This form will allow you to save your responses and continue later. Please periodically save your responses by clicking the “Save and continue later” link located at the top of each following page to retain your work.

You will be asked to enter an email address, and a specific link to your answers will be sent to you.

If you do not receive an email, please check your spam folder.

You may wish to designate SurveyGizmo.com as a “safe sender.”

To complete this application, you must click on the next button at the bottom of the page. You will be asked to submit your application on the subsequent page.

Contact Name
Rebecca L. Johnson, MD

Contact Email Address
rjjohnson@abpath.org

Name of Sponsoring Board(s):
American Board of Pathology

1. Provide the name of the proposed area of focused practice:
Clinical Chemistry

2. State the purpose of the proposed area of focused practice and include the rationale for how this area of focused practice is different than a subspecialty, in two paragraphs or less:

The purpose of focused practice designation in Clinical Chemistry is to recognize diplomates who have successfully completed the Commission on Accreditation in Clinical Chemistry (ComACC) accredited training. Clinical chemistry is based in traditional clinical laboratory chemistry, but the field now includes the emerging disciplines of forensic toxicology, molecular diagnostics, information sciences, laboratory management sciences, and point-of-care testing. With development of the "core" laboratory concept, i.e., the integration of high volume testing services into a central facility, clinical chemists are also trained in automated hematology, coagulation, urinalysis, serology, and infectious diseases. ComACC has standards of education and training of physicians consistent with this progress in medicine and clinical laboratory sciences. Basic and/or applied clinical research is a major part of all ComACC training programs. Graduates of these 2-3 year training programs qualify for certification by the American Board of Clinical Chemistry. Based on the standards and rigor of training and theComACC accreditation process, the ABP would like to recognize these diplomates with focused practice designation. We would also like to recognize board certified physicians whose practice has been primarily or exclusively devoted to clinical chemistry.

3. Focused practice usually falls under one of these areas. Please describe which of the following this application addresses.

   a. Evolving area of practice
   b. Area of practice limited in scope or size
   c. Specialized procedure

Clinical Chemistry is a small specialty with a growing need for specialists in this area. There are currently only three ACGME accredited programs in Chemical Pathology with a total of four positions, and this training is for one year only. There are 33 ComACC accredited programs and training is for 2-3 years and includes research.

4. Please outline the eligibility criteria required of candidates in the proposed area of focused practice, as it pertains to the following:
4a. Certification in a specialty or subspecialty by an ABMS Member Board:

Candidates must have ABPath primary certification in combined Anatomic/Clinical Pathology or in Clinical Pathology, or primary certification from another ABMS member board. All candidates with time-limited certification must be participating in Maintenance of Certification and up-to-date with MOC requirements.

4ai. If diplomates of multiple ABMS Member Boards would be allowed to apply for this area of focused practice, please list those Member Boards:

Diplomates of other ABMS boards who complete ComACC accredited training and pass our exam and/or meet our practice requirements could qualify for focused practice designation in Clinical Chemistry. It is unlikely that there will be diplomates from other ABMS boards.

4b. What specialty and/or subspecialty certificate(s) will a diplomate be required to hold in order to be eligible for this area of focused practice?

see 4a.

4c. Clinical practice experience (both in terms of time and patient volume) in the area of focused practice, beyond initial training:

A diplomate who has spent at least 30% (an average of 16 weeks/year) of their practice in three of the past five years practicing clinical chemistry could qualify for this designation after passing our examination.

4d. Additional qualifications (if any):

Candidates would have to take and pass an examination in clinical chemistry and participate in MOC for continuing focused practice designation.

5. With regard to Board-based assessment for candidates prior to awarding this area of focused practice, which assessment methods would be required? (Check all that apply)

- Examination (Written)

5a. Please describe the rationale behind the method(s) required in the assessment process:

An examination is the best way to assess a diplomate's medical knowledge in the area of clinical chemistry.

6. Please outline the Maintenance of Certification (MOC) program planned for this area of focused practice:

The MOC program will have the same requirements that our diplomates now have for maintaining their primary and/or subspecialty certification. If the candidate has a non-time limited certificate, he/she would have to participate in MOC to maintain their focused practice designation.

7. Document the professional and scientific status of this area of focused practice by addressing (a) through (d) below.

7a. Please describe how the existence of a body of scientific medical knowledge underlying the proposed area of focused practice is in large part distinct from, or more detailed than, that of other areas in which certification or focused practice are offered:

Clinical chemistry includes the emerging disciplines of forensic toxicology, molecular diagnostics, information sciences, laboratory management sciences, and point-of-care testing. With development of the "core" laboratory concept, i.e., the integration of high volume testing services into a central facility, clinical chemists are also trained in automated hematology, coagulation, urinalysis, serology, and infectious diseases. This area of focused practice is broader than the current subspecialty of chemical pathology.

7b. Explain how this proposed area of focused practice addresses a distinct and well-defined patient population and care need:

Clinical chemists are important consultants to the health care team for the appropriate selection of tests, the correct interpretation of results, for recommendations for additional testing, and laboratory utilization management. They contribute to better patient care with lower cost to the system.
7c. Please provide information about the group of diplomates concentrating their practice in the area of focused practice, if known:

7ci. The projected number of such diplomates (along with the source(s) of the data):

There are currently 33 ComACC accredited training programs with 36-39 positions in the US (www.comacc.org/training). The length of training is 2-3 years. These programs train both physicians and PhDs; however, the ABP would only recognize ABMS certified physicians for focused practice designation. We do not have a reliable estimate of diplomates who would qualify by experience, but believe there would not be large numbers.

7cii. The annual rate of change of such diplomates in the recent past and projected annual rate of change for the near future (along with the source(s) of the data):

Physicians practicing clinical chemistry declined after TEFRA legislation passed in early 1990s and physicians were paid based on RBRVS and there was no longer direct payment for clinical pathology by Medicare and most insurers. There has been a resurgence of interest in clinical chemistry by physicians since alternate payment models have emerged, diagnostic teams have become popular, the need for expert consultation by health care providers has increased, and institutions are interested in laboratory utilization management. There is a retirement "cliff" occurring in pathology. See: Arch Pathol Lab Med. 2015;139:1413–1430; doi:10.5858/arpa.2014-0559-OA

7ciii. The current geographic distribution of this group of diplomates, its projected spread in the next five (5) years, and an explanation of how you arrived at this projection:

Most physicians practicing primarily or exclusively clinical chemistry are located in academic medical centers, large hospitals/health systems, and commercial laboratories, such as Quest and LabCorp. We project with consolidation of hospitals and health systems and increased insurance company contracts with commercial laboratories, the need for these specialists may increase slightly over time.

7d. Please identify the existing national societies that have a principal interest in the area of focused practice:

- Academy of Clinical Laboratory Physicians and Scientists
- American Association for Clinical Chemistry
- American Chemical Society
- American Society for Clinical Pathology
- Association of Clinical Scientists
- National Academy of Clinical Biochemistry (AACC Academy)

7di. Indicate the existing national societies’ size and scope, along with the source(s) of the data:

Size and scope based on email correspondence and association websites.

- ACLPS has approximately 150 physician members; mission-- dedicated to the advancement of teaching and scholarship in laboratory medicine. AACC Annual Scientific Meeting and Clinical Lab Expo is the largest clinical lab meeting in the US with approximately 20,000 attendees annually; membership open to entire lab community, so they do not have the number of physician members; mission is to provide global leadership in advancing the practice and profession of clinical laboratory science and medicine. ACS has an international membership of 157,000 chemists; membership is open to the laboratory community, so they do not know the number of physician members; mission--to advance the broader chemistry enterprise and its practitioners for the benefit of Earth and its people. ASCP has 120,000 members from the laboratory community, with approximately 7000 physician/pathologist and resident members; administers the annual Resident In-Service Examination; certifies laboratory professionals; mission--provide excellence in education, certification, and advocacy on behalf of patients, pathologists, and laboratory professionals across the globe. ACS has 200 members with approximately 100 physician members; mission--to promote education and research in clinical science; to improve the development, selection, accuracy, utilization, and interpretation of tests performed for clinical diagnosis, prognosis, monitoring, and research. NACB (new name is the AACC Academy) has approximately 400 clinical doctoral scientist members and describes itself as " a learned society that represents the academic, research, and hospital-based clinical chemists".

7dii. Indicate the distribution of academic degrees held by their members, along with the source(s) of the data:

All organizations have physician and doctoral scientist (PhD) members; some have associate members who hold masters or baccalaureate degrees, often in clinical laboratory science.
7diii. Indicate the relationship of the national societies’ membership with the proposed focused practice designation:

All organizations have physician members in academic, community, or commercial laboratory settings, who are interested in education, research, and the practice of clinical chemistry, clinical pathology, and/or laboratory medicine. Some of these physicians would welcome the "focused practice in clinical chemistry" designation.

8. Please describe how the cognitive knowledge, clinical and interpersonal skills, professional attitudes, and practical experience of diplomates in this area of focused practice will be distinct from diplomates in other specialties, subspecialties, and areas of focused practice in terms of:

8a. Clinical competence:

Diplomates with the focused practice designation will have equivalent or will exceed the education, knowledge, skills, and experience as those subspecialty certified in Chemical Pathology.

8b. Scope of practice:

Clinical pathology and laboratory medicine. See also #2.

8c. Body of knowledge and skills:

Clinical chemistry, clinical pathology, and laboratory medicine. Ability to be experts and consultants in all areas of the clinical laboratory. See also #2.

9. For (a) through (e) below, please project the need for and the effect of the proposed new focused practice on the existing patterns of certification or other areas of focused practice. Please indicate how you arrived at your response.

9a. Please indicate whether there is any overlap between this area of focused practice and existing subspecialty certifications or other areas of focused practice.

There is partial overlap with the subspecialty of Chemical Pathology. In addition to routine chemistry, these diplomates will have expertise in forensic toxicology, molecular diagnostics, information sciences, laboratory management sciences, point-of-care testing, automated hematology, coagulation, urinalysis, serology, and infectious diseases. This is more education and/or broader experience than current ACGME trained candidates who qualify for subspecialty certification in Chemical Pathology.

9b. Please outline plans for evaluation of the impact of the proposed area of focused practice on your own programs of specialty and subspecialty certification and any other areas of focused practice:

There have only been 11 diplomates certified in Chemical Pathology since 2000, so this focused practice designation will not affect the number of subspecialty certified diplomates, but will expand the pool of recognized clinical chemists.

9c. Please outline plans for evaluation of the impact of the proposed area of focused practice on other Member Boards' programs of specialty and subspecialty certification and any other areas of focused practice:

This should have no impact on any other ABMS Member Boards, since Clinical Chemistry is a unique discipline, not certified by any other board.

9d. The impact of the proposed area of focused practice on practice, both existing and long-term, specifically:
9di. Access to care (please include your rationale):

The IOM defines access to health services as "the timely use of personal health services to achieve the best health outcomes." It includes finding a health care provider whom the patient trusts and can communicate with (personal relationship). While clinical chemists may have limited interaction with patients directly, as a non-patient facing specialty, they are critical to the health care team and health system in the appropriate selection, utilization, and interpretation of laboratory tests. They contribute to the triple aim of better patient care, improving population health, and lowering costs by their activities. (the right test, at the right time, with the right interpretation and action). Because of their access to big data and expertise in informatics, they have a unique role in improving population health.

9dii. Quality and coordination of care (please include your rationale):

see 9di.

9diii. Benefits to the public (please include your rationale):

See 9di.

9e. Please explain the effects, if known, of the proposed area of focused practice on:

9ei. Immediate costs and their relationship to the probable benefits (please indicate your methodology):

The cost is the fee for an examination and associated travel and time away from work costs, if they take the exam in our Tampa exam center. The exam fee will likely be between $700-1800, similar to the MOC and subspecialty exam fees, respectively. We could consider remote, secure testing for this exam, such as we use for our MOC Part III exam. The benefit is focused practice designation.

9eii. Long-term costs and their relationship to the probable benefits (please indicate your methodology):

Long-term cost are the fees for MOC and required MOC activities (e.g. CME).

9f. Please explain the effects if this area of focused practice is not approved:

Many physicians who practice Clinical Chemistry will not receive the recognition that they deserve as specialists.

10. Please indicate how the proposed area of focused practice will be evaluated periodically (e.g., every five years) to assure that the area of focused practice remains viable:

We will track the number of applications and approvals for focused practice and survey these physicians regarding the professional value of the designation.

11. Please list key stakeholder groups from which ABMS may wish to solicit commentary on the proposed area of focused practice:

see 7d.

To be completed for areas of focused practice for which formalized training is currently available to meet some of the requirements for clinical experience and patient volume:

12. Please provide the following information for those training programs that have a primary educational effort devoted to the proposed area of focused practice, along with their geographic locations and the source(s) of the data:
12a. Please list the names of training programs in the proposed area of focused practice:

Baylor College of Medicine and Texas Children's Hospital
Children's Hospital Boston
Cleveland Clinic
Cleveland State University
Dartmouth Hitchcock
Emory University
Hennepin County Medical Center
Houston Methodist Hospital/Weill Cornell Medical College
Johns Hopkins Medical Institutions
Mayo Clinic
Medical University of South Carolina
Memorial Sloan Kettering Cancer Center
National Institutes of Health
Texas A&M Health Science Center
University of Calgary
University of California, Los Angeles
University of California, San Diego
University of California, San Francisco
University of Chicago Medicine
University of Louisville School of Medicine
University of Maryland School of Medicine
University of Minnesota School of Medicine
University of North Carolina Hospitals
University of Texas MD Anderson Cancer Center
University of Texas Medical Branch at Galveston
University of Texas Southwestern Medical Center at Dallas
University of Toronto
University of Utah School of Medicine
University of Virginia School of Medicine
University of Washington
Vanderbilt University Medical Center
Washington University in St. Louis School of Medicine
Yale University and Yale-New Haven Health

12b. Indicate the total number of trainee positions available currently (along with the source(s) of the data):

Source: www.comacc.org/training
There are 33 ComACC accredited training programs with 36-39 total positions and training is 2-3 years.

12c. Provide the number of trainees completing the training annually (along with the source(s) of the data):

Source: www.comacc.org/training
Unknown, but based on information in 12b (above) there should be approximately 15-18 graduates/year.

12d. Organization(s) providing accreditation or oversight for training programs:

Commission on Accreditation in Clinical Chemistry (ComACC). Their program requirements and accreditation process are similar and as rigorous as ACGME subspecialty accreditation.

13. How much additional clinical experience is required beyond training?

None. These are 2-3 year training programs. ACGME training programs are only one year.

NOTE: When submitting this application, please attach the following items:
Copy of proposed application form for the candidates for this area of focused practice
A written statement indicating concurrence or specific grounds for objection from each Primary and Conjoint Board having expressed related interests in the same field
Written comments on the proposed area of focused practice from at least one (1) public stakeholder group
An example of how diplomates will be recognized for this area of focused practice
Thank you for your application for an Area of Focused Practice. ABMS staff will review your application and follow up as appropriate. If you have any questions about the submission of your form, please contact Paul Lawlor via phone (312-436-2690) or email plawlor@abms.org
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Lois Margaret Nora, MD, MBA, JD
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July 12, 2017

Dear Dr. Nora,

I am writing as President of the Academy of Clinical Laboratory Physicians and Scientists (ACLPS), and on behalf of the Executive Council of ACLPS, in strong support of the proposal by the American Board of Pathology to create an area of focused practice in Clinical Chemistry. ACLPS is a cooperating society of the American Board of Pathology, and its membership is composed of clinical pathologists, clinical chemists, clinical geneticists, and clinical microbiologists.

Creating this area of focused practice will, to quote the news release on focus practice designation, “recognize an evolution of practice that occurs following initial certification and is relevant to continuing certification.” Specifically, those with initial American Board of Pathology certification in Anatomic/Clinical Pathology or Clinical Pathology who develop specific interest and expertise in Clinical Chemistry will be able to take the appropriate sub-specialty American Board of Pathology exam. The criteria proposed by the American Board of Pathology for qualification in Clinical Chemistry as an area of focused practice are appropriate requirements for education and experience for this purpose. The requirements for maintenance of certification are also appropriate and consistent with usual practice by the American Board of Pathology. Those who qualify for an area of focused practice in Clinical Chemistry will significantly benefit from the recognition that sub-specialty board certification will provide and so we very much support this proposal. Please contact me if you require any additional information.

Sincerely,

Alexander J. McAdam