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Non-Direct Healthcare Services Questionnaire

Instructions:

- This questionnaire must be completed in addition to the Healthcare Facility General Application for Liability Insurance.
- Please print or type clearly all responses and answer all questions as instructed.
- If you need more space for a response, continue in the Comments section of this questionnaire or attach a separate sheet of paper.
- Coverage will not be considered until this questionnaire and the general application are completed and all required documents are provided.

Name of Applicant: _____
(Whenever used, the term "Applicant" shall mean all entities proposed for coverage.)

Indicate the type of service(s) provided by the Applicant and complete the sections as instructed.

TYPE OF SERVICE	QUESTIONNAIRE INSTRUCTIONS
☐ Laboratory	Complete Sections A and B
☐ Pharmacy	Complete Sections A and C
☐ Blood/Plasma Bank	Complete Sections A and D
☐ Organ Bank	Complete Sections A and E

A. General Information

1. Specify where services are provided:

   ☐ Free Standing ☐ Hospital ☐ Outpatient Facility
   ☐ Inpatient Facility ☐ Long Term Care Facility ☐ Physician Office
   ☐ Other (specify): _____

2. Is the Applicant involved in any research activities? ☐ Yes ☐ No
   If yes, please describe the research activity in the Comments section.

3. Include all states in which business is conducted: _____

4. Are management services performed for other facilities? ☐ Yes ☐ No
   If yes, please describe the services provided in the Comments section.

B. Laboratory

1. Does the Applicant provide any of the following services?

   ☐ Assisted Reproductive Treatment/Techniques
   ☐ Paternity Testing
   ☐ Cytology

2. Is sperm or embryo storage provided? ☐ Yes ☐ No

C. Pharmacy

1. Does the Applicant manufacture any drugs or drug products? ☐ Yes ☐ No
   If yes, please describe in the Comments section.

2. Are any of the following services provided? Please indicate if not applicable. ☐ N/A

☐ Administration of Medication ☐ Case Management ☐ Compounding
☐ Pain Management ☐ Patient Monitoring

If any of these services are provided, please further describe the service in the Comments section and include the percentage these services represent in comparison to all services provided.

D. Blood/Plasma Bank

1. Does the Applicant check with the Donor Deferral Register before donor blood is taken and/or transfused? ☐ Yes ☐ No
2. Is a list of deferred donors maintained to prevent the use of collections from them? ☐ Yes ☐ No
3. Is Nucleic Acid Testing (NAT) performed?
   If yes, what percentage of blood is tested by this means? %
4. Is leukoreduction performed? ☐ Yes ☐ No
5. Is pathogen inactivation performed? ☐ Yes ☐ No
6. Have FDA recommendations been implemented for the following:
   a. Preventative measures to reduce the possible risk or transmission of CJD and VCJD? ☐ Yes ☐ No
   b. Assessment of donor suitability and blood and blood product in cases of possible exposure to anthrax? ☐ Yes ☐ No
   c. Questions related to potential donors who have recently received the smallpox vaccine? ☐ Yes ☐ No
   d. Quarantine and disposition of prior collections from donors with repeatedly reactive screening tests for HCV? ☐ Yes ☐ No
7. Is Applicant involved in any operations other than blood banking? ☐ Yes ☐ No
   If yes, describe in the Comments section.
8. Does Applicant contract with another facility to test blood on their behalf? ☐ Yes ☐ No
   If yes, please answer the following questions.
   a. Is there a contract in place between Applicant and the other facility? ☐ Yes ☐ No
   b. What professional liability limits does Applicant require the facility to carry? $ _____
   c. Is a copy of their most recent FDA report kept on file? ☐ Yes ☐ No
   d. Provide the type of test(s) and total number of tests performed on an annual basis: _____

E. Organ/Sperm/Embryo Bank

1. What is handled, stored or processed by the Applicant?

☐ Tissue ☐ Organ ☐ Sperm ☐ Embryo ☐ Bone Marrow
☐ Other (specify): _____

2. Indicate which types of services are provided?

☐ Recovery ☐ Processing ☐ Storage ☐ Evaluation ☐ Distribution
☐ Determination of Donor Eligibility ☐ Other (specify): _____

3. What is the percentage of donor distribution?

Donor Distribution	Percentage	Donor Distribution	Percentage
For Transplant	%	For Teaching	%
For Research	%	Other (describe):	%

4. Is infectious disease testing performed by an outside laboratory? ☐ Yes ☐ No
   If yes, is the laboratory: ☐ registered with the FDA ☐ CLIA certified
5. Are Applicant's refrigerators calibrated against the National Institute of Standards and Technology (NIST) standard thermometer at least annually? ☐ Yes ☐ No
6. In the event of a power failure, is there an emergency power supply? ☐ Yes ☐ No
   If no, what emergency plans are in place? _____
7. Does each specimen have a unique identification number to allow tracking and recall? ☐ Yes ☐ No
8. Is each specimen individually packaged and sealed with tamper-evident seals? ☐ Yes ☐ No
9. Has the Applicant had any adverse events, recalls, warnings and/or withdrawals related to donation? ☐ Yes ☐ No
   If yes, describe in the Comments section.

F. Comments

Section and Question	Comments

Applicant Signature _____ Title _____ Date _____