America's Blood Centers®
It's About Life.

Protecting Patient Care: Exempting Blood Center LDTs from Regulation

Background

In May 2024, the FDA issued a far-reaching final rule that subjects in vitro diagnostic products (IVDs) to unprecedented regulatory scrutiny. Right now, blood centers are preparing to implement this mandate that will significantly impact laboratory developed tests (LDTs), potentially jeopardizing critical, life-saving procedures. The rule threatens to create a perfect storm of delayed patient care, increased costs, stifled innovation, and resource diversion—all of which could compromise the efficiency and effectiveness of blood center operations.

The Vital Role of Blood Center LDTs

- Laboratory developed tests in blood centers are not just diagnostic tools; they are lifelines in urgent, life-saving situations. These tests:
- Are performed exclusively for healthcare providers treating patients in clinical settings
- Provide rapid, crucial information for time-sensitive medical decisions
- Form an integral part of the blood supply chain, ensuring safe and timely transfusions

The Existing Regulatory Framework: A Robust Safety Net

Blood centers currently operate under a comprehensive regulatory framework that ensures the quality and validity of their tests:

1. Federal, state, or local facility licensure
2. Clinical Laboratory Improvement Amendments (CLIA) certification
3. Compliance with extensive FDA regulatory requirements
4. State-specific requirements
5. Accreditation by appropriate bodies

The Case for Exemption

- Redundancy: The current regulatory framework already provides multiple layers of oversight and inspection.
- Established Safeguards: Blood centers have significant measures in place for developing and utilizing LDTs.
- Potential Harm: Additional regulation could hinder patient care by introducing unnecessary delays and bureaucratic hurdles.

Congressional Concerns and the Call for Action

Congress has expressed reservations about the FDA's new regulatory framework, questioning whether it falls within the agency's authority. This sentiment aligns with the broader healthcare community's concerns about the potential impact on patient care.

To ensure uninterrupted, life-saving care for patients across America, we urge Congress to:

1. Encourage the FDA to revoke the 2024 Lab Developed Test final rule
2. Exempt blood center LDTs from any new reforms of LDT regulation

By taking action, Congress would maintain the efficiency and effectiveness of life-saving procedures, uphold the robust existing regulatory framework, and ensure that blood centers can continue to provide critical care without unnecessary bureaucratic impediments.