# New Pricing Formula for Advanced Diagnostic Tests

## New law defines ADTs and directs CMS to use HCPCS codes and list prices for these new tests

***CEO SUMMARY: One section of the federal H.R. 4302: Protecting Access to Medicare Act of 2014 is getting positive reviews from many lab experts. The law defines advanced diagnostic tests (ADTs) and directs CMS to assign a temporary HCPCS code and use list prices to pay labs for such tests while it is determining reimbursement guidelines. However, because few labs perform ADTs, this section of the law affects only a handful of lab companies performing sole-source lab tests.***

PASSAGE OF THE NEW FEDERAL LAW TITLED THE "Protecting Access to Medicare Act of 2014," creates a statutory definition of an advanced diagnostics test (ADT) and requires the federal **Centers for Medicare & Medicaid Services** to set payment rates for those clinical lab tests that are ADTs.

Lab industry groups seem to like this specific section of the new law. However, its benefit is limited to a specific group of laboratories that offer proprietary or sole-source diagnostic tests.

"While the ADT section in the legislation is positive for the lab testing industry, it does not affect many clinical lab companies because few labs offer these single-source tests that are either multi-analyte assays with algorithmic analyses (MAAAs) or FDA-cleared LDTs," said Jacqueline Huang, Senior Associate at **Quorum Consulting Inc.**, a company in San Francisco, California, that specializes in clinical reimbursement issues.

However, for those laboratory companies that do offer tests that meet the definition of an ADT, the language of this law will be highly beneficial. "Overall, this [section of the] law represents a clear win for labs performing complex or esoteric single-source tests as well as for labs that have obtained FDA clearance for their LDTs [that qualify as ADTs]," wrote Quorum in a summary of the new law for its clients. "As the sole providers of such tests, these labs have stronger bargaining power with private payers, which will in turn influence Medicare payment rates as well."

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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Industry Affairs for **Xifin, Inc.**, in San Diego, agreed with Huang that the number of labs running ADTs was relatively small. "But the issue is important nonetheless because labs are continually introducing new diagnostic tests and many of these tests could fit the definition for an ADT," she explained.

## Definition Of An ADT

"On that point, the definition of an ADT is not exactly clear when you consider that the law says an ADT may also be defined as meeting 'other agency criteria,'" observed Wolf. "If you think about it, that definition is rather broad.

"Thus, how will federal regulators define the growing number of diagnostic tests now moving to next-generation sequencing and that neither require algorithms nor are FDA-cleared?" she asked. "This is just one of dozens of questions that the lab industry has about this law and it will take some time to get all the answers."

An advanced diagnostic test must meet the following statutory definition: a clinical diagnostic laboratory test that is offered and furnished by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner). In addition, the test must meet at least one of the following three criteria:

1) It is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result;
2) It is cleared/approved by the FDA; or,
3) It meets other similar criteria that the secretary of HHS will establish.

Through 2016, the current methods of crosswalking or gapfilling will be used to set prices for ADTs. After that, labs offering new ADTs will need to provide the comparative market data after the first three quarters. Further, while establishing a price, the law says CMS should base payment on the laboratory list price of the tests for three quarters after launch.

"Everyone in the lab business will want to pay close attention to the details of how this law is implemented by following the clarifying language that the specialty associations and other stakeholders put forth for consideration by the secretary," advised Katherine Tynan, President of **Tynan Consulting LLC**, of San Francisco, California. "What the lab professional societies and other stakeholders recommend to the federal regulators and what gets accepted from their recommendations will be the key to how this law will work."

The story behind this section of the law is interesting. It starts in late March, just weeks before Congress passed the law. That was when the **Rare Disease Legislative Advocates** announced that it had suggested language related to the development of diagnostic tests that was included in the legislation. In the announcement, RDLA touted two specific areas of concern in the law.

"First, the bill would establish a temporary HCPCS code for advanced diagnostics so that healthcare providers can quickly begin using new tests, greatly speeding patient access," the RDLA announced. "Second, the bill establishes an expert advisory panel to better determine the payment rates for diagnostic tests. The creation of this panel will be a positive step in demonstrating the value of diagnostics and driving innovation in the field of personalized medicine."

## Standardized Rate-Setting

A number of sources interviewed by THE DARK REPORT stated that the special provisions for ADTs were clearly the result of work by the RDLA. In its analysis of the issue, Quorum Consulting wrote that the method of setting payment rates for ADTs will help to standardize how rates are established for advanced molecular diagnostic tests. Labs are likely to prefer this method especially when compared with the gapfilling methodologies that CMS used to set payment rates for Tier 1 and Tier 2 molec-

## Rule-Making to Implement New Laws's ADT Section Will Be Key to Developing Appropriate Pricing

**AMONG THE KEY ISSUES TO WATCH** in the coming months will be the definitions that evolve at CMS as regulators write the rules to implement the Protecting Access to Medicare Act of 2014, said Katherine Tynan, Ph.D., a consultant for diagnostics companies and the Founder and President of Tynan Consulting LLC, in San Francisco, California.

"For example, will next-generation sequencing tests fall under that definition of ADTs?" she asked. "If it does, that could be both good and bad. It would be good in that you could argue for more value-based pricing for these tests. But it would be bad in that we may not have the health economic skills across the healthcare community to communicate effectively the value of many of these tests.

"Everyone in the lab business will want to pay close attention to the details as this law is implemented," she advised. "They can do this by following the clarifying language that the specialty associations and the 'outside advisory panel' (that the secretary must establish by July 1, 2015) put forth. What they recommend and what gets accepted from their recommendations will be the key to how this section of the law will work.

"Another key issue that affects the current molecular testing industry is that, because payment for all these tests is based on the clinical laboratory fee schedule (CLFS), the professional work that goes into developing tests does not usually get built into pricing," she added. "There's a similar problem with LDTs.

"With LDTs, there is the development time, the validation time, and the professional work to interpret the results," said Tynan. "None of that is compensated on the CLFS. That is why careful attention must be paid to the rule-making to ensure these cost components are incorporated into the lab reimbursement paid for molecular tests.

"Clinical labs and professional societies need to influence the rule-making in the most positive manner by educating CMS about the value of molecular diagnostics," said Tynan. "In turn, laboratories must improve the quality systems they use to develop tests. They also must think through how to objectively substantiate claims of clinical utility for tests."

Tynan's message reflects the fact that the laboratory profession, and its various societies and associations, have generally been poor communicators of the value of lab testing. Also, it is seldom that the laboratory profession can speak with one voice about the range of issues that surface during lawmaking and when federal agencies are seeking public comment before issuing rules.

ular pathology codes last year under the MolDx program, Quorum suggested.

The section of the law that addresses ADTs may have another consequence. "Labs may be encouraged to apply for FDA approval for their LDTs because they will have more authority over their Medicare payment rates, at least in the short term," Huang said.

"However, there is a question as to whether this would provide enough incentive for labs to actually go through the regulatory process, since it would be yet one more hurdle for these labs," she noted. "Labs will need to weigh the pros and cons of each pathway and consider what will be the best way to optimize reimbursement in the long run. Either way, more LDT-developers will be interested in going down the FDA approval process. In turn, that could prompt the FDA to establish formal guidelines on FDA regulation over LDTs." TDR

*—Joseph Burns*

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