

September 26, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

DELIVERED ELECTRONICALLY

RE: Docket Number: CMS-3326-P. Changes to § 493.1443 Standard; Laboratory Director

Administrator Brooks-LaSure,

On behalf of the hundreds of thousands of laboratory professionals that see enormous potential for the clinical laboratory to play a central role in improving our nation's healthcare system, the American Society for Clinical Laboratory Science (ASCLS) strongly supports CMS's intended interpretation of §493.1443 Standard; Laboratory director qualifications to include the Doctor of Clinical Laboratory Science (DCLS) advanced professional doctorate degree as a qualifying degree.

DCLS degree-holders are laboratory leaders that recenter the clinical laboratory's work on patients and more closely integrate the work of clinical laboratories into the broader patient care team. In addition, this change will expand pathways within clinical laboratories to utilize the knowledge, skills, and experience of our most talented and diverse laboratory professionals more effectively. As a group these professionals have the capacity to make an immediate and profound impact on health inequities and the negative effects of social determinants of health.

As CMS notes, and ASCLS confirms, these professionals exceed the requisite scientific skills necessary to increase efficiency, facilitate patient management outcomes, and improve timely access to accurate and appropriate laboratory information by participating directly in patient care decisions, monitoring laboratory utilization, and conducting research on the diagnostic process to improve test selection, interpretation, and the diagnostic process.

Since the ASCLS House of Delegates adopted the position paper, "Advanced Practice: Doctorate in Clinical Laboratory Science" (<https://ascls.org/advanced-practice-doctorate-in-clinical-laboratory-science/>) in August of 2016, the first three DCLS programs will have graduated 43 practitioners by the end of 2022. Based on current enrollment, that number will more than double by the end of 2025.

With high interest among laboratory professionals, we anticipate additional programs will become available. For the Fall 2022 term, all available slots at Rutgers University, University of Texas-Medical Branch, and University of Kansas Medical Center are filled. In the aggregate, 85 applications were received for just 26 slots.

The National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) has fully accredited, or is in the process of accrediting, all three programs. The ASCP Board of Certification has committed to offering a certification for the DCLS and has already begun work to produce it.

In June of 2022, after years of cooperative development, the ASCLS House of Delegates adopted the DCLS Body of Knowledge (BOK) (https://ascls.org/wp-content/uploads/2022/08/DCLS_BOK_ADOPTED_20220630.pdf), encompassing the essential knowledge base for what is recognized and practiced, and specifies the knowledge unique to the profession and defines the relationship of DCLS practitioners to other health professionals, administrators, patients, and the public.

It's time that clinical laboratory personnel standards are set to meet the challenges of our 21st Century health system. The old standards have created an insular culture within clinical laboratories that obscure the full capacity and value of our professionals.

We note with some concern that those who have traditionally objected to recognizing the DCLS as a qualifying degree do so without any reference to patients or the impact the clinical laboratory's work has outside its walls. This sclerotic perspective minimizes the impact of clinical laboratory professionals, leading to underappreciated value and exacerbating long-term workforce shortages.

We urge HHS to exercise caution, however. Some of the organizations associated with certifying boards approved by HHS have raised unfounded concerns about the holders of DCLS degrees. HHS should clearly communicate with those boards that arbitrary failure to recognize the DCLS would be an inappropriate restraint of these professionals' practices.

Sincerely,



Kimberly Von Ahsen, MHA, MLS(ASCP)^{CM}, SLS(ASCP)^{CM}
President