Carter BloodCare

Date: September 6, 2016

To: Medical Directors, Laboratory Directors and Transfusion Services Managers

From: Laurie J. Sutor, MD, MBA
Vice President of Medical and Technical Services

Subject: Zika Virus Update

On August 26, 2016, FDA published a revised final Zika Guidance* requiring all donations collected in the United States to be tested with an Investigational Individual Donor Nucleic Acid Test (ID-NAT) for Zika virus under an investigational new drug application (IND). Implementation in the state of Texas is required within 4 weeks of the guidance issue date.

Carter BloodCare will implement testing of all blood donors for Zika virus under the IND on **September 23, 2016**.

Products tested and found negative for Zika RNA must include a statement that they are "NEGATIVE FOR ZIKA VIRUS BY AN INVESTIGATIONAL TEST" on their label. Please note that it is possible for your inventory to contain products that are both Zika negative and untested for Zika for up to one year following initiation of testing, specifically frozen products. The following statement will also be added to the Circular of Information: "Units labeled as negative for Zika virus RNA were tested with an investigational nucleic acid test (NAT) and found to be nonreactive." Transfusion facilities that manipulate blood components in house and do relabeling must also follow the Zika test labeling requirements.

As mentioned in our last memorandum, the FDA and our study sponsor have withdrawn the original requirement for patient transfusion consent to address the Zika IND in high risk patients (or any patients).

Upon implementation of testing, the fee for Zika testing will be applied to each red blood cell and apheresis platelet through a Zika surcharge. The fee distributes the actual cost of Zika testing to red blood cells and apheresis platelets based on historical shipments while taking into account concurrent products collected and produced from single donations.

* Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components. Guidance for Industry.
http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf

Product	Zika Testing Fee
Red Blood Cells	$5.54
Apheresis Platelets	$3.30

The Zika surcharge service codes and label examples will follow.

Feel free to contact me (lsutor@carterbloodcare.org or 817-412-5601) with questions or concerns.

Please direct billing questions to:
B.J. Smith (bjsmith@carterbloodcare.org; 817-412-5158) or
Veronica Moore (vmoore@carterbloodcare.org; 817-412-5328).