March 12, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Submitted via: regulations.gov

Re: [CMS-3326-NC] Requests for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under Clinical Laboratory Improvement Amendments of 1988 (CLIA)

Dear Ladies and Gentlemen:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and health professionals, appreciates the opportunity to provide input on Requests for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under Clinical Laboratory Improvement Amendments of 1988 (CLIA). Rheumatologists provide care for millions of Americans, both adults and children, and are the experts in diagnosing, managing and treating arthritis and rheumatic disease. These life-long, chronic conditions include rheumatoid arthritis, systemic lupus erythematosus, vasculitis and gout. Rheumatologic diseases including arthritis are the leading cause of disability in the United States, and early and appropriate treatment by a rheumatologist is vital to controlling disease activity, preventing and slowing progression, improving patient outcomes, and reducing the need for costly downstream procedures and care. Rheumatologists practice in every state, the District of Columbia, and Puerto Rico, and in communities urban and rural, providing critical care for people with diseases that can be crippling, life changing, and life threatening.

We are pleased to see that the Centers for Medicare and Medicaid Services (CMS) is working to update existing CLIA regulations that have not been updated in decades. The ACR believes some of these regulations are overly burdensome for providers and create barriers to timely, high quality care for their patients. Currently, only laboratories that are CLIA certified level 2 and 3 are permitted to perform (and bill) for synovial fluid crystalline analysis. All rheumatologists receive fellowship level training to perform synovial fluid crystal analysis. This point of care test allows for rapid and cost effective evaluation of patients with crystalline arthritis and reduces unnecessary and costly additional testing to include advanced imaging procedures. Unfortunately, the current CLIA certification requirements are unduly burdensome and prohibit the routine performance of this test in the appropriate clinical setting.
The evaluation of synovial (joint) fluid is integral for the diagnosis of gout and other types of crystalline arthritides. Synovial fluid analysis is the chemical and microscopic examination of joint fluid for cells, chemical composition and crystals to diagnose and distinguish types of inflammatory arthritis. While cell counts (RBCs, WBCs, differentials) and chemical analysis (glucose, protein) are conducted with automated laboratory machines, crystal analysis is done by a trained expert looking at the synovial fluid with a microscope and polarizing light filters. Examination for crystals is best done on ‘fresh’ joint fluid by the physician who is most involved with the process. Appropriately trained medical technologists and/or pathologists are not available at all times when clinical decisions need to be made, and transportation of the specimen to the lab as well as communication back to the provider takes hours under the best circumstances. Rheumatologists diagnose and treat more than one hundred types of arthritis and autoimmune diseases. Within minutes of the joint aspiration, critical decisions about treatment can be made by a provider with proper training and a basic microscope. It is one of the few great bargains of modern medicine – if rheumatologists are allowed to perform the analysis.

Further, the technique of synovial fluid analysis was developed by rheumatologists and has historically been an integral part of clinical training in rheumatology. Through fellowship training and continuing medical education, rheumatologists become experts in arthrocentesis and in the interpretation of synovial fluid crystal analysis. The directors of rheumatology fellowship programs in the United States have developed a core curriculum in this area to ensure program quality and consistency. Correct identification of crystals in synovial fluid is required for initial rheumatology board certification and for maintenance of certification.

**The ACR recommends two options to address this problem:**

First, while CMS is reviewing and updating requirements for CLIA personnel and testing, the ACR recommends CMS create a special category of waived tests that would include the synovial fluid analysis when performed by a rheumatologist for care of their own patients. Creating this option would exempt a provider performing any CMS designated “waived tests” from burdensome CLIA level 2 and 3 requirements. No such category exists now, but there are other clear examples of bedside tests in addition to synovial fluid analysis that should be considered (e.g., microscopic urinalysis by nephrologists and urologists, KOH preps of skin scrapings by dermatologists, etc.).

Second, although there is no special category of waived tests, there is a list published by CMS entitled “Provider-performed Microscopy Procedures“. We would ask that the synovial fluid analysis is included on this list if it would allow rheumatologists to perform crystal analysis in the clinical setting without undue administrative burden. We urge CMS to downgrade or change the synovial fluid analysis from a ‘high complexity’ test to a ‘provider-performed microscopy’ procedure as is currently designated for urine dipstick and KOH prep, which would do away with the overly burdensome requirement for certification. To our knowledge, in order to perform these tests most facilities must pass evaluations that are sent via mail annually, and full lab certification is not required. Rheumatologists could meet a similar requirement in order
to complete the synovial fluid analysis in their clinic. The full lab certification that is required currently is harming patient care and increasing burdens to the system.

The ACR is dedicated to ensuring that patients with arthritis and rheumatic diseases have access to continuous comprehensive high-value and high-quality care. We appreciate the work that the CMS does and the opportunity to respond to Requests for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under Clinical Laboratory Improvement Amendments of 1988. We look forward to being a resource to you and to working with the agency as new CLIA recommendations are made. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797 if you have questions or if we can be of assistance.

Sincerely,

Colin Edgerton, MD, FACP, RhMSUS
Chair, Committee on Rheumatologic Care
American College of Rheumatology