

***Government Affairs Committee (GAC)***

***e-newsletter***

***Issue #16 Part II – June 2014***

One of the strategic goals for our committee is to improve communication to the broader ASCLS membership and to provide more consistent and timely legislative and regulatory information for our members. The GAC e-newsletters are also available on the ***ASCLS Advocates for You*** section of the ASCLS website.

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* Laboratory provisions of the Protecting Access to Medicare Act (PAMA) of 2014
	+ Developed from a bill summary by Patrick Cooney, ASCLS Legislative Consultant

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**Section 216, *“Improving Medicare Policies for Clinical Diagnostic* *Laboratory Tests”***.

As stated in Part I of the GAC eNewsletter, this section contained many provisions affecting the future of clinical laboratory reimbursement. They include:

**Reporting of Private Sector Payment Rates**

Beginning January 1, 2016, applicable laboratories (to be defined in the regulations that CMS is writing) will report to CMS, for the previous 12-month period, the private payer reimbursement received for each laboratory test, along with the volume of tests billed to each payer. While needing more clarification, “applicable” laboratories are currently defined as those which bill Medicare under the Clinical Laboratory Fee Schedule (CLFS). (If a laboratory only receives payment through DRGs or other bundled payment systems, they will not have to report.)

The law requires that an “officer of the laboratory” shall certify the accuracy and completeness of the information reported. If CMS determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information, fines up to $10,000 per day may be assessed.

**Payment for Clinical Diagnostic Laboratory Tests**

The data gathered will determine CLFS reimbursement rates going forward. For a clinical diagnostic laboratory test furnished on or after January 1, 2017, the payment amount shall be equal to **the weighted median determined for the test for the most recent data collection period**. In other words the CLFS reimbursement will be based on market rates. ASCLS is concerned that the rates negotiated by the large national reference laboratories could negatively impact reimbursement for hospital and clinic laboratories.

Payment amounts determined for a clinical diagnostic laboratory test for each of 2017 through 2022 shall not result in a reduction in payments greater than 10 percent for years 2017 through 2019 and 15 percent for years 2019 through 2022. No reduction in payment will apply for new tests or for a new advanced diagnostic test. **Note: We are awaiting interpretation as to whether this means no more than a 10 or 15% decrease for each year or for each of the three-year periods. This difference would be significant.**

**Specimen Collection Fee:** One positive provision in the legislation is the reimbursement for specimen collection (phlebotomy) for patients in skilled nursing facilities or on behalf of home health agencies was increased by $2.00 per collection.

**Payment for new ‘advanced diagnostic laboratory tests (ADLT)’ - terminology similar to “laboratory developed test (LDT)”:** This section of the legislation is very detailed. Of most interest is the definition of the term ‘advanced diagnostic laboratory test’. An ADLT is a clinical diagnostic laboratory test offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria

* the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result or
* the test is cleared or approved by the Food and Drug Administration.

If the advanced diagnostic laboratory test has not been paid under the fee schedule, during an initial period of three quarters, the payment amount for the test shall be based on the actual list charge for the laboratory test. If, after CMS is able to obtain market data, it is determined that the payment amount for an advanced diagnostic laboratory test during the period was greater than 130 percent of the payment amount for the test established during the initial three quarters, CMS shall recoup the difference between such payment amounts for tests furnished during such period. CMS shall adopt temporary HCPCS codes to identify new advanced diagnostic laboratory tests and new laboratory tests cleared or approved by the Food and Drug Administration.

**Payment for Tests that are not ‘advanced diagnostic laboratory tests’:** For each test assigned a new or different CPT code, and not considered “advanced diagnostic tests”, payment will be determined by using the current cross-walk (to the most similar, appropriate existing test) or a new gap fill processes, until a payment rate through the new market-based analysis can be determined.

**Advisory Panel:** CMS shall consult with an expert outside advisory panel, established by not later than July 1, 2015, composed of an appropriate selection of individuals with expertise to provide input into the establishment of payment rates and the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests.

**GAO Study and Report; Monitoring of Medicare expenditure and implementation of new payment system:** Because this legislation will result in a dramatic change in terms of how Clinical Laboratory Fee Schedule reimbursement rates are determined, the legislation also calls for a retrospective study on the impact of the change. The Comptroller General of the United States shall conduct this study and submit it, by October 1, 2018, to the House Ways and Means Committee, the House Energy and Commerce Committee and the Senate Finance Committee.

In general, this report must include the following:

* payment rates paid by private payers for laboratory tests including all practice settings and trending over time
* trends by private payers to move to alternative payment methodologies
* how the new payment system impacts beneficiary access to testing and impacts laboratories which only do very specialized testing.
* the number of new HCPCS procedure codes issued for laboratory tests;
* the spending trend for laboratory tests;
* whether the new payment rates for laboratory tests accurately reflect market prices; and
* changes in the number of advanced diagnostic laboratory tests and laboratory tests cleared or approved by the FDA.

We will keep you informed about where this is all going and will alert you when CMS publishes the proposed rule. All of us must be prepared to comment on the rule to ensure that our data and experiences count!

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Rick Panning, GAC chair (2013-2014)

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