September 4, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1590-P
Baltimore, MD 21244-8013

Submitted electronically

Re: Revisions to Payment Policies Under the Physician Fee Schedule, DME Face to Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations; Proposed Rules; [CMS-1590-P]

Dear Acting Administrator Tavenner:

On behalf of the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), representing independent community and regional clinical laboratories, thank you for the opportunity to submit comments on the Calendar Year (CY) 2013 Physician Fee Schedule Proposed Rule. Our comments below address payments for new molecular pathology tests and physician signature requirements on laboratory requisitions.

AAB and NILA represent the owners, directors, supervisors, and technologists of independent, regional and community clinical laboratories who currently work in contract arrangements with physician practices, outpatient care settings, skilled nursing facilities, and home health care agencies. A number of our members are small, independent businesses.

Section II. Provisions of the Proposed Rule

I. Payment for Molecular Pathology Services

AAB and NILA support the creation of the proposed new molecular pathology services that were assigned CPT codes. Our organizations' members include local, community, and regional laboratories, many of which perform molecular diagnostic tests and include Ph.D. molecular biologists—scientific experts who serve as directors of clinical laboratories and are experienced and trained in interpreting complex test results.

We appreciate CMS's effort and dialogue with the laboratory community to establish appropriate reimbursement for the molecular diagnostic tests and to determine the appropriate fee schedule assignment for these tests, whether that be the Medicare Physician Fee Schedule (PFS) or Clinical Laboratory Fee Schedule (CLFS). Our comments focus on our recommendations for determining the appropriate fee schedule assignment for these tests in response to the questions raised by CMS in the CY 2013 PFS proposed rule. We expect to comment on the reimbursement rates for these molecular tests when CMS publishes its proposal later this year.

Interpretation of services

As CMS weighs the important issue of where to appropriately place the new molecular pathology codes—the PFS or CLFS—it is important that CMS first recognize and acknowledge that laboratory science is changing rapidly. The continued introduction of new, complex molecular and genetic diagnostic tests is meant to offer Medicare providers more precise diagnostic tools for Medicare beneficiaries with the end result of improving their care while reducing overall health care costs by better targeting treatment decisions. As such, the new molecular and genetic tests are a vital step forward in the development of personalized medicine. As CMS is concerned first and foremost with the quality of patient care, it is essential that the individual who knows and understands the science behind these tests be the one to provide the consultation and interpretation to attending physicians.

The expertise of those conducting laboratory testing, particularly in the field of molecular diagnostics, is also expanding, as Ph.D. laboratory scientists receive specialized training in new forms of testing and molecular biology techniques and on how to read, interpret, and clinically validate results to provide physicians the information they need to make patient care decisions. While evolving, the same type of specific training has not kept pace within the medical community, or specifically, medical pathology, as evidenced by the current pathology workforce, where the great majority of pathologists are trained in anatomic pathology, not clinical pathology or molecular diagnostics.

Currently, the expertise for molecular testing and the interpretation of that testing largely resides within laboratory science and the clinical laboratory itself through Ph.D. laboratory directors. The challenge of assessing the qualifications of those who would be permitted to interpret these new tests, in addition to the other PFS formula-related challenges expressed in the proposed rule, must be considered by CMS as it seeks to make a decision on the appropriate fee schedule placement for the new molecular pathology test codes. Again, patient safety and optimal patient care require that the most qualified individual be the one to provide interpretation of these complex new molecular tests.

Should new molecular pathology codes be paid under the PFS or the CLFS?

AAB and NILA believe that interpretation services required for the molecular/genetic tests under review by CMS are best provided by laboratory directors with appropriate qualifications in molecular diagnostics—in most cases they are Ph.D. laboratory directors trained in molecular diagnostics. Further, AAB and NILA believe that payment for these tests should be made through the Part B CLFS to ensure that the interpretation services can be provided by qualified Ph.D. molecular biologists/laboratory directors.

At this time, there are not a sufficient number of qualified pathologists with the necessary expertise to clinically interpret all of the new molecular tests being considered for possible placement on the PFS. If all of these tests were placed on the PFS, then we share the expressed concern of our colleagues within the American Association for Clinical Chemistry who stated in their submitted comments on the CY 2013 PFS proposed rule that "a blanket placement of the molecular tests on the PFS could result in: (1) laboratories being forced to provide interpretive services for free; (2) physicians signing off and laboratories billing for interpretations that were actually conducted by Ph.D. scientists, which is fraud under Medicare; or (3) a delay in interpretations, which could adversely affect patient care."

The rationale for putting the new molecular tests under the CLFS is that the best interpretation for these new molecular tests can take place under the CLFS. There are many codes under the current CLFS for which Ph.D. molecular biologists already provide extensive consultations (e.g., cytogenetics) and the Clinical Laboratory Improvement Act (CLIA) requires that professional interpretation and consultation be provided by a Clinical Consultant (Ph.D. or M.D.) for all CLIA-covered tests, regardless of the fee schedule they are paid under. NILA and AAB strongly believe that CMS should compensate laboratories for CLIA-required consultation services provided for tests, current and future, paid under the CLFS (i.e. a component of the CLFS payment should cover the CLIA-required consultation).

In conclusion, AAB and NILA believe that CMS should place the new molecular tests under consideration on the CLFS for the benefit of patient care. Payment for these tests and their professional interpretation should be directed to the experts who have the requisite knowledge, training, and experience. It is not in patients' interests to have these tests paid under a fee schedule where the clinical interpretation is not being conducted by individuals with the necessary level of expertise to do so.

Section V. Collection of Information Requirements

A. ICRs Regarding Diagnostic X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions (§ 410.32)

In this section, CMS suggests that in order to document medical necessity, "both the medical record and the laboratory requisition (or order) would be required to be signed by the physician or qualified non-physician practitioner who orders the service." CMS suggests that the burden associated with these requirements would be "incurred by persons in the normal course of their activities and therefore considered to be usual and customary business practices." We are very concerned with this section, as it was made clear by CMS in a proposed rule published in the June 30, 2011 Federal Register, "Clinical Laboratory Fee Schedule: Signature on Requisition," [CMS-1436-P], that it did not intend to require the signature of a physician or non-physician practitioner on a requisition for clinical diagnostic laboratory services.

We are also very concerned with the equation of the terms "requisition" and "order" by CMS in this proposed rule. A physician's signature is required on an order for a clinical laboratory test; however, a requisition is often generated automatically from a physician order via phone call, fax, electronic submission, or a standing order in a health record and therefore is not physically generated by the physician—making a signature sometimes impossible.

AAB and NILA issued comments on August 19, 2011, in favor of the abovementioned proposed rule in which we outlined the serious implications of requiring a physician signature on clinical laboratory requisitions. These comments are repeated below in reference to the current proposal to have both the medical record and the laboratory requisition signed by the ordering physician or non-physician practitioner. There are two main concerns with requiring a physician signature on clinical laboratory requisitions: a threat to access to care for Medicare beneficiaries and an added administrative burden and cost to the health care system.

Threat to Access to Timely and Necessary Care

Requiring physician signatures to be provided on all laboratory requisitions puts laboratories in an unfair and potentially dangerous position if a signature is missing. Timely laboratory testing is often essential to patient care. In the skilled nursing home environment, obtaining a physician signature on requisitions for daily laboratory orders and STAT requests would create additional documentation requirements without any improvement in the order validation process and could endanger a vulnerable Medicare beneficiary's health if tests were delayed.

Administrative Burden

A requirement for physician signatures on laboratory requisitions would significantly increase the administrative burden for laboratories and the health care system. Under this requirement, there would be duplication of record keeping, as the physician would need to sign the requisition in addition to the patient's medical order/chart, as is already required. Many physicians collect laboratory specimens in their offices. In this case, mandating a signature for specimens collected by office staff, based on the physician's charted orders, layers another redundant process upon the implied consent found in the use of pre-printed requisitions and on-site office collections.

AAB and NILA feel very strongly that the proposal to require a physician's signature on all clinical diagnostic laboratory tests paid through the clinical laboratory fee schedule is not sound public policy and would create an unsafe environment for patient care.

Again, we very much appreciate the opportunity to comment on the Calendar Year 2013 Physician Fee Schedule Proposed Rule regarding payments for new molecular pathology tests and physician signature requirements on laboratory requisitions.

If you have questions or would like more information about any of the examples used in these comments, please contact me at (314) 241-1445, birenbaumm@birenbaum.org or Julie Allen at (202) 230-5126, julie.allen@dbr.com.

Sincerely yours,

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