

- §483.30 - Physician Services
- §483.35 - Nursing Services
- §483.70(f) - Use of Outside Resources
- §483.70(g) - Medical Director
- §483.75 - Quality Assessment and Performance Improvement

## **KEY ELEMENTS OF NONCOMPLIANCE**

To cite deficient practice at F770, the surveyor's investigation will generally show that the facility failed to do any one or more of the following:

- Have a current CLIA certificate appropriate for the level of testing it performs;  
**OR**
- Meet the needs of residents with regard to the quality and/or timeliness of providing laboratory services and reporting laboratory results: **OR**
- Provide or obtain laboratory services, to meet the needs of its residents.

## **F771**

*(Rev. 229; Issued: 04-25-25; Effective: 04-25-25; Implementation: 04-28-25)*

**§483.50(a)(1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.**

**(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter.**

## **GUIDANCE §483.50(a)(1)(ii)**

Transfusion services includes the process of transferring blood or blood components received from one person to another. Blood components include red blood cells, plasma, platelets, clotting factors, immunoglobulins, and white blood cells. Facilities must use processes for transfusion, including positive confirmation of the correct blood or blood components into the intended recipient.

Only authorized personnel in accordance with State law, including scope of practice laws, shall verify the correct identification of transfusion recipients and administer blood or blood components. Personnel performing blood and/or blood component transfusions shall have the competencies and training to perform these services and identify and manage adverse events appropriately.

For concerns related to staff competencies or training refer to:

- Nursing Services §483.35(a)(3);
- Administration §483.70(e);

- Training §483.95.

Recipients of transfusion services must be closely monitored during and after the transfusion for signs of adverse reactions and all transfusion-related activities must be documented in the resident's medical record. Examples of adverse events/reactions either during or after transfusion include, but may not be limited to:

- Increase in temperature or pulse rate
- Conjunctival edema
- Edema of lips, tongue and uvula
- Erythema and edema of the periorbital area
- Generalized flushing
- Hypotension
- Localized angioedema
- Maculopapular rash
- Pruritus (itching)
- Respiratory distress; bronchospasm
- Urticaria (hives)

The above examples are based on information from the American Association of Blood Banks (AABB) <https://www.aabb.org>.

## **PROCEDURES**

If a nursing home provides blood transfusions (cross-matched at an outside laboratory), it must hold an appropriate CLIA certificate and must meet all of the requirements of §493.1103 for transfusion services and document all transfusion-related activities as required under §493.1103(d). The facility must have procedures for preventing transfusion reactions and promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory that provided the blood or blood products and as appropriate, to Federal and State authorities.

If facility staff failed to properly identify the resident receiving the blood/blood products or failed to monitor the status of the resident during and/or after a transfusion, it should be cited under Quality of Care at F684.

Nursing home surveyors should not evaluate compliance with the requirements in 42 CFR part §493. Questions or concerns must be referred to State Agency or Regional Office CLIA surveyors to determine whether or not the nursing home provided transfusion services in accordance with the requirements for specified in part §493. If it is verified by State Agency or CMS *Location* CLIA surveyors that requirements in part 493 were not met cite a deficiency under this Tag F771.

The facility must have procedures for preventing transfusion reactions and promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory that provided the blood or blood products and as appropriate, to Federal and State authorities.

If the facility provides transfusion services, determine whether they have policies, procedures, and protocols for:

- (a) Transfusion processes that include adverse reaction identification and corrective actions to be taken;
- (b) Investigating all transfusion reactions; and
- (c) Reporting all transfusion reactions to the appropriate officials and agencies.

Review the facility's procedures to ensure their process includes the positive identification of the blood or blood components to be transfused into the intended recipient.

If a facility has not established policies as referenced above **do not** cite here but cite under §483.70(d) Governing body, F837. Also consider requirements at §483.70(g) Medical director, F841 for the responsibility to implement resident care policies.

If a transfusion will be performed during the survey, observe the transfusion preparation process. Observe to determine whether or not a positive recipient verification and a second independent recipient verification were conducted prior to the initiation of the transfusion. If a surveyor has reason to suspect a resident is having an adverse reaction to a transfusion or the transfusion itself is not being properly administered, the surveyor shall immediately notify the facility Director of Nursing and the facility administrator.

Assure that blood and blood components are stored in a clean and orderly environment which ensures the integrity of the component. Whole blood, red blood cells, and thawed plasma shall be stored in accordance with §493.1103(c). If there are questions or concerns, consult with CLIA surveyors. If blood and blood components are not stored to ensure the integrity of these components do not cite here, cite under §483.45(h) - Storage of drugs and biologicals.

## **KEY ELEMENTS OF NONCOMPLIANCE**