64J-2.021 Trauma Center Readiness

(1) As used herein, the term:

(a) "Blood products" means human whole blood and transfusable components including red blood cells, platelets, plasma, Cryoprecipitated Antihemophilic Factor, and granulocytes.

(b) "Continuity plan" means a written policy detailing procedures and information designed to keep a trauma center's critical operations running during a period of displacement or interruption of normal operations. A continuity plan must include: 1) a procedure for the cessation of non-emergent in-facility procedures or procedures where patients are likely to need blood products to preserve the existing supply of onsite blood products; and 2) a procedure for the regular performance of secure, redundant on-site and off-site data backups and verification of the restorability of backed-up data. Off-site data backups must not be stored outside the continental United States.

(c) "Data" means information and representations of information, knowledge, facts, concepts, documents, instructions, images, and recordings, whether humanly-perceivable or machine-readable, in any form, and whether in use, storage, physical or electronic transit, or presented on a display device.

(d) "Disaster" means an emergency occurrence or information technology incident beyond the control of the trauma center, whether accidental or intentional, and whether natural, technological, or manmade, which impairs the trauma center's normal operations or renders the trauma center inoperable at its verified premises.

(e) "Information technology" means equipment, hardware, software, firmware, programs, systems, networks, infrastructure, media, and related material used to automatically, electronically, or wirelessly collect, receive, access, transmit, display, store, record, retrieve, analyze, evaluate, process, classify, manipulate, manage, assimilate, control, communicate, exchange, convert, converge, interface, switch, or disseminate data of any kind or form.

(f) "Information technology incident" means an observable occurrence or data disruption or loss in an information technology system or network that permits or is caused by unauthorized access of data in electronic form. Good faith access by an authorized employee or agent of a trauma center or blood product supplier does not constitute an information technology incident, provided that the data is not used in an unauthorized manner or for an unauthorized purpose.

(2) A Level I, Level II, or Pediatric trauma center must have a continuity plan that includes the following:

(a) Procedures for the restoration of critical operations at the trauma center's verified premises or at a temporary location.

(b) Procedures for the secure restoration of backed-up data and reporting of information technology incidents.

(c) Written agreements with at least two suppliers of blood products sufficient to ensure that blood products will be available 24 hours per day, 365 days per year, for all trauma patients treated at the trauma center.

1. Agreements that make the provision or purchase of blood products exclusive to a single supplier are prohibited.

2. At least one supplier must have the ability to deliver, within 24 hours of the trauma center's request, blood products sourced from outside the state of Florida independently of the Association for the Advancement of Blood & Biotherapies, the terms of any mutual aid agreement, or the action of any state or federal agency.

(d) A written policy signed by the trauma medical director and the blood bank medical director that details how blood products will be rationed if either the trauma medical director or the blood bank medical director determines, notwithstanding the federal or state declaration of a state of emergency in the trauma service area in which the trauma center is located, that a disaster is likely to deplete the trauma center's existing supply of blood products or the supply of blood products that are scheduled or available for delivery to the trauma center within 45 days of the date of the determination ("future supply").

(e) Procedures for maintaining a record of the 365-day rolling daily average of their supplies of existing blood products.

(3) A Level I, Level II, or Pediatric trauma center must notify the department and the Agency for Health Care Administration within 24 hours of the occurrence or discovery of any disaster which impairs the trauma center's normal operations or renders the trauma center inoperable.

Rulemaking Authority 395.401(2), 395.4025(9), (10), 395.405 FS. Law Implemented 395.401(2), 395.4025(9), (10), 395.405 FS. History–New, _____.