Redline of Proposed Changes to Chapter Number 0720-20 Standards for Ambulatory Surgical Treatment Centers

0720-20-.01 DEFINITIONS.

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- (7) Ambulatory surgical treatment center (ASTC). Any institution, place or building devoted primarily to the maintenance and operation of a facility for the performance of surgical procedures. Such facilities shall not provide beds or other accommodations for the stay of a patient to exceed twelve (12) hours duration, provided that the length of stay may be extended for an additional twelve (12) hours in the event such stay is deemed necessary by the attending physician, the facility medical director, or the anesthesiologist for observation or recovery, but in no event shall the length of stay exceed twenty-four (24) hours. Individual patients shall be discharged in an ambulatory condition without danger to the continued well-being of the patients or shall be transferred to a hospital. Excluded from this definition are the private physicians' and dentists' office practices. For the purposes of this rule, those medical and denal offices, facilities, and other settings at which surgical procedures exclusively are performed are ASTC's and not private office practices. ASTC's must comply with the following for purposes of these regulations:
 - Surgical procedures performed must be limited to those procedures which are commonly
 performed on an inpatient basis in hospitals but may safely be performed in an ASTC;
 - (b) If anesthesia is required for a surgical procedure, it must be local, regional or general anesthesia and routinely be four (4) hours or less in duration;
 - (c) Surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, or are considered emergency or life-threatening in nature may not be performed.

ASTC's may not perform surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, or are considered emergency or life threatening in nature.

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(16) Commission. Health Facilities Commission.Commissioner. Commissioner of the Tennessee Department of Health or his or her authorized representative.

. . . .

Regulated Waste. Liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials, as defined in United States Department of Labor Occupational Safety & Health Administration, 1910.1030, Bloodborne Pathogens.

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0720-20-.03 Disciplinary Procedures

(5) If the same or different deficiencies are cited on the third revisit survey, then the department may pursue disciplinary action against the facility before the board, including seeking reimbursement for the un-recouped costs associated with subsequent revisit surveys that were incurred by the department. ...

- (7) Order of Compliance This procedure is available only when a petitioner has completely complied with the provisions of a previously issued disciplinary order, including an unlicensed or uncertified practice civil penalty order, and wishes or is required to obtain an order reflecting that compliance.
 - (a) The Board will entertain petitions for an Order of Compliance as a supplement to a previously issued order upon strict compliance with the procedures set forth in subparagraph (b) in only the following three (3) circumstances:
 - When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued reflecting that compliance; or
 - 2. When the petitioner can prove compliance with all the terms of the previously issued order and is seeking to have an order issued lifting a previously ordered suspension or probation; or

(b) Procedures

- 1. The petitioner shall submit a Petition for Order of Compliance, as contained in subparagraph (c), to the Board's Administrative Office that shall contain all of the following:
 - (i) A copy of the previously issued order; and
 - (ii) A statement of which provision of subparagraph (a) the petitioner is relying upon as a basis for the requested order; and
 - (iii) A copy of all documents that prove compliance with all the terms or conditions of the previously issued order. If proof of compliance requires testimony of an individual(s), including that of the petitioner, the petitioner must submit signed statements from every individual the petitioner intends to rely upon attesting, under oath, to the compliance. The Board's consultant and administrative staff, in their discretion, may require such signed statements to be notarized. No documentation or testimony other than that submitted will be considered in making an initial determination on, or a final order in response to, the petition.
- 2. The Board authorizes its consultant and administrative staff to make an initial determination on the petition and take one of the following actions:
 - (i) Certify compliance and have the matter scheduled for presentation to the Board as an uncontested matter; or
 - (ii) Deny the petition, after consultation with legal staff, if compliance with all of the provisions of the previous order is not proven and notify the petitioner of what provisions remain to be fulfilled and/or what proof of compliance was either not sufficient or not submitted.
- If the petition is presented to the Board the petitioner may not submit any additional documentation or testimony other than that contained in the petition as originally submitted.
- 4. If the Board finds that the petitioner has complied with all the terms of the previous order an Order of Compliance shall be issued.

	<u>5.</u>	If the petition is denied either initially by staff or after presentation to the Board and the petitioner believes compliance with the order has been sufficiently proven the petitioner may, as authorized by law, file a petition for a declaratory order pursuant to the provisions of T.C.A. § 4-5-223 and Rule 1200-10-111.
(c)		Form Petition
		on for Order of Compliance d of Social Worker Licensure
		oner's Name: oner's Mailing Address:
		oner's E-Mail Address: bhone Number:
	Attor	ney for Petitioner:
		ney's Mailing Address:
		ney's E-Mail Address: phone Number:
	that	petitioner respectfully represents, as substantiated by the attached documentation, all provisions of the attached disciplinary order have been complied with and I am ectfully requesting: (circle one)
	1.	An order issued reflecting that compliance; or
		An order issued reflecting that compliance and lifting a previously ordered ension or probation; or
	of the testine every Board state	— You must enclose all documents necessary to prove your request including a copy e original order. If any of the proof you are relying upon to show compliance is the mony of any individual, including yourself, you must enclose signed statements from y individual you intend to rely upon attesting, under oath, to the compliance. The d's consultant and administrative staff, in their discretion, may require such signed ments to be notarized. No documentation or testimony other than that submitted will considered in making an initial determination on, or a final order in response to, this on.
	Resp	pectfully submitted this the day of , 20 .
		Petitioner's Signature

0720-20-.10 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each ambulatory surgical treatment center must develop, maintain and implement written policies and procedures for the definition and handling of its <u>infectious regulated</u> and hazardous wastes <u>...</u>

†These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.

- (2) The following waste shall be considered to be infectious regulated waste:
 - (a) liquid or semi-liquid blood or other potentially infectious materials (OPIM);
 - items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed;
 - items that are caked with dried blood or OPIM and are capable of releasing these materials during handling;
 - (d) contaminated sharps; and
 - (e) pathological and microbiological wastes containing blood or OPIM.
 - (a) Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals";
 - (b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures:
 - (c) Waste human blood and blood products such as serum, plasma, and other blood components;
 - Pathological waste, such as tissues, organs, body parts, and body fluids that are removed during surgery and autopsy;
 - (e) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;
 - (f) Contaminated carcasses, body parts, and bedding of animals that were exposed to pathogens in research, in the production of biologicals, or in the in vivo testing of pharmaceuticals;
 - (g) Other waste determined to be infectious by the facility in its written policy.
- (3) Infectious and hazardous Regulated waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.
- (4) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.
 - (a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed;

- (b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of <u>infectious_regulated_waste</u> must be conspicuously identified. Packages containing <u>regulated_infectious</u> waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards:
- (c) Reusable containers for infectious regulated waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste;
- (d) Opaque packaging must be used for pathological waste.
- (5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.
 - (a) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal;
 - (b) Plastic bags of regulated infectious waste must be transported by hand.

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(8) Except as provided otherwise in this section a facility must treat or dispose of <u>regulated</u>infectious waste by one or more of the methods specified in this part.

(a) A facility may treat regulatedinfectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious wastes treated in such a device are rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Regulated Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectioushazardous. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (nonhazardous) solid waste under current rules of the Department of Environment and Conservation.

- (b) The facility may discharge liquid or semi-liquid regulated infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §§ 69-3-101 et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.
- (c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

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(11) All garbage, trash and other non-infectious hazardous wastes shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, be constructed of easily cleanable material and be kept on elevated platforms.

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