

Board of Health Proposed Rules Pertaining to Milk Bank Standards

The Arkansas Department of Health, Center for Health Advancement and Public Health Lab, invited the public to comment on proposed new rules “To Establish Arkansas Standards for Human Breast Milk; and to Encourage the Development of Human Breast Milk Depositories and Banks in Arkansas,” pursuant to Act 216 of 2019. See Ark. Code Ann. 20-7-140. Copies of the proposed Rules were available for public inspection and copying at the Center for Health Advancement, 4815 West Markham Street, Little Rock, Arkansas 72205. The rules are available on the internet at <https://www.healthy.arkansas.gov/proposed-new-rules> . The public was also invited to submit written comments to: Comments – Milk Bank Rules, ADH Center for Health Advancement, 4815 West Markham, Slot 41, Little Rock, AR 72205, so that the comments were received no later than 4:30 PM on September 3, 2020. Two commenters provided comments as summarized below:

Summary of Public Comments and ADH Responses September 2020

Commenter’s Name:

American Association for Laboratory Accreditation (A2LA)

Commenter’s Business/Agency: A2LA is a non-profit, accreditation body with over 3750 actively accredited certificates representing all 50 states and international, including 27 organizations accredited in Arkansas.

A. Summary of Comment:

Specific to the use of the ISO/IEC 17025 standard for medical testing and calibration, the recommended language is inserted in **bold**. In section 4.4.3, the requirements specify “A CLIA certified high complexity clinical laboratory or an ISO 17025 accredited clinical laboratory does the tests...” Please note that an ISO standard exists that is based on ISO/IEC 17025 and ISO 9001 but specifies requirements for quality and competence that are particular to medical laboratories. We recommend that 4.4.3 be revised to “**A CLIA certified high complexity clinical laboratory or an ISO 15189 accredited clinical laboratory, that achieved accreditation from an International Laboratory Accreditation Cooperation recognized accreditation body, does the tests...**”

Agency’s response to Comment:

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe. After consultation with the Director of the Public Health Laboratory, the recommended change is made as suggested.

B. Summary of Comment:

In section 15.3.2, the requirements specify, “Thermometers may be certified calibrated by National Institute of Standards and Technology (NIST) (or similar agency), or calibrated quarterly by the milk bank using an NIST certified reference thermometer. The milk bank must keep records of calibration.” It is industry practice to rely on NIST calibration or rely on an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized

accreditation body for calibration of the reference thermometers. Then the milk bank may verify working thermometers against the reference thermometers.

We recommend the following revision to section 15.3.2: “Thermometers may be calibrated by a national metrology institute (NMI) such as the National Institute of Standards and Technology (NIST) or an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body, for the calibration of the reference thermometers. The milk bank shall verify working thermometers against the calibrated reference thermometers at least quarterly. The milk bank must keep records of the calibration and verification records.”

Agency’s response to Comment:

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe. After consultation with the Director of the Public Health Laboratory, the recommended change is made as suggested.

Commenter’s Name:

Scott Eaker, Chief Operations Officer, Prolacta Bioscience

Prolacta is a national hospital provider of human milk-based nutritional products, which are currently used in Arkansas.

C. Summary of Comment:

Section 2. Definitions

2.11 – Milk Donor – This definition refers to, “a lactating woman who voluntarily contributes milk to a human milk bank.” Some milk banks remunerate donors for their milk, and some do not. Act 216 of 2019 makes no mention of remuneration received by donors. We request that the definition is amended to read as follows, “A lactating woman who voluntarily contributes milk to a human milk bank.” A donor may or may not be remunerated.

Agency’s response to Comment:

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe. After consideration of the proposed language to this definition, the recommended change is made.

D. Summary of Comments:

Section 2. Definitions

2.6 – Donor Human Milk. This section refers to donor human milk as milk pasteurized using the Holder Pasteurization Method. We request this is amended to read, “donated by lactating women, pasteurized using the Holder Pasteurization Method subjected to a validated pathogen inactivation method, and dispensed...”

2.6.3 – “Bioburden Reduced Milk”,

and that the specifics of the Holder Pasteurization are replaced to read as follows, “fresh-raw and/or fresh-frozen milk that has been heated to 62.5 degrees Celsius, for 30 minutes subjected to a validated method of pathogen reduction.”

2.12 – Milk Processing Centers –this subsection should be omitted.

Agency’s response to Comments:

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe. After consideration and consultation with a Senior Medical Advisor, the recommended changes to these definitions will not be made at this time, but will be considered at the next regular review of these rules.

E. Summary of Comments:

Section 3. Administrative Structure

3.1 –add Medical Director within the Administrative Structure

Section 4. Donor Qualifications/Screening

4.2 – and 4.4.1—revise Electronic communication

4.4.3 –revise Requalifying donor and 4.4.3.1 –Donor communication

4.4.4 –provide for Medical Director review

4.4.4.5 –revise Prospective donors medications

Section 6. Exclusion Criteria

6.10 – remove Redundant language

6.12 – amend Vegans and supplemental nutrition

Section 7. amend Tattoo temporary disqualification

Agency’s response to Comments:

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe. After consideration and consultation with an ADH Senior Medical Advisor, the recommended changes to the administrative structure, qualifications, and exclusion will not be made at this time, but will be considered at the next regular review of these rules in 2021.

F. Summary of Comments:

Section 8. Serological Tests

8.1 – Screening consistency throughout the guidelines, proposed “within 6 months prior to a woman’s becoming a donor.”

Section 26 – Milk Bank Records

26.1.2 – In line with the comments made re. subsection 8.1, we would like for the serology testing to be consistent throughout the guidelines.

Agency’s response to Comments:

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe. After consideration of the proposed language, the recommended changes for serology testing are made for consistency.

G. Summary of Comments:

Section 9 – revise Donor Approval
Section 11 – clarify Donor Education and Procedures in 11.2 – Instructions
Section 12 – review Procedure Manual every two years
Section 14 – clarify Equipment
Section 15 – suggested language change for Thermometers
Section 17 – remove Thermometer Calibration Procedure
Section 23 – revise Aliquoting and Heat Processing and 23.2– Heat Processing.
23.4.1 – revise Labeling of Milk expiration.

Agency’s response to Comments:

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe. After consideration and consultation with an ADH Senior Medical Advisor, the recommended changes to the donor approval and education, procedure manual, equipment, thermometers, aliquoting and heat processing, and labeling will not be made at this time, but will be considered at the next regular review of these rules in 2021.

H. Summary of Comment:

23.6.1 –Revise requirement of “the microbiology Standards of Practice (SOP) available in their banks, distributed by Human Milk Bank Association of North America (HMBANA),” which would require all milk banks to comply with the SOPs put forth by another milk bank. Instead, we suggest the rules require compliance with the FDA’s Bacteriological Analytical Manual (BAM).

Agency’s response to Comment:

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe. After consideration of the proposed language, the recommended changes are added to allow for following either HMBANA SOP or FDA’s BAM.

I. Summary of Comments:

26.1.4 –revise Birth date
Section 27 – Tracking and Recall of Donor Milk and 27.1 and 27.2– suggested language for adverse event reporting

Additional requested language for the Human Milk Bank Rules included Definitions for Donation Date, Expression Date, and Medical Director. Also, requested language on Section 4. Donor Qualifications/Screening, and Requested language on Physician Attestations, Testing of Milk Donations for infectious disease and adulterants, involvement of a Medical Advisory Board, and whether a donor will be accepted or deferred based on the screening test.

Agency’s response to Comments:

Were any changes made to the Proposed Rule as a result of this Comment? If so, please describe. After consideration and consultation with an ADH Senior Medical Advisor, the recommended changes to the birth date, tracking and recall, and additional definitions and other suggested additions will not be made at this time, but will be considered at the next regular review of these rules in 2021.