RegenMed

ARTICLE

THE NEW FEDERAL MANDATE FOR CLINICAL VERACITY

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THE REGULATORY CATALYST: REMOVING THE IDENTITY BARRIER

In December 2025, the FDA issued a final guidance that fundamentally changed how it evaluates Real-World Evidence (RWE). For years, the agency largely required "identifiable" patient-level data — specific names or social security numbers — to verify the accuracy of medical studies. Because privacy laws (HIPAA) and security protocols often require data to be de-identified, this created a structural barrier that disqualified vast amounts of high-value clinical information from being used for drug or device approvals.

The new mandate removes this requirement. Commissioner Marty Makary has characterized this as a shift toward "radical transparency," where the agency no longer asks "Who is the patient?" but rather "Is the data true?". The FDA will now accept de-identified datasets, provided the source can prove the information is accurate, reliable, and scientifically sound

THE EVIDENCE GAP: ADMINISTRATIVE PROXIES VS. GROUND TRUTH

While this "unlocks" massive amounts of data, it also exposes a significant flaw in current healthcare systems. Most medical data today consists of "administrative proxies"— billing codes, insurance claims, and fragmented notes captured for the purpose of payment. These proxies are often inaccurate and lack the clinical depth required for federal audits or high-stakes licensing.

To take advantage of this new regulatory path, organizations must move toward **Regulatory-Grade Governance**. This means defining the data architecture and clinical guardrails before the patient encounter begins. By using Circles' Observational Protocols (OPs), providers create an Audit-Ready "Ground Truth" that makes billing errors or protocol deviations technically impossible.

THE ECONOMIC MODEL: FROM SERVICE TO ASSET

This shift transforms the clinical record. Historically, documentation has been a regulatory burden — a cost center. In the new FDA environment, verified data becomes a high-margin, licensable asset.

The **Circles** platform provides the infrastructure for this transformation across any medical specialty — from oncology to neurology. By capturing **Standardized Longitudinal Scores** and objective outcomes at the point of care, Circles ensure that every patient encounter generates **Verified Clinical Veracity**. This data does not just meet the new FDA standard; it exceeds it, providing the **Insurable Integrity** that allows for faster approvals and lower liability risks.

STRATEGIC OUTCOME: VALUATION EXPANSION

For Management Services Organizations (MSOs) and healthcare boards, the objective is **Multiple Expansion**. By transitioning from a "Service Business" focused on volume to a **"Tech-Enabled Asset"** focused on high-veracity data, organizations can significantly increase their valuation multiples. The value of the enterprise is no longer just in the procedure performed, but in the **Insurable Integrity** of the evidence created.

GET INVOLVED OR LEARN MORE — CONTACT US TODAY!

If you are interested in contributing to this important initiative or learning more about how you can be involved, please contact us*:

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