American College of Embryology
Defining Standards in Clinical Embryology

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Nhan H. Nguyen, MD, JD
Attorney at Law / Outside General Counsel
American College of Embryology

Mark Horton, MD, MSPH
State of California, Health and Human Services Agency
California Department of Public Health

Re: Notice of Proposed Rulemaking, Title 17, California Code of Regulations
Comments to Clinical Laboratory Personnel Standards, DPH-08-001

Dear Dr. Horton:

The following comments are a compilation and synopsis of opinions and positions from the thought leaders of the members of the American College of Embryology (ACE), a non-profit organization dedicated to achieving the minimum standard of embryology practice in the United States with regards the above referenced Rulemaking proposal.

The ACE's managing and advisory boards are made of some of the most prominent individuals in the field of assisted reproduction, and are both physicians and embryology practitioners. (Please see more information about the ACE at our web site: www.embcol.org).

1. **Objection to Inclusion of Embryology in DH-08-001**

The American College of Embryology rejects inclusion of Embryology in the proposed ruling on the following grounds:

> *The proposed rules state that "Many clinical embryologists are trained in the United Kingdom or Australia, and are unable to legally perform tests or examinations in California. They have asked that their board certification be recognized for licensure purposes in California. That is the purpose of these proposed licensing standards."*

Embryology practice is currently not regulated at the federal level, nor to the best of our knowledge, is it regulated on the state and local levels in California. Therefore, it is unclear why clinical embryologists trained in the United Kingdom or Australia or any other country requires special accommodations to practice embryology in California. Furthermore, it is not understood why the proposed rules for embryology practice are being introduced under the framework of diagnostic testing regulations.

Within diagnostic laboratories that deal with human specimens, there are clear pre-analytical, analytical and post-analytical phases within protocols. At the end of the process, the specimen is discarded as biological waste or stored, but in either case, the specimen is rendered non-viable.

Diagnostic laboratory quality is measured in accuracy, sensitivity and specificity standards and also according to the standards set by CLIA 88.

On the other hand, human embryos do not become specimens at any stage of the process in the embryology laboratory. To the contrary, embryos are created with the intent to be transferred into the uterus to achieve conception and pregnancy, and all efforts are made to keep them viable. Embryology laboratory quality is measured in the percentage of embryos becoming live-born children.

Therefore, the only similarity between a diagnostic testing laboratory and an embryology laboratory lies only in the word "laboratory", which makes the matter confusing as a practical matter. The term "***Embryology Facility***" is much more appropriate.

Consistent with the above, the proposal fails to identify a single embryology laboratory-specific test:

> *Section 1029.210. Tests or Examinations in Clinical Embryology.*
>
> *As used in this chapter," tests or examinations in "clinical embryology" means evaluation of patient blood, gametes and associated fluids to assess viability, morphology, and function of a human biological specimen to assist in reproductive technology. Tests and examinations include, but are not limited to, determination of hormone levels, identification of antibodies, and sperm analysis.*

The specific tests listed above are covered by CLIA under Endocrinology and Andrology, respectively, and are already regulated in California under their respective licenses and licensing requirements. Those tests are clearly diagnostic and dealing with specimens, whereas Embryos, as has been illustrated above are not specimens.

It is the opinion of the ACE that no embryology-specific diagnostic tests are listed in this section, because no such tests exist.

Thus, it is the ACE's contention that the rules pertaining embryology should be excluded from the pending regulations, because of the following reasons:

1. The stated purpose of the regulations (as it concerns embryology) has no grounds or basis;
2. The terms "Embryology Laboratory" does not fulfill any criteria of diagnostic laboratories the current regulation is designed to address;
3. The proposed regulation fails to take into account live birth rates, which are the only measure of embryology laboratory quality (albeit indirect); and
4. The proposed wording of the legislation may result in increased costs to patients without any apparent public benefit

Since there is no current embryology regulation model in the United States, some lessons and models may be drawn from Great Britain, the birthplace of the human embryology laboratory.

In that country, a separate entity, "The Human Fertilization and Embryology Authority" was established under the Department of Health to regulate issues unique and specific to Embryology.

This is in agreement with the ACE's position that embryology cannot be regulated as a diagnostic testing laboratory, nor as a practice of medicine. Instead it has to be regulated as a separate and unique practice of embryology with an organization of embryology practitioners playing a major role in shaping policy and best practices.

2. **Additional Comments:**

Post-Bachelor Credit Hours Requirement

> *The proposed rules state that, "A clinical embryologist applicant must have an earned doctorate degree in biological or clinical laboratory science with at least 30 semester hours of post-baccalaureate biology."*

As does any specialty, Embryology or Reproductive Laboratory Science, requires specialized education and training. Therefore the ACE does not endorse the premise that a certain requisite number of credit hours in any discipline creates an educational foundation for the specialty, unless the respective courses have been accredited toward the degree in that specialty. Instead, education must be curriculum-based and relevant to the profession, as is education for other related fields. For the same reason that 30 credit hours in biology do not create educational background in, for example, cytogenetics, and would not qualify an individual to be admitted to the licensing exam in that specialty, in the same manner it does not create a specialized background in embryology. As another example; a physician has earned many more credit hours in clinical medicine than a massage therapist, nonetheless, he or she would not be able to practice massage therapy without going through massage therapy school, and only then, after taking and passing an examination in that specialty.

Due to the variety of post-graduate educational backgrounds of current embryology practitioners, according to the proposed rules an individual with fewer credit hours of highly relevant postgraduate education will be at a disadvantage to an individual with more credit hours of less relevant education. Furthermore, it would be extremely difficult to validate the relevance of random biology courses for embryology practice without referencing them against an existing accredited program of the same nature.

The first, and only, accredited PhD level program in Reproductive Science became available only recently from the University of Kentucky and the first PhD will graduate in 2012. That program's director, Dr. Doris Baker, is also a Chair of the American College of Embryology Education Committee and supervises the creation a structured doctoral level online course in clinical embryology for ACE members.

The ACE proposes that any specific credit-hours requirement only be applied to future graduates of specialized doctoral level programs in reproductive laboratory science. However, those individuals who entered into clinical embryology before the field matured and were effectively contributing to creating this specialized knowledge must be able to grandfather as described below.

Furthermore, because historically and uniquely for embryology, internationally-trained individuals represent a large percentage of the current embryology laboratory directors, it would be appropriate that their PhD models be acceptable regardless of the number of credit hours since they have served as the basis for their immigration, certification and current employment in the capacity of the embryology laboratory directors.

Approved Internship Programs

> *The proposed rules stipulate that "He or she must complete two years of post-doctorate training on human specimens in an ART facility approved by the American Association of Bioanalysts Board of Registry (AAB BOR) for board certification of embryologists, and then must complete at least two more years of practical experience in a facility."*

The College supports the idea of Internship, which in fact was pioneered by the ACE almost two years ago and the College developed accreditation criteria for such training facilities.

In the current proposal, criteria for training facilities are absent and have to be clarified as well as the number of such facilities and number of trainees accepted every year. Furthermore, it is not understood why a single private corporation would be placed in an exclusive position to approve a program for internship which may effectively give the organization the authority to control the market.

It is also unclear why the proposed duration of training is fixed at "2" years. The ACE proposes that the duration of training be dependent on the prior experience of the candidate. The ACE has developed a respective model to define candidate readiness through the practical skills examination and has already administered such testing (video can be found on ACE web site).

Furthermore, embryology programs in California are no different than anywhere else in the country. Therefore the rational for the requirement of training specifically in California as a licensure pre-requisite is not apparent, and in the ACE's view, creates an unnecessary burden for applicants.

It is also not clear how current directors who work full time can fulfill the requirement of such an internship.

Grandfathering

While strongly advocating differentiation of embryology practitioners based on educational background, the ACE is not endorsing such sudden changes, which would be disruptive for the industry and result in increased cost of operations in these difficult economical times without demonstrating a clear public benefit. We also do not support disqualifying some current laboratory directors who have, and continue to, successfully operate IVF laboratories.

Since at this time, a very small number of practicing Embryology laboratory directors, including those with PhDs, have post-graduate credit hours in subjects accredited specifically toward a degree in reproductive laboratory or pre-implantation embryology, and their expertise is acquired primarily through on-job-training, the ACE recommends that those who have a minimum of a

Bachelor of Science degree in biology or related discipline be grandfathered as laboratory directors, provided they are serving in that capacity at the time the regulations are in effect. All those who grandfathered, would be required to enroll in a structured continued education program based on an accredited post-graduate program in Reproductive Sciences or Embryology

Alternative Pathways to Licensure

The proposed regulation seeks to appoint a single corporation to qualify and examine candidates and to choose approved training facilities. Even though historically this corporation was the first and only to provide certification in Embryology (ELD), this certification was not required to practice embryology and therefore it was not a cause for the concern. However, if such certification becomes the pathway to licensure, it would seem appropriate that additional pathways through such major organizations, representing embryology practitioners as ASRM and ACE be opened. This would be consistent with multiple routes of certification in other specialties.

Oversight, Accountability and Appeal Process

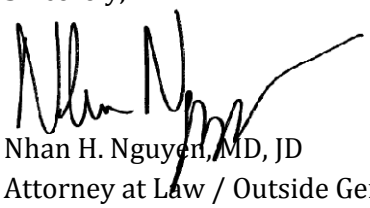
The proposed ruling is lacking a clear procedure for oversight, accountability and an appeals process related to every stage of certification, particularly those that this proposal outsources to a single private corporation.

Conclusion

The above positions again are the compilation of the thought leaders in the industry as reflected by the members of the ACE. The College hopes and trusts that you will take these comments under consideration in the Proposed Rulemaking that may form and shape the model of embryological professional requirements and industry and laboratory standards for many years to come. We hope your consideration does not only view the Proposed Rulemaking merely based upon technical definitions and requirements but also considers the impact of these rules on the most important stakeholders, which are the patients we serve. The College's opinions and comments make these considerations.

Thank you in advance for your attention and consideration. Should you have any questions or desire further comment or clarification from the ACE, please do not hesitate to contact the leaders of the College for further discussion.

Sincerely,



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