



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

# Cutting Red Tape to Better Support Patients and the Blood Supply

## Background

Community blood centers face unnecessary regulatory barriers that hinder their ability to efficiently collect and distribute life-saving blood products. These outdated regulations impede innovation, delay the opening of new donation sites, and ultimately impact patient care.

## Key Issues and Proposed Solutions

### 1. Streamline Licensure for New Donation Sites

- Current Problem: Opening a new donation site that allows blood products to be shipped across state lines requires an extensive licensure process, taking over a year despite using the same procedures and equipment as existing facilities.
- Proposed Solution: Update the FDA licensure process to allow blood centers to quickly and safely meet changing demands for blood components.

### 2. Modernize Testing Requirements to Match Modern Testing Technology

- Current Problem: As technology has advanced, we are left with some FDA infectious disease testing requirements that no longer increase blood safety.
- Proposed Solution: Apply evidence-based decision making to eliminate unnecessary tests (e.g., HBsAg) while maintaining safety standards.

### 3. Unnecessary and Duplicative Regulation of Lab Developed Tests (LDT) will Eliminate Patient Access to Necessary Tests and Drive-Up Health Care Costs

- Current Problem: FDA overreach resulted in onerous and duplicative regulations blood centers will soon need to comply with that will increase costs and decrease patient access without any increase in patient safety.
- Proposed Solution: Eliminate the FDA's guidance and ensure any future LDT reform efforts carve out blood center tests that are already covered by multiple regulatory frameworks and are conducted for use by healthcare providers treating patients in a clinical setting.

### 4. Maximize the Platelet Donations That Can Be Used For Patient Care

- Current Problem: U.S. Platelet Content Requirement (PCR), the number of platelets in a bag, is higher than necessary for ideal patient care, resulting in some unnecessary wastage.
- Proposed Solution: Lower the PCR to expand platelet supply availability, improving access to millions of patients each year.

### 5. Increase Plasma Regulation Flexibility to Increase Efficiency and Reduce Costs

- Current Problem: Inflexible regulation of plasma products requires blood centers to store plasma products no longer needed for transfusions to avoid wasting useful plasma.
- Proposed Solution: Implement a rational, flexible approach, including FDA licensure of recovered plasma for more effective inventory management to maximize the optimal use of all donated blood components.



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### 6. Maximize Available Blood by Allowing Blood Centers to Safely Process Blood in a Timely Manner

- Current Problem: Restrictive time limits for blood processing make it challenging for blood centers to do some blood drives, especially in remote locations, and requires staffing during off hours to comply with processing time requirements that do not improve safety or efficacy of the blood products.
- Proposed Solution: Allow blood to be held for up to 24 hours prior to processing, in line with current evidence.

### 7. Expand the donor base by aligning deferral periods

- Current Problem: While FDA has updated most of the deferrals for risk of HIV in line with modern test sensitivity, those recently incarcerated remain subject to a deferral 4 times longer than those at similar disease risk.
- Proposed Solution: Reduce the deferral period for those incarcerated for more than 72 hours to three months, aligning with other similar risk deferrals.

## The Impact

By implementing these changes, we can:

- Increase the efficiency of blood collection and distribution
- Enhance blood product availability for patients in need
- Reduce unnecessary costs and resource allocation
- Support innovation in blood banking and transfusion medicine

## Call to Action

We urge the Administration to implement these commonsense reforms to cut red tape to support a safe, efficient, and available blood supply to ensure that all patients have the blood they need.