



March 17, 2025

Dora Hughes, M.D., MPH
Chief Medical Officer and Director
Center for Clinical Standards and Quality (CCSQ)
Centers for Medical & Medicaid Services
7500 Security Blvd, Baltimore, MD 21244

**Re: Agents of CMS misunderstanding of 42 CFR Part 493 Subpart M
Laboratory Requirements: Personnel for Nonwaived Testing**

Dear Dr. Hughes:

On behalf of the College of Reproductive Biology (CRB), we write to express our concern about the recognition of qualifying academic degrees in biological science under regulations to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), specifically as it affects clinical laboratory professionals in reproductive biology.

Since new CLIA personnel requirements were implemented effective December 28, 2024, it has been brought to our attention that in multiple instances, agents of the Centers for Medicare and Medicaid Services (CMS) serving as surveyors of the CLIA Program have been misapplying CLIA personnel requirements relating to earned academic degrees in biological science pursuant to 42 CFR Part 493 Subpart M of the regulations to CLIA '88.

Academic Degrees and Definitions

CLIA regulations stipulate separate personnel qualification requirements for individuals who hold medical degrees from individuals who hold non-medical degrees in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution.

For example, under 42 CFR 493.2, CLIA regulations define “doctoral degree” to mean an earned post-baccalaureate degree with at least 3 years of graduate level study that includes research related to clinical laboratory testing or advanced study in clinical laboratory science, medical laboratory science, or medical technology. For purposes of this part, **doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatric medicine (DPM), doctors of veterinary medicine (DVM) degrees, or honorary degrees.**

Thus, it is evident that in defining “doctoral degree,” CMS intentionally separated out medical degrees and excluded them from the definition, as described above. While the definition of “doctoral degree” also excludes degrees in veterinary medicine (DVM or VMD), non-medical degrees related to animals are not excluded from the definition.

Because CLIA regulations do not define chemical or biological science, academic courses taken are not limited to human application. Biology or biological science is the study of the life of all living things. If an academic transcript, academic course catalog, or other official documentation from an accredited college or university indicates that coursework completed was in biological science or a branch of biological science, it qualifies under CLIA regulations, as those regulations are written.

Accordingly, neither degrees in animal science nor veterinary science are medical degrees, but rather degrees in biological science.

Distinction Between Degrees

It is essential to distinguish between the different disciplines within biological sciences:

Veterinary Science vs. Veterinary Medicine

- ❖ While a Doctor of Veterinary Medicine (DVM or VMD) is the degree required to practice veterinary medicine (a medical degree), a Doctorate in Veterinary Science is a research-based biological science degree that focuses on the biology of animals, their health, diseases, and the prevention and treatment of illnesses.

Animal Science vs. Veterinary Science

- ❖ Animal science focuses on the study of animals and their management, while veterinary science focuses on the health of animals and how to treat them. However, both animal science and veterinary science are biological sciences.

Animal Science vs. Zoology

- ❖ While both are biological sciences, Animal Science is the study of animals under human control, such as pets and farm animals. Zoology is the broader study of the animal kingdom, including the distribution, evolution, and behavior of animals.

This clear distinction between medical degrees and biological science degrees demonstrates that degrees in Animal Science, Veterinary Science, and Zoology are biological science degrees that qualify under CLIA and should not be excluded by CMS or its agents who inspect CLIA laboratories.

Because of ethical issues in reproductive biology, training with human gametes and embryos is rarely possible. Most educational courses in reproduction at both the undergraduate and graduate levels are non-medical courses in biological science often found in animal science or agricultural departments of accredited academic institutions of higher learning.

CMS State Operations Manual

Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

In an advance copy of CMS revisions to CLIA Interpretive Guidelines in Appendix C of the State Operations Manual dated December 6, 2024, CMS policy does not limit degrees in biological science to human beings, and we believe CLIA surveyors/inspectors are not independently authorized to arbitrarily disqualify degrees in biological sciences, such as Animal Science, Veterinary Science, or Zoology, inconsistent with federal regulations and CLIA interpretive guidelines.

Ensuring Patient Access to In Vitro Fertilization (IVF) is a National Priority

On February 18, 2025, President Donald J. Trump signed an Executive Order directing federal agencies, including the Centers for Disease Control and Prevention (CDC) and CMS, who administers the CLIA program, to investigate measures to protect patient access to IVF.

Restricting qualified professionals from working in embryology and andrology laboratories by arbitrarily rejecting Animal Science, Veterinary Science, or Zoology degrees contradicts the intent of this order. Any regulation or policy that limits laboratory staffing in assisted reproductive technology (ART) programs directly threatens patient access to fertility treatment, undermining the President's directive.

The IVF field already is facing a workforce shortage and disqualifying highly trained professionals without just cause exacerbates this crisis. CMS, the CLIA Program, private laboratory accreditation programs, and all other regulatory agencies must ensure that their policies align with the Executive Order by recognizing the full scope of biological sciences, including Animal Science, Veterinary Science, and Zoology as valid educational pathways for reproductive laboratory professionals.

Action Requested

- 1) The U.S. Department of Health and Human Services (HHS) and all relevant agencies must align with the President's Executive Order by ensuring that all biological science coursework and degrees qualify under CLIA.
- 2) Regulatory bodies must immediately cease the arbitrary disqualification of degrees in Animal Science, Veterinary Science, or Zoology.
- 3) Surveyors must be advised that under CLIA, biological science includes Animal Science, Veterinary Science, and Zoology.

We appreciate your immediate attention to this critical issue.

Sincerely yours,

Michael Baker, PhD, HCLD(ABB)

Chair, Credentialing and Membership Subcommittee
College of Reproductive Biology (CRB)

Melanie Clemmer, PhD, HCLD(ABB)

President, College of Reproductive Biology (CRB)

AAB College of Reproductive Biology (CRB)

906 Olive Street, Suite 1200

St. Louis, Missouri 63101

United States of America

Phone: (314)241-1445 | Fax: (314)241-1449

Website: www.aab.org/aab/CRB1.asp | Email: crb-aab@aab.org