



September 6, 2016

Via Electronic Mail

Acting Administrator Andy Slavitt
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Rm. 445-G
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare Program; Hospital Outpatient Prospective Payment System and Ambulatory Surgery Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Proposed Rule (CMS-1656-P)

Dear Mr. Slavitt:

The National Independent Laboratory Association (NILA) welcomes the opportunity to provide comments on the proposed CY 2017 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Rule. NILA represents a broad spectrum of laboratories, from small community laboratories to large multi-state regional laboratories, which work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients. For the majority of NILA's members, 30-50 percent of their testing services are provided to Medicare beneficiaries. Some NILA laboratories provide a full range of clinical diagnostic testing services, while others are focused primarily on providing routine and emergency (STAT) diagnostic services to allow physicians to manage chronic diseases.

Our comments focus on CMS's plan to amend its laboratory test packaging policy as established in CY 2014 and adjusted in CY 2016, and specifically, the implications the proposed policy has on existing regulations to establish laboratory payment reform under the *Protecting Access to Medicare Act of 2014*.

Proposed Clinical Diagnostic Laboratory Test Packaging Policy: Unrelated Laboratory and Molecular Pathology Test Exceptions

The proposed rule suggests three primary changes affecting reimbursement for clinical laboratory testing services that are provided in the hospital outpatient setting, including off campus hospital-owned laboratory facilities. First, the proposed rule would eliminate the current exclusion for

“unrelated” laboratory tests, thereby allowing for the packaging under the hospital outpatient prospective payment system of all laboratory tests that appear on a claim with other hospital outpatient services whether or not they are directly related to the service provided or ordered by the same physician providing other services on the claim. Secondly, the rule implements the 2015 amendment to the OPSS statute relating to tests furnished by an off-campus outpatient department. Under the proposed rule’s implementation of “site-neutral” payment, such off-campus tests would be billed under the Medicare Physician Fee Schedule or the Clinical Laboratory Fee Schedule (CLFS), as appropriate. Third and finally, the proposed rule expands the molecular pathology packaging exception to include advanced diagnostic laboratory tests (ADLTs).¹

Packaging of Unrelated Laboratory Tests

While NILA understands CMS’ rationale for discontinuing the use of the L1 modifier to identify unrelated laboratory tests previously excluded from packaging under the hospital outpatient payment system, we question how CMS will set rates for these testing services going forward. Under the packaging payment system, a comprehensive payment will be set for the services on a given claim, including laboratory tests that might truly be unrelated to other services on the claim. CMS does not explain in the proposed rule what evaluation will be conducted to set payment rates for laboratory tests that are unrelated or otherwise. NILA asks that CMS provide an explanation as to how laboratory test payment rates will be set under the proposed packaging policy. We are concerned about the appropriate value being assigned to clinical laboratory tests under any and all Medicare fee arrangements.

Expansion of Laboratory Test Exceptions from Packaging

Under the proposed rule, CMS expands its molecular pathology packaging exception to include advanced diagnostic laboratory tests. Going forward, these tests would be paid under the CLFS when provided by a hospital outpatient department or a hospital-owned off campus department. For some hospitals, particularly those focused on expanding their testing menus to offer new molecular testing services and/or advanced diagnostic laboratory testing (ADLT) services to patients, CMS’ proposed policy will result in significant billings to the CLFS. As the new ADLT application process gets underway, there are also other tests that may not qualify for ADLT status but for which laboratories may also seek separate payment outside of the hospital packaging payment and under the CLFS going forward. Any expansion of CMS’ molecular pathology packaging exception, now or in the future, only further results in a greater number of hospital outpatient departments that bill under the CLFS in higher volumes.

CMS is proposing a policy to expand the number of tests provided in the hospital outpatient setting or by a hospital-owned off campus facility that are to be paid under the CLFS while at the same time instituting and implementing a final rule that excludes hospital outpatient laboratories from reporting laboratory payment and test volume data under the *Protecting Access to Medicare Act of 2014* (P.L. 113-93) (“PAMA”). Data collected from laboratories under PAMA will be used by CMS to adjust laboratory payment rates under the CLFS, beginning in January 2018.

CMS makes clear in its preamble to the PAMA final rule that it does not believe hospital outpatient laboratory data should be included in its laboratory market data assessment, pointing to the packaging payment policy in effect, which with few exceptions, does not currently pay for clinical laboratory

¹ 81 FR 45628-9.

services under the CLFS. To ensure hospital outpatient laboratory data is excluded from consideration in the PAMA data review system, CMS set forward a standard that limits the type of laboratory that is required to report data to the agency. While the PAMA statute states that a laboratory that receives 50 percent or more of its Medicare revenue from the CLFS or Physician Fee Schedule (PFS) has to report its payment data to CMS, CMS has implemented a regulation that assesses that 50 percent revenue threshold across an entity's National Provider Identifier (NPI) number. Since no hospital outpatient laboratory has its own NPI, but rather falls under the larger hospital's or health system's NPI, the 50 percent revenue threshold is assessed across the entire hospital's Medicare revenues. Under this broad assessment, hospital outpatient laboratory payments under the CLFS will never make up 50 percent of payments when compared to all Medicare revenues across the entire hospital or health system.

NILA vehemently disagrees with CMS's exclusion of hospital outpatient laboratory payment data under the PAMA reporting system, especially now that CMS seeks to amend and expand its policy to allow more outpatient laboratory tests to be billed and reimbursed separately under the CLFS. The PAMA reporting system finalized by CMS is not designed to reflect the full laboratory market or the associated payment rates across the entire market. CMS has limited private payor data reporting to independent laboratories, intentionally excluding private payor data from hospital laboratories that have a far broader range of payment rates in the commercial market. The resulting data imbalance following the reporting process will ultimately result in a biased rate adjustment that is based on one segment of the laboratory market - the one that is dominated by two national laboratories, which have more than 54 percent of the test volume in that one segment. This will lead to a significant reduction in CLFS payment rates under PAMA and make it impossible for small and mid-size laboratories to compete in the market going forward.

HHS' baseline assessments for 2014 indicate that roughly 24% of Medicare Part B lab test payments were made to hospital-based laboratories.² Under the existing structure and the Proposed Rule, the expansion of the molecular and pathology and ADLT test exceptions from packaging will result in an increased billing of hospital laboratory tests under CLFS, including off-campus "site-neutral" operations. In many cases, such as for laboratories that specialize in molecular pathology, the majority of a particular laboratory's revenue will be derived from tests billed under the CLFS. Yet, despite the directive set out in Section 216 of PAMA, CMS has structured the reporting in such a way that these laboratories will not be included in the evaluation of Medicare rates. The inclusion of a statistically relevant number of hospital laboratories in the PAMA rate evaluation is critical to ensure that the full clinical laboratory market is reflected in the data. Without the inclusion of hospital laboratory payment data from hospital laboratories that receive the majority of their Medicare revenues from the CLFS or PFS, the CMS reporting structure places artificial weight and preference on the private payor rates received by the two largest national laboratories. The resulting payment adjustments based on a biased rate evaluation method are certain to lead to a duopoly in the Medicare laboratory testing market.

Conclusion

Community and regional independent laboratories are essential to ensuring access to testing services for Medicare beneficiaries. They provide the majority of testing services to rural communities and to

² The data mix of outpatient and outreach laboratories in this study is unclear, but HHS specifies that inpatient data is excluded. Department of Health and Human Services Office of the Inspector General, *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data*, September 2015, available at <https://oig.hhs.gov/oei/reports/oei-09-15-00210.pdf>.

niche care settings such as skilled nursing facilities, assisted living facilities, federally qualified health centers, and for homebound patients. As CMS seeks to allow hospital outpatient laboratories to expand the number and type of tests they bill under the CLFS, NILA urges CMS to recognize the problems with the PAMA reporting system as planned and amend its private payor rate reporting structure to ensure it represents the full laboratory market, including hospital outpatient laboratories, as appropriate. If you have questions concerning these comments, please contact Julie Allen, NILA's Washington Representative, at 202-230-5126, Julie.allen@dbr.com.

Sincerely yours,

A handwritten signature in blue ink that reads "Mark S. Birenbaum". The signature is fluid and cursive, with a long horizontal flourish at the end.

Mark S. Birenbaum, Ph.D.
Administrator