3.0 General Policies

3.1 Disaster Plan

Security and disaster preparedness have always been important areas for Carter BloodCare. Although it is impossible to predict any and all disasters that might occur, Carter BloodCare will make every possible effort to provide the blood and services necessary to support the healthcare organizations in our region.

In the event of an area-wide disaster, Carter BloodCare will enact its Emergency Response System. This system is designed to ensure adequate blood supplies are available where and when they are needed throughout the community. While Carter BloodCare maintains a stock inventory of blood and blood products, the majority of the inventory is located throughout the service area in the facilities served by Carter BloodCare. Once the Emergency Response System is activated, all major trauma centers will be contacted by a key Carter BloodCare employee who will provide specific instructions for blood routing and delivery. In the event that roads are deemed impassible, Carter BloodCare will make every effort available to ensure product delivery, enlisting the aid of state and local authorities and emergency response organizations. The main Carter BloodCare campus is equipped with back-up devices to ensure operational activities remain largely unaffected by area-wide disasters. Facilities will be kept updated on all relevant information throughout an emergency.

The key to any emergency or disaster response is good communication. Carter BloodCare's first response to any external emergency will be to mobilize our "Emergency Response Team" and make contact with the proper external governing authorities for communication. During most emergencies, Carter BloodCare will be able to send mass news release or advisories to media entities quite easily via fax and e-mail. The Public Relations Department maintains close relationships with local media to help ensure Carter BloodCare may continue to rely on their assistance in getting our message out.

3.1.1 Coordinating the Local Blood Supply during Disasters

3.1.1.1 Purpose

- Determine local medical need for blood.
- Facilitate transportation, if needed, of blood from one facility to another.
- Communicate a common message to the community about the status of the blood supply in the disaster-affected community

3.1.1.2 Introduction

Following the events of September 11, 2001, the blood banking community recognized the need to evaluate its actions in response to the tragedy, examine "lessons learned," and develop recommendations relating to its response to future domestic disasters and acts of terrorism. The recommendations are as follows:

- a) Control collections in excess of actual need
- b) Ensure that facilities maintain inventories to be prepared for disasters at all times in all locations (note that a seven-day supply of the combined inventory of both blood collectors and hospitals is recommended to be prepared for a disaster)
- c) Overall inventory management within the United States

3.1.2 Glossary of Terms

Current hospital admissions - disaster-related patients actually admitted to a hospital

Disaster – includes any domestic disaster or act of terrorism that: suddenly requires a much larger amount of blood than usual **OR** temporarily restricts or eliminates a blood collector's ability to collect, test, process, and distribute blood **OR** creates a sudden influx of donors, requiring accelerated drawing of blood to meet an emergent need elsewhere.

Expected hospital admissions – the potential for expected disaster-related (live) victims to be admitted to a hospital

Immediate medical need – the amount of Type O blood needed by the affected facility(ies) for disaster-related transfusion purposes within the first 24 hours of an event

Non-disaster-related need – the amount of blood needed for pre-disaster operations/transfusions

3.1.3 Carter BloodCare's Responsibilities

Carter BloodCare maintains contact with the offices of **Public Information and Emergency Management from Dallas, Tarrant, and McLennan counties.** All emergency or disaster-related information is to be distributed through systems already in place within these counties. The **Parkland Health and Hospital System** is the contact for the Dallas Emergency Management offices; the Fort Worth Emergency Management office is the contact for Tarrant County. Carter BloodCare participates on several local and regional emergency response committees.

In an effort to maintain good communication during a disaster event, Carter BloodCare routinely maintains: Master Telephone Lists, After Hours Contact Lists, Neighborhood

Donor Centers Listings, Emergency Contacts and Emergency Numbers, and Hospital and Hospital Blood Bank Contact Lists.

Contact local hospital customers and appropriate regional or national authorities to determine impact of event, including:

- a) Type of event (e.g. disaster, terrorism)
- b) Current and expected hospital admissions
- c) Current blood inventory levels of Type O RBC
- d) If blood is immediately needed, Carter BloodCare will distribute blood to hospital from existing Carter BloodCare inventories
- e) Interact with local, state and national agencies as appropriate
- f) Provide the hospitals with an appropriate message to be relayed to media requests. Hospitals may choose whether or not to use the message.
- g) If there is need for blood in excess of what is available in the local community, then arrangements will be made to coordinate the immediate shipment from other blood collector(s) with access to the most rapid means of transportation.
- NOTE: If hospital is supplied by more than one blood collector, report information to the primary supplier (to prevent duplication).

3.1.4 Customer's Responsibilities

3.1.4.1 Pre-Disaster Preparation Checklist

- a) Keep Carter BloodCare up-to-date with appropriate contacts at the hospital(s) to determine the complete medical need once an event occurs.
- b) Identify redundant contacts between the hospital and Carter BloodCare to ensure that communication can be established and maintained during an event.

3.1.4.2 During the Disaster

- a) Activate any previously devised contingency plans.
- b) Keep Carter BloodCare informed of current inventory levels of Type O RBC by returning a completed Hospital Medical Needs Assessment form.
- c) Identify contact person and best means of communication with that person
- d) Regularly communicate with Carter BloodCare until event has been resolved, especially about any changes in medical need for blood as soon as possible.
- e) Notify Carter BloodCare of interruptions to normal transportation methods, new points of delivery, or emergency staging areas.
- f) Act as liaison to resolve security/identification issues with drivers.

3.1.4.3 Working with the Media

When a disaster has occurred, it is imperative to inform the general public about blood supply needs. As past experience shows, many individuals will want to do all they can to help. Hospital transfusion services should coordinate messages about blood needs with Carter BloodCare. The hospital may wish to refer media inquiries to Carter BloodCare, or contact us for an appropriate message to convey.

3.1.5 Biological Attack Response Process

If a community is faced with a biological attack with infectious agent(s), the issues facing blood collectors and hospitals regarding the potential impact on the blood supply and medical needs will not necessarily mirror those that arise following other types of disasters. Biological attacks may or may not require more blood. By affecting donor suitability, a biological attack may substantially limit the blood supply. The impact on the donor population will depend on which biological agent is involved in a disaster. The spread of certain agents may require immediate deferral policies. (For example, FDA has developed deferral policies relating to small pox, in case there is an attack and/or a need for mass smallpox immunization).

3.1.6 Regulatory Concerns

While the availability of blood may be the primary concern in the event of a disaster, the safety of the blood supply is also paramount. Adherence to FDA regulations once an actual event has occurred is crucial. It is important to follow current good manufacturing practice (cGMP) and AABB Standards. Any consideration of regulatory exemptions will be driven by medical need and FDA policy.

Blood collection should be performed only by facilities that routinely collect allogeneic blood. Facilities that routinely collect only autologous blood or do not collect blood routinely should NOT collect allogeneic blood during times of disaster. Blood donor screening, collection, and labeling for autologous donors is quite different from the requirements for allogeneic donors, and must be performed by personnel who are trained in these functions.

Units of blood released for transfusion should be fully tested, including infectious disease testing. Transfusion services should maintain policies and procedures for emergency and exceptional release that may be applied if absolutely necessary to meet immediate needs.

Testing should be performed only by facilities that routinely test allogeneic blood. Infectious disease testing is highly regulated. Facilities that do not routinely test allogeneic blood may inadvertently fail to meet these stringent regulated testing requirements.

All regulated functions should be performed by existing trained staff. Volunteer personnel may be used for non-regulated functions only.

Carter BloodCare Crossmatch Service Manual © www.carterbloodcare.org

Unlicensed, registered allogeneic collection facilities may ship blood only within the state. In times of disaster, FDA may allow interstate shipment provided the product is appropriately labeled. FDA must grant permission prior to any such shipment.

3.1.7 Handling Internal Disasters at Carter BloodCare

Carter BloodCare maintains an internal disaster plan. In addition, most individual departments at Carter BloodCare have action and communication plans for their respective departments.

In the event of an emergency or disaster, **Carter BloodCare's "Emergency Response Team"** will meet to determine the nature, level of damage, or severity of the emergency/disaster situation. Carter BloodCare will immediately make the necessary contacts with the local, state and/or governmental agencies, coordinate with local hospitals that might be affected and contact all internal Directors/designees to insure a **coordinated direction of response**.

The facility in Bedford is designed to be self-sufficient to help maintain operations. The facility is equipped with the following redundant systems: air conditioning and heating, generated power, specially designed refrigeration equipment for blood storage, uninterrupted power sources, and duplicated processes for many of our critical operations. With the exception of a catastrophic disaster, directly to the campus, Carter BloodCare's facility in Bedford will be operational.

3.2 Blood Service Agreement Statement

Contact Information:

Hospital Relations Carter BloodCare 2205 Highway 121 Bedford, TX 76021

Phone: 817-412-5365 Fax: 817-412-5991

Carter BloodCare is required by regulating agencies to have a signed, current Blood Service Agreement on file before providing blood products and services to any facility. To initiate a Blood Service Agreement or to obtain a copy of your current Blood Service Agreement, please contact the Hospital Relations department. It is highly recommended that you maintain a copy of your current Blood Service Agreement on file.

3.3 Finance and Billing Policies

Contact Information:

Accounting & Finance Carter BloodCare 2205 Highway 121 Bedford, TX 76021 Phone: (817) 412-5123 or (817) 412-5139 Fax: (817) 412-5136

Carter BloodCare is a 501(c)(3) not-for-profit organization that provides critical transfusion services for our local communities. Carter BloodCare assesses fees directly to the hospital or facility for <u>services</u> rendered.

The hospital or facility placing the order for products or services is responsible for payment.

3.3.1 Third Party Payments

Carter BloodCare is unable to bill physicians, Medicaid, Medicare, patients or third-party payers.

3.3.2 Payment Options

You may pay by check or credit card. Visa®, MasterCard®, and American Express® are accepted; however, a percent service fee will be charged. Please contact Accounts Receivable for details.

3.3.3 Billing Periods

Billing invoices are sent to your facility at the end of each billing period, according to the following schedule:

- First period, $1 7^{th}$ days of month
- Second period, 8 14th days of month
- Third period, 15 21st days of month
- Fourth period, 22 end of month

3.3.4 Payment Terms

The total amount, as listed on the billing invoice, is due within 30 days of the invoice date.

3.3.5 Billing Transaction Documentation

The following chart outlines the different Carter BloodCare billing transaction documentation and when each is generated. An example of each document is included in the back of this section.

NOTE: Payment should be made from the weekly invoice only.

CBC BILLING DOCUMENT	GENERATED
*Weekly Invoice	Weekly summary of all billing transactions for the customer. NOTE: This is the document from which your Accounts Payable Department should pay.
Credit Memo	When a product (not physically returned) or a service is credited to the customer.
Debit Memo	When services not associated with a product are charged to the customer. <i>Example:</i> Reference and Transfusion associated fees.
Return Slip	When products are physically returned from the customer.
Pack List	When products and services associated with those products are delivered to the customer.

3.3.6 Weekly Invoice

Carter BloodCare produces a Weekly Invoice, which provides a comprehensive list of the transactions of the previous week. The Weekly Invoice provides information that:

- Identifies the customer being billed.
- Includes transactions by the customer within that billing period.
- Includes the total amount of each transaction.

Transactions made between the customer and Carter BloodCare are documented on one of the following forms. The forms are listed in the order they will appear on the Weekly Invoice:

- Credit Memo
- Debit Memo
- Return Slip
- Pack List

It is recommended that each of the billing transaction documents be reconciled with the products and services delivered or picked-up, at the time of the transaction. The level of information included in the Weekly Invoice allows customers to perform a second reconciliation of the documentation, but is not intended to replace the reconciliation performed at the time of transaction.

3.3.7 Credit Memo

A Credit Memo is issued to a customer to correct any billing inaccuracies. It is also used to show a product credit when the product cannot be physically returned to Carter BloodCare.

The Credit Memo details the following information:

- The customer receiving the credit
- The products and services that were credited
- The reason for the credit
- The amount of the credit

Each Credit Memo is identified by a unique credit identification number beginning with the prefix "CM". The Credit Memo can be reconciled with the Weekly Invoice by matching the credit identification number to the transaction number recorded on the Weekly Invoice.

3.3.8 Debit Memo

The Debit Memo is issued to a customer who has ordered special services. If a service is ordered for a specific patient, the patient's name will appear on the Debit Memo.

Each Debit Memo is identified by a unique debit identification number beginning with the prefix "DM". The Debit Memo can be reconciled with the Weekly Invoice by matching the debit identification number to the transaction number recorded on the Weekly Invoice.

3.3.9 Return Slip

The Return Slip is issued whenever a product is physically returned to Carter BloodCare.

The Return Slip details the following information:

- The customer returning the product
- The product returned
- The reason for the return
- The dollar credit of the return.

Each Return Slip is identified by a unique return identification number beginning with the prefix "RT". The Return Slip can be reconciled with the Weekly Invoice by matching the return identification number to the transaction number recorded on the Weekly Invoice.

3.3.10 Pack List

A Pack List is issued whenever products are shipped to a facility.

The Pack List provides the following information:

- Information identifying the person that placed the order
- A summary of the order
- Details on each product and associated service provided
- The cost of those products and services
- If special products are ordered for a specific patient, the patient's name will appear on both the Pack List and the Weekly Invoice

Products from multiple orders can be shipped in the same shipment, resulting in Pack Lists that have products from two or more orders listed. Products from the same order can also be shipped on multiple shipments, resulting in two different Pack Lists for the same order.

Each Pack List is identified by a unique identification number.

- The prefix for each Pack List is "SH"
- The next six digits are the date the order was packed and shipped
- The next two letters signify the status of the order
- The last four digits represent the order number

The Pack List can be reconciled with the Weekly Invoice by matching the identification number to the transaction number recorded on the Weekly Invoice.

3.3.11 Questions

For any questions related to any financial services listed in this section, please contact the Finance and Billing department.

3.4 Notification of Policy Changes

Carter BloodCare periodically updates processes and policies to remain on the forefront of transfusion medicine and to meet customer needs. Examples of such changes may include:

- New blood products
- New technologies
- New tests for infectious diseases
- New or revised forms

If the process or policy change affects customers, a detailed memo outlining the change, the effective date, and how the change will impact customers will be sent. In most cases, notice will be provided at least <u>30 days prior to</u> the change. However, due to unforeseen mandates by regulating agencies, regulating committees or product manufacturers, it may be necessary to implement a change before a 30-day notice can be given. In these rare cases, notification of the change will be given with as much advance notice as possible.

3.5 Forms

- Weekly Invoice
- Credit Memo
- Debit Memo
- Return Slip
- Pack List