



June 13, 2014

Ms. Liz Richter
Deputy Director
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Richter:

On behalf of the National Independent Laboratory Association (NILA), we thank you and your team for meeting with Dr. David Smalley, Julie Allen, and Erin Will Morton (representatives of NILA), and other members of the Clinical Laboratory Coalition on April 17, 2014, to discuss the reform of the Clinical Laboratory Fee Schedule (CLFS) included in the *Protecting Access to Medicare Act of 2014*.

NILA represents community and regional clinical laboratories that work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and home health care agencies. NILA members range in size from community-based small businesses to large multi-state regional laboratories. For the majority of NILA's members, 30 percent or more of their work is in the Medicare program, and many serve rural geographic locations and unique service markets, including skilled nursing facilities (SNFs). NILA's members typically provide traditional and "stat" (immediate) diagnostic laboratory services relied on by physicians across the country to diagnose and manage chronic diseases that are primarily reimbursed through the Part B CLFS.

As we expressed during our meeting, NILA is extremely concerned about the impact this law will have on regional and community laboratories and the Medicare beneficiaries they serve. While NILA does not support the approach of this law, we want to ensure that the new process for determining Medicare reimbursement rates does not force community or regional laboratories out of Medicare or, perhaps, out of business altogether—negatively affecting access to Medicare laboratory services. We are particularly concerned about how Medicare's payment changes could affect competition in rural communities and with laboratories that perform a majority of laboratory testing for specific sites of service, including skilled nursing facilities, home health, homebound patients, and federally qualified health centers. We strongly believe that the agency's focus on implementation of the new program must be about more than deriving a savings by cutting payment rates. The best outcome for the Medicare program is for the regulations to take a surgical approach, rather than an ax, to the Part B CLFS to ensure adequate competition in the market and continued access to laboratory services.

Following our meeting, we convened an internal association workgroup to address many of the issues raised during our discussion and to plan a written response in follow-up to your request. The following outlines our preliminary recommendations and issues for consideration as you develop proposed regulations.

Applicable laboratories:

- The law seeks to outline which laboratories (applicable laboratories) must report private market rates under a new mandatory reporting system. For CMS to capture the full laboratory market and the variances in rates and volume, it is important that hospital laboratory payment rates and physician office laboratory rates be included. We recognize the law specifically excludes capitated rates and bundled payments from the reporting requirements, but other market rates from all laboratory players, such as hospital laboratories, must be included in order to fully represent the market. It was Congress' intent to include certain hospital payments in the market reporting system outlined by the law, as referenced during a colloquy between Senate Finance Committee Ranking Member Orrin Hatch and Senate Finance Committee member Richard Burr on May 8, 2014.
- The law requires laboratories that earn a majority of their Medicare revenue from payments made from either the Part B CLFS or Medicare's Physician Fee Schedule to report their private payor rates. We advise CMS to ensure that a loophole does not exist to exclude laboratories that may gain the majority of their Medicare revenue from Medicare Part C (Medicare Advantage). The law requires Medicare Advantage rates to be reported along with commercial payor rates; therefore, it would be inappropriate to exclude laboratories with a higher percentage of Medicare Advantage business from the reporting requirements.

Reporting of Rates and Review Process:

- CMS must not limit its rate reporting requirements and subsequent payment review process to focus exclusively on, or on a majority of, routine laboratory tests. Some laboratories, including many community and regional laboratories, do not offer a testing menu that includes a broad portfolio of tests beyond routine testing (e.g., esoteric, molecular, genetic, or specialized tests). For these laboratories, the majority of services provided to physicians and other health providers are routine testing services because the Medicare beneficiaries they serve tend to be chronically ill patients in need of ongoing care management (e.g., SNF residents). Data show that the rate of increase in the volume of routine testing services has been flat, seeing little-to-no growth over the last several years, whereas other types of tests, particularly molecular tests, have experienced high growth rates. As CMS determines which tests are ultimately to be included under a new reporting system, it should seek to ensure that reporting requirements are not restricted to, or primarily focused on, routine tests. CMS should diversify its focus and also require reporting on, and the review of, high dollar tests and those tests that are seeing large growth in Medicare utilization.

- To ensure CMS is appropriately capturing the full payment rate as provided by private payors, laboratories should be asked to report the total “allowable amount” paid by private payors, and these amounts must include all patient cost sharing associated with each laboratory testing service (e.g., copayments, coinsurance, deductibles) in order to ensure the accuracy of the payment for each individual laboratory test.
- Many large commercial payors have negotiated contracts with large national laboratory providers that restrict or eliminate the participation of community and regional laboratories. In cases where the community and regional laboratories can still work with physicians under the commercial contracts, the laboratories must provide services as an out-of-network provider. Out-of-network payments represent a growing segment of the laboratory payment market and should be reported to demonstrate the variances in market payment rates.
- There are some laboratories that do not bill Medicare for the testing services they provide but serve as reference laboratories for those laboratories that ultimately do bill Medicare for services. Reference laboratories charge referring laboratories rates that can greatly vary from the rate paid by Medicare or a commercial payor. In order for CMS to understand the market rates associated with providing reference testing services, the agency is encouraged to collect reference laboratory payment rate information.
- There are instances where private payors make adjustments to contract rates and determine they will no longer pay for certain tests individually. Reporting requirements must be flexible to permit laboratories to explain such discrepancies. For example, it would be inaccurate for a laboratory to report \$0 for a given test because the payor adjusted how or when it would pay for a specific test, as this would skew the reporting data.
- Laboratories should not be required to report rates that are undergoing an appeals process with any given payor prior to a final appeal decision.

Rate Setting Process:

- The process by which CMS determines the new rates for the CLFS must be transparent and allow for comment from stakeholder groups on rate calculations prior to the initiation of revised Medicare laboratory rates. The law establishes a new Clinical Laboratory Expert Advisory Panel for guidance on laboratory test payment rates. CMS should utilize this advisory panel for support and insight on adjustments to tests currently on the CLFS in addition to new tests under consideration. CMS will need expertise and support on all the complexities of laboratory payments and billing—issues including contract rates, the contracting process, volume variances, and nuances in private payor payment schedules.
- The law establishes a phased-in approach to Medicare laboratory reimbursement rate reductions. However, if the tests subjected to reductions are primarily a specific type of testing (e.g., routine tests), the subsequent negative effect on the Medicare testing market and beneficiary access will be immense. CMS has a responsibility under the law to collect and assess payment data based on reported payment rates and volume. But CMS also has the responsibility to ensure there is no significant disruption, and a resulting crisis, in access to Medicare laboratory services.

- CMS must also consider other factors in its payment evaluation. Some laboratories deeply discount routine tests in their commercial contract negotiations, knowing they will make up these losses from the income received by providing esoteric, molecular, genomic, and other types of tests that have significantly higher payment rates and much higher profit margins than routine tests. Focusing reductions on a narrow set of laboratory testing services (e.g., routine tests), therefore, would provide some laboratories with an unfair market advantage over others. The impact on those laboratories that do not have the high testing volumes of the national laboratories or the diversity of testing options that can help absorb losses from the significant reductions outlined by the phased-in approach will threaten those laboratories' existence, and ultimately access to community-based laboratory testing services. Reducing the number of laboratory service providers within the Medicare program will ultimately lead to higher Medicare laboratory pricing and reduced access to laboratory services for beneficiaries.

Clinical Laboratory Expert Advisory Panel:

- CMS has discretion to determine the types of individuals to serve on the new Clinical Laboratory Expert Advisory Panel. The agency should ensure diversity in the participation of this panel and that there are panelists that understand how clinical laboratories operate and the costs associated with providing laboratory services in a diversity of settings (geographic, specific service sites, etc.). For laboratory-specific panelists, in order to ensure there is an understanding of the variances in how different segments of the laboratory community operate and the associated costs, we urge CMS not to limit laboratory representative participation to national laboratory providers. It is imperative that the Advisory Panel include representatives from community and regional laboratories.

Civil Monetary and Other Penalties:

- The law gives the agency discretion to establish civil monetary (up to a maximum of \$10,000 per day) and other penalties against laboratories that fail to comply with reporting requirements. The new reporting requirements constitute a new, significant, unfunded mandate on the clinical laboratory community that is being fast-tracked under the requirements of the law. The opportunity for glitches and mistakes, both on the part of the agency and the reporting laboratories, are immense as the new system is put in place. CMS should not establish significant threatening penalties in the face of a newly established program, especially penalties that could never be financially met by small community laboratories that make innocent mistakes as the new reporting requirements are instituted.
- CMS should establish an appeals process for laboratories that are accused of wrong doing in association with the reporting process in order to ensure fairness and the opportunity for a laboratory to address accusations and present evidence when appropriate to contradict such accusations.

Sample (Specimen) Collection Fee Adjustment:

- The law increases the sample (specimen) collection fee for collection services conducted by a laboratory in a skilled nursing facility or on behalf of a home health agency from a nominal amount of \$2.00 to a rate of \$5.00. We ask that CMS immediately move to initiate this rate adjustment for this service, recognizing that the payment rate for this service has been below market level for many years, having been set in 1984 with no increase in payment for 30 years. Just based on inflation, Medicare's specimen collection fee should now be \$6.85.

CMS Final Rule; 42 C.F.R. § 414.511:

- With the laboratory reform provisions of the Protecting Access to Medicare Act of 2014, Congress intended to immediately rescind the laboratory regulation included in 42 C.F.R. § 414.511, and requested that the agency proceed with rules to implement the new laboratory law. As a result, the agency should immediately withdraw its regulation to adjust prices on the Part B CLFS based on technological changes.

We respectfully request that CMS consider these comments as you work through the rulemaking process. We look forward to working with you and your team as regulations are developed, and we offer our association as a resource as you plan and test any processes intended to implement the rule. If we can provide additional information at this time, please contact us or our Washington, DC-based representative, Julie Allen, at 202.230.5126 or julie.allen@dbr.com.

Sincerely yours,



Mark S. Birenbaum, Ph.D.
Administrator