American
Clinical Laboratory
Association

September 24, 2018

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, Maryland 21244-8016

RE: Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model; Proposed Rule (CMS-1695-P)

Dear Ms. Verma,

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the proposed rule addressing the Medicare Hospital Outpatient Prospective Payment System for CY 2019 and other issues ("Proposed Rule").[1] ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital, and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion annually to the nation's economy.

ACLA's comments on the Proposed Rule are focused primarily on the "Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information."[2] The Centers for Medicare and Medicaid Services ("CMS") states that it "encourage[s] all providers and suppliers of health care services to undertake efforts to engage in consumer-friendly communication of their charges." ACLA agrees with CMS that, to the extent possible, providers and suppliers should help patients understand what their potential financial liability may be for services they obtain. In some circumstances, this may help patients become savvier health care consumers, and at the very least, it may decrease the number of "surprise bills" that patients receive.

ACLA member laboratories furnish both clinical laboratory tests reimbursed under the Clinical Laboratory Fee Schedule ("CLFS") (*e.g.*, complete blood count, HbA1c, breast cancer gene expression), and anatomic pathology services, which are reimbursed under the Physician Fee Schedule ("PFS") and generally include both a technical component and a professional component (*e.g.*, surgical pathology, immunohistochemistry, fluorescent in situ hybridization). Medicare

[1] 83 Fed. Reg. 37046 (Jul. 31, 2018).
[2] *Id* at 37211.

beneficiaries are not subject to out-of-pocket costs for tests reimbursed under the CLFS; they may be subject to out-of-pocket costs for anatomic pathology services reimbursed under the PFS.

While ACLA supports healthcare price transparency conceptually, there are several operational and logistical barriers for independent laboratories, particularly with respect to informing a patient how much his or her out-of-pocket costs for a service will be before furnishing the service. Other entities involved in a patient's healthcare, such as the payor or a hospital, are far better positioned to inform a patient about potential costs than an independent laboratory. And only a payor has complete information about what a patient's out-of-pocket costs would be, given the patient's particular health insurance plan design, deductible, covered services, and service frequency limits.

In the overwhelming majority of cases, an independent laboratory does not have any face-to-face encounter with a patient; the specimens it tests most often are collected by others and forwarded to the laboratory. Oftentimes, an independent laboratory does not get full contact information for a patient, and if it does, it is not always correct or complete. Another factor is the importance of maintaining specimen integrity by performing testing as quickly as possible after receiving a specimen and of adhering to tight turn-around times for test results. Simply put, it would be operationally infeasible for an independent laboratory to attempt to contact a patient, following receipt of a specimen and prior to accessioning and analyzing a specimen, to inform the patient what the cost might be. This extra step may allow a specimen to degrade and possibly negatively affect specimen integrity, and it would delay reporting test results to the treating health care practitioner and, consequently, delay patient treatment. (In any event, where a physician collects a patient specimen and forwards it to a laboratory, the patient may not know the name of the laboratory that will be testing his or her specimen and may not welcome contact from an unknown entity.)

Layered on top of the very real logistical challenges outlined above are hurdles that are specific to anatomic pathology services. Most anatomic pathology services involve microscopic examination of tissue taken during a biopsy procedure or surgery. This is often aided by the use of special staining techniques and other associated tests, such as antibodies, to identify different components of the tissue. In most cases, the independent laboratory performing the anatomic pathology procedure is not involved in taking a biopsy, so there is no face-to-face interaction with a patient. It is not always apparent when a specimen comes in to a laboratory whether special stains may be required and how many. This, and the lack of face-to-face interaction with a patient, makes it impossible to provide a pre-service estimate to a patient of potential out-of-pocket costs.

For laboratory services furnished by an independent laboratory to hospital inpatients and outpatients, it generally is more appropriate for the hospital to share information with a patient about possible charges, rather than the laboratory. In the inpatient and outpatient context, most clinical laboratory tests and the technical component of anatomic pathology services are bundled into a primary hospital service under Medicare policy. When an independent laboratory furnishes these laboratory services to a hospital pursuant to an agreement with the hospital, the laboratory bills the hospital for the services and the hospital, in turn, submits a claim to a payor. Once again, the independent laboratory does not have face-to-face interaction with a patient and may receive even less demographic and contact information than it does for non-hospital patients.

For the foregoing reasons, independent laboratories cannot be expected to provide information to patients on potential out-of-pocket costs before providing a laboratory service. ACLA members will continue to promote price transparency where it is operationally feasible and where it does not pose undue burdens for the patients receiving the laboratory services nor the laboratories furnishing them. Thank you for your consideration of our comments.

Sincerely,

Sharon L. West
Vice President, Legal and Regulatory Affairs
American Clinical Laboratory Association