automates clinical decision-making or replaces independent medical judgment is subject to FDA regulation (FDA, 2019) [5]. NarxCare does exactly this—healthcare providers rely on its risk scores to dictate prescribing decisions rather than using their own independent assessment. This further confirms that NarxCare is subject to FDA oversight.

4. **NarxCare does not meet the exemption criteria under Section 520(o)(1)(E)(ii), which excludes software intended to support or provide recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition.**

   - Substance Use Disorder (SUD) is a chronic disease recognized by leading federal and medical organizations. **NIDA** defines addiction as a "chronic, relapsing disorder" rooted in brain changes and treatable with proper care (*NIDA, Principles of Drug Addiction Treatment*) [6]. **ASAM** classifies SUD as a "chronic medical disease" influenced by brain circuits, genetics, and environment (*ASAM, Definition of Addiction*) [7]. **SAMHSA** affirms as a disease (*SAMHSA, Why Addiction is a "Disease," and Why It's Important*) [8]. These authorities confirm that SUD is a disease requiring medical intervention and regulatory oversight.

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- NarxCare explicitly markets itself as a comprehensive tool designed to "identify, prevent and manage substance use disorder" by providing "advanced analytic insights" into "potential drug misuse or abuse," explicitly positioning itself as a preventative clinical intervention (Bamboo Health, NarxCare Product Overview) [9]. This directly contradicts the exemption criteria outlined in Section 520(o)(1)(E)(ii), clearly demonstrating that NarxCare is intended to actively prevent disease and thus must be regulated by the FDA as a medical device.

Since NarxCare fails to meet the statutory requirements for exemption, it must be classified as a regulated medical device subject to FDA oversight.

V. Demonstrating Harm to Consumers

In February 2025, a Minnesota patient in her fifties was denied surgical consideration after an orthopedic surgeon cited her NarxCare score, chronic pain status, and prescribed medications as justification. While the patient waited for a diagnostic injection, she accessed her patient portal and discovered the surgeon had documented NarxCare as a reason for ineligibility.

Additionally, a separate patient received a formal termination of care from her OB-GYN explicitly due to concerns raised by her prescription history as reported by the NarxCare database (The Doctor Patient Forum, 2025) [10]. The OB-GYN cited NarxCare's risk assessment as the basis for ending the physician-patient relationship, instructing the patient to seek care elsewhere and restricting medication provision to emergent needs only.

These cases underscore the dangers of unregulated risk-scoring systems in clinical decision-making, highlighting how NarxCare is used to justify denial of necessary medical care and termination of established physician-patient relationships. The lack of transparency and accountability in these decisions not only harms patients but also raises serious ethical and regulatory concerns that require immediate FDA oversight.

VI. Environmental Impact

Pursuant to 21 C.F.R. § 25.30, this petition qualifies for a categorical exclusion from the requirement to submit an environmental assessment, as it has no environmental impact.

VII. Economic Impact

The unregulated use of NarxCare has led to significant economic consequences. Patients flagged inaccurately as high-risk face increased healthcare costs due to:

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- Unnecessary emergency room visits
- Additional medical evaluations
- Prolonged appeals for proper treatment

The inability to access necessary pain management can result in:

- Lost productivity and workforce displacement
- Increased reliance on disability benefits
- Financial strain on both patients and healthcare providers

Additionally, when patients are unable to access appropriate pain management through legal and medical channels, they may, out of desperation, turn to the illicit drug market for relief.

This can:

- Increase the risk of overdose
- Further strain public health resources
- Lead to higher emergency response and addiction treatment costs

The growing crisis of opioid-related overdoses already presents a significant economic burden, and failing to regulate NarxCare could contribute to worsening this public health emergency.

VIII. Conclusion

The Doctor Patient Forum and the undersigned urge the FDA to take immediate action to regulate NarxCare as a Software as a Medical Device (SaMD). The lack of oversight for risk-scoring tools like NarxCare has already resulted in patient harm, and continued inaction will only exacerbate these issues. We call on the FDA to use its existing authority to ensure transparency, validation, and accountability in clinical decision-support software.

IX. Certification

We, the undersigned, certify that, to the best of our knowledge, this petition includes all relevant information, is true and accurate, and contains no material misrepresentation.

Thank you for your time and consideration. We welcome the opportunity to discuss this matter further and provide additional input if needed. Please feel free to contact us at **bev@thedoctorpatientforum.com** or 862-812-6827.

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Sincerely,

Beverly C. Schechtman
Vice President
The Doctor Patient Forum
bev@thedoctorpatientforum.com
862-812-6827

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Claudia A. Merandi
President
The Doctor Patient Forum

Chad D. Kollas, MD, FACP, FAAHPM
Chair, AMA Pain & Palliative Medicine Specialty Section Council

Jennifer D. Oliva, JD
Professor of Law

Dan Laird MD
Certified Pain Management Fellowship
Board Certified Anesthesiologist

Robert Twillman, Ph.D., FACLP
Pain Management Psychologist
Saint Luke's Health System

James E. Gierach, J.D.
Former Cook County prosecutor
Formerly LEAP Board member

Christopher R. Russo, M.D.

Todd Hess, M.D.

Christopher Austin, M.D.

Daniel Wolfe, MPH

Mary Ann Dunkel, LPN (retired)

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Jason Andrews

Joanne M Taylor

Alexa Krause-Girton, CPhT

Anne Fuqua, BSN

Elizabeth G. Dost, RN

Tina Marie Johnson, RN

Duane Pool, RN

Cara Redhorn, LPN

Tanya Unruh, BSN

Heather Yount, RN

Stephanie L. Stone, RN

Linda Kaye Fisher, Retired RN

Brenda Jefferson, Retired RN

Tammy Murphree Smothers

Carrie Judy

Nolan Erdody

Tori Dorsey

Heather M. Jackson

Cynthia Wohlschlaeger

Sarah Patterson

Georgine Robertshaw

Taryn Gallagher Mull

Scottie Unruh

Cynthia B. Chambers

Thomas Marselle

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Ruthie Marselle

Julie Kasel

Christina Burgess

Suzanne Hellums

Cammie LaValle

June Vander Wyden

Melinda Endress

Robert Endress

Brandy Hoerauf
The Doctor Patient Forum

Kevin Hoerauf

Deborah C Good

Linda McCarty

Wendy Hart

Jerri Downey

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