Tissue Banks Comments 10.50.01

	Date and Time Submitted	Name of Submitter and Organization	Comment(s)	OHCQ Response
1	03/01/24 12:10 PM	Bill Speir, Plasma Protein Therapeutics Association	10.50.03 Definitions. We would recommend adding “or for further manufacturing” to the definition of “Tissue Bank” found in (31)(a). (31) Tissue Bank. (a) "Tissue bank" means an establishment that obtains, stores, processes, distributes, or sells human blood or other human tissue for use in the human body or for further manufacturing.	The language "or for further manufacturing" will not be included in the regulations. The definition of Tissue Banks in the regulations is the same language as in the statute, HG 17-301 (c) (1) (2) and any change in this definition would require a statutory change. The law states the definition of "tissue bank means an establishment that obtains, stores, processes, distributes, or sells human blood or other human tissue for use in the human body".
2	03/01/24 12:16 PM	Keosha Barrett, CSL Plasma Inc	I want to thank the department for the revised regulations. We know the restraints the Department is under to include Plasma Centers under the tissue banking license, but we look forward to continuing to work through the appropriate channels for the issues. I do have one question about the Personnel Section for the Technical Director. I do appreciate that you added the additional option of the RN, but I am hoping that the regulations can clarify the position on if multiple qualified individuals can function in that role. For most Plasma centers we are open for more than 40 hours a week so it limits our business if only one person can function in that role.	The draft regulation does not place a limitation on the number of designated qualified employees; therefore, there is no prohibition to delegate to multiple employees.
3	03/07/24 9:32 AM	Roger Brinser, BioLife Plasma Services - Plasma Derived Therapies Takeda Pharmaceutical Company Limited	COMAR 10.50.03 B(22) Qualified Person We are requesting clarification on the training and experience requirement for the qualified person to perform one or more responsibilities by the Technical Director or Medical Director. A few examples include: Sec.10.50.01.10 B(3)(b) This section indicates a Medical Director may delegate to a qualified person the evaluation and determination of each donor’s acceptability. Takeda interprets this requirement as met if the qualified person meets the requirements of 21 CFR 630.5. Sec.10.50.01.10 C(2) This section indicates a Technical Director may delegate to a qualified person on-site supervision of tissue bank operations and personnel during the tissue bank’s regular hours of operation. Takeda interprets this requirement as met if the qualified person meets the requirements of 21 CFR 630.5.	The request to include DHHS Food and Drug Administration regulation 21 CFR 630.5 will not be included in COMAR 10.50.01. These federal regulations do not relate to state's oversight of tissue banks. The draft regulation does not place a limitation on the number of designated qualified employees. There is no prohibition to delegate to multiple employees.
4	03/07/24 9:33 AM	Roger Brinser, BioLife Plasma Services - Plasma Derived Therapies Takeda Pharmaceutical Company Limited	COMAR 10.50.01.04 B(3) Incorporation by Reference (2) American Association of Blood Banks, 29th Edition should be updated to reflect the association current name Association for the Advancement of Blood and Biotherapies, current edition. (3) PPTA Voluntary Standards Program (Plasma Protein Therapeutics Association) We request this be Takeda 1200 Lakeside Drive Bannockburn, IL 60015 amended to state International Quality Plasma Program (iQPP) Standards (Plasma Protein Therapeutics Association) which more accurately reflects the reference document	The Incorporation by Reference section has been updated to include Association for the Advancement of Blood and Biotherapies and International Quality Plasma Program Standards.

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5	03/07/24 9:33 AM	Roger Brinser, BioLife Plasma Services - Plasma Derived Therapies Takeda Pharmaceutical Company Limited	COMAR 10.50.01.06 E Change of Technical Director, Medical Director (1) Notify the OHCQ 10 days before a change occurs; and (2) Apply to the OHCQ for an amended permit or provisional permit within 30 days after a change takes place. Comment: These changes can occur without prior knowledge, however facilities routinely operate with more than one individual that qualifies as Technical Director including the Medical Director. We request notification is only required with a change in Medical Director.	Technical Director has been removed from the notification section of 10.50.01.06 Permits - Change of Medical Director name or location. Thank you for your contribution to the regulatory process.
6	03/07/24 9:34 AM	Roger Brinser, BioLife Plasma Services - Plasma Derived Therapies Takeda Pharmaceutical Company Limited	COMAR 10.50.01.12 Tissue Bank Standards — Technical In addition to the requirements and standards in this chapter, where applicable, we request the addition of the technical requirement for Source Plasma: L. International Quality Plasma Program (iQPP) Standards (Plasma Protein Therapeutics Association) Takeda is committed to delivering the safest donation process from start to finish and this update increases the qualified candidate pool for the Technical Director role by expanding requirements to include appropriate healthcare providers. Plasma-derived therapies make a vital difference in the lives of people with rare and complex chronic diseases such as hemophilia, immunodeficiencies, hereditary angioedema, and alpha-1 antitrypsin deficiency. For many patients, some of whom live in Maryland, these therapies are often the only treatment option. Global demand for these lifesaving and life-sustaining therapies has increased dramatically over the last 20=--- years and continues to grow. Since plasma-derived therapies can only be produced using human plasma, enabling a sustainable supply of plasma to meet the growing patient demand for plasma therapies is crucial. BioLife invests approximately $4 6M in initial capital investment in each center. We also work closely with local vendors and suppliers to help foster a broader economic impact in the local community. In addition, our employees and donors infuse many millions in the local area as a result of donor compensation and employee wages, an estimated $4-5 million per year for each center. Our employees participate in local activities and organizations, volunteer in the community, establish partnerships with municipal leaders and support educational programs. We are grateful for the Department’s willingness to establish a process that would allow Source Plasma donation centers to operate according to uniform, well-established standards for safety, our partnership with you throughout the regulatory process.	OHCQ has included International Quality Plasma Program Standards in the Incorporation by Reference section of the regulations. Thank you for your contributions to Maryland's Tissue Bank Regulations.
7	03/12/24 9:12 AM	Bill Speir, Plasma Protein Therapeutics Association	.04 Incorporation by Reference. We would recommend switching the reference in Paragraph (3) to the PPTA International Quality Plasma Program (Plasma Protein Therapeutics Association) since it is the PPTA voluntary standard that applies to source plasma donation centers. (3) PPTA Voluntary Standards Program International Quality Plasma Program (Plasma Protein Therapeutics Association); We would recommend adding a new paragraph (7) to this section that references the CFR sections that apply to source plasma donation. (7) 21 CFR 630 and 640, as amended.	The Incorporation by Reference section has been updated to include Association for the Advancement of Blood and Biotherapies and International Quality Plasma Program Standards. The request to include DHHS Food and Drug Administration regulations 21 CFR 630 and 640 will not be included in COMAR 10.50.01. These federal regulations do not relate to state's oversight of tissue banks.

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8	03/12/24 9:12 AM	Bill Speir, Plasma Protein Therapeutics Association	The Plasma Protein Therapeutics Association appreciates this opportunity to provide informal feedback on proposed regulatory changes to COMAR 10.50.01 Tissue Banks. We would like to thank the Office of Health Care Quality (OHCQ) for proposing these changes that will improve source plasma donation in Maryland. Source Plasma is defined in 21 CFR 640.60 “as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. The definition excludes single donor plasma products intended for intravenous use.” Our members operate 11 of the 17 source plasma donation centers in Maryland. The source plasma donated at these centers is used as the starting material for plasma-derived therapies including immune globulins, albumin, and blood clotting factors. We do have a few recommended changes to the proposed regulations to offer. It is our hope that these recommendations will assist OHCQ in their efforts to improve the regulations.	The request to include DHHS Food and Drug Administration regulations 21 CFR 640.60 will not be included in COMAR 10.50.01. These federal regulations do not relate to state's oversight of tissue banks. The definition of source plasma will not be included in the regulations. The definition of Tissue Banks in the regulations is the same language as in the statute, HG 17-301 (c) (1) (2) and any change in this definition would require a statutory change. The law states the definition of "tissue bank means an establishment that obtains, stores, processes, distributes, or sells human blood or other human tissue for use in the human body".
9	03/13/24 11:14 AM	Emily Ogden, CSL Plasma	Comments from letter separated into individual rows.	N/A
10	03/20/24 2:43 PM	Emily Ogden, CSL Plasma	Section 10.50.01.03 – Definitions (22) "Qualified employee" means an employee who has been delegated one or more responsibilities by the technical director or medical director and who possesses the training and experience to perform the responsibility. CSL Plasma seeks greater clarification that the “qualified employee” can be more than a single individual for purposes of fulfilling the responsibilities delegated by the technical director or medical director. Our centers operate more than 40 hours a week, being open on weekends and extended hours of the day, and thus we would require more than a single individual to serve in the role as “qualified employee” during the multiple shifts of our operating hours.	The draft regulation does not place a limitation on the number of designated qualified employees. There is no prohibition to delegate to multiple employees.

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11	03/20/24 2:44 PM	Emily Ogden, CSL Plasma	Section 10.50.01.10(C) – Tissue Bank Standards – Personnel (2) Responsibilities. The technical director shall oversee and be responsible for all technical aspects of the tissue bank's operations and shall retain the overall responsibility when a task is delegated to a qualified employee. The technical director or qualified employee shall: (a) Provide on-site supervision of tissue bank operations and personnel during the tissue bank's regular hours of operation; and (b) Participate in and actively supervise the tissue bank's: (i) Planning; (ii) Organization; iii) Staffing; (iv) Training and continuing education; (v) Staff competency; (vi) Quality control and quality assurance; (vii) Standard operating procedures (SOPs); (viii) Facilities; (ix) Donor selection; (x) Equipment; (xi) Products; (xii) Records; (xiii) Services; and (xiv) Compliance with the requirements and standards of this chapter. CSL Plasma seeks greater clarification regarding who may be delegated these responsibilities in our plasma centers. Each of our centers employ “managers” who are responsible for administrative duties within the center; this includes but is not limited to staffing, planning, center organization, and ensuring compliance with state requirements and standards. We appreciate your consideration of these changes in the regulations governing tissue banks in Maryland. As we have communicated with you previously, we still believe that source plasma should not be regulated as tissue, but we also understand the constraints the department is under due to the definition included in statute. We will continue to look for ways to appropriately resolve this issue going forward. Thank you again for the ability to submit these comments and requests for clarification. We look forward to working with you to bring these draft regulations to their final stage. We would be very pleased to answer any questions you have or to continue to discuss these concerns.	The proposed regulation does not place a limitation on the number of designated qualified employees; There is no prohibition to delegate to multiple employees. The definition of source plasma will not be included in the regulations. The definition of Tissue Banks in the regulations is the same language as in the statute, HG 17-301 (c) (1) (2) and any change in this definition would require a statutory change. The law states the definition of "tissue bank means an establishment that obtains, stores, processes, distributes, or sells human blood or other human tissue for use in the human body".