



American  
Clinical Laboratory  
Association

**NIH Public Meeting: Developing the Genetic Test Registry**  
November 2, 2010

American Clinical Laboratory Association  
Public Comment

The American Clinical Laboratory Association (“ACLA”) is pleased to have the opportunity to present this public statement to the National Institute of Health (“NIH”) on its plan to develop a Genetic Test Registry. ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. Many of ACLA’s members offer extensive menus of genetic tests. As a result, we have a direct interest in the development of the registry.

As stated in our comments in response to the Request for Information, we believe that a registry will provide easy access to information about genetic tests and could increase the understanding of users, including patients and providers, about the valuable information these tests offer. Our comments today focus largely on the issue of what mechanisms can be used to provide materials that explain the Genetic Test Registry’s data elements to audiences with varying technical expertise.

One of the tools ACLA recently developed that would be useful as a mechanism for deploying the GTR is a framework for its Laboratory Test Compendium to provide the ability, electronically, to exchange a Directory of Services (eDOS). This effort aims to simplify the exchange of data related to test Directories of Services and associated orders, while increasing their functionality and value within compatible electronic medical record (EMR) systems. Using the Compendium Framework benefits NIH by standardizing the process by which laboratories would make data submissions to the Genetic Test Registry.

Development of a standard Laboratory Test Compendium Framework addresses and defines how information that differs from laboratory to laboratory, such as the following, easily can be exchanged among all provider laboratories used by a client and the client’s EMR system:

- The codes used to order laboratory tests and the description of the laboratory tests
- The nature of the test (profile, single observation, etc)
- The potential reflex observations
- The specimen requirements
- The processing priorities (ability to order as stat, routine, or other priorities)

- A list of analytes included in the Lab Order Code
- The additional clinical and useful information required at the time of ordering

In July of 2010, formal ownership of eDOS was relinquished to Health Level Seven International (HL7), an ANSI accredited standards developer. In September, eDOS was successfully balloted at HL7, with plans to move towards certification in the near future.

Finally, ACLA recognizes that the Compendium Framework may have to be modified to meet the needs of NIH to facilitate data submissions. As such, ACLA stands ready to work with NIH on modifications to help facilitate use.

Thank you for the opportunity to comment. I'll be happy to answer any questions at this time.



November 11, 2010

VIA EMAIL TO [cfomous@od.nih.gov](mailto:cfomous@od.nih.gov)

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**Re: Supplemental Comments on the National Institutes of Health (NIH) Genetic Test Registry**

Dear Dr. Fomous:

On behalf of the American Clinical Laboratory Association (ACLA), I am pleased to submit these supplemental comments on the proposed National Institutes of Health (NIH) Genetic Test Registry (GTR). ACLA represents national, regional, and local laboratories across the country, many of which offer extensive menus of genetic tests. As a result, we have a direct interest in the development of the registry.

ACLA very much appreciated the opportunity to participate in the November 2, 2010 public meeting, during which NIH solicited stakeholder feedback on several questions related to the GTR. One of those questions related to whether the price of a test should be included as a data element in the GTR, and ACLA was pleased to participate on a panel discussion of that topic at the November 2 meeting. The purpose of these supplemental comments is to explain in further detail why price should not be included as a data element in the GTR.

First, if a single "list price" for each test could be provided in the GTR, it would more often than not be completely irrelevant, both to the amounts actually paid by patients, providers, and insurers, and to the amounts actually received by laboratories for the test. As a result, posting a price for each test in the GTR would not advance the goal of transparency, but would instead be misleading in most cases.

To illustrate the point, imagine a test for which the "list" price is \$10. What if the patient is uninsured and indigent? In some cases, labs negotiate agreements with clinicians to provide indigent care at a reduced price, and sometimes even for free, where permitted by law. In that case, the "list" price would not accurately reflect either the amount paid by the patient or the amount received by the lab. What if the patient is insured? If the lab has negotiated an agreement with the insurer, the lab may have agreed to accept \$9 to perform the test for members of that insurer. If the patient has not met his or her deductible, he may pay \$9 for the test; if he

has met his or her deductible, he may pay some percentage of the negotiated price as coinsurance after payment by the insurer. Again, in this case, the "list" price does not accurately reflect the amount paid by the patient or the insurer or the amount received by the lab. Further, the same insurer may have different rates negotiated for different health plans issued by that insurer in different geographical locations, and obviously, different insurers often have different negotiated rates with the same lab for the same tests, and different deductible, copayment and coinsurance agreements with their members. Medicare Administrative Contractors and carriers often pay different rates for the same lab tests, many of which are substantially below the National Limitation Amount. The "price" may also vary depending upon whether the lab is an "in network" provider for an insurer or an "out-of-network" provider for an insurer. What if the lab is operating in a state that permits client billing (also known as "pass-through" billing)? The lab may have agreed to accept \$9.20 from one physician client and \$8.80 from another physician client for performing the same test, based on differences the lab is legitimately entitled to consider in establishing the pricing of its services. The first physician client may in turn bill the patient \$15 for the test, while the second physician client may in turn bill the patient \$12 for the test. Again, the \$10 "list" price would not have accurately reflected the amount paid by the physician or the patient, or the amount received by the lab.

Second, as the illustration above should make clear, there is no such thing as a single price for any lab test. For each lab test that would be included in the GTR, each of the scenarios above, and more, would be applicable with regard to the pricing of the test. Any given laboratory may have hundreds of managed care agreements and thousands of client pricing agreements with different prices for the same tests. This complexity is compounded by the fact that these negotiated arrangements are not static; at any given time, some portion of a lab's portfolio of negotiated prices is undergoing re-negotiation and change, as are prices established without negotiation by the government or other payors. So, even if a lab had the capability to post every negotiated and non-negotiated price for every one of its tests in the GTR, the burden of keeping up with changes would be severe.

Third, there are other very good legal and policy reasons why prices should not be posted in the GTR. Many of the agreements that labs negotiate with insurers and clients contractually obligate the parties to maintain the confidentiality of the pricing. Violation of these contractual obligations could harm one or both parties economically and expose the breaching party to civil liability. Further, while price transparency may have beneficial effects on competition and costs in some contexts where identical "apples" are clearly being compared (although, even then it can result in higher prices in some cases were lower prices are discovered to have been an anomaly in the market), it is not at all clear at this point that the GTR will provide that kind of forum. Genetic tests, particularly those developed and performed in clinical laboratories, are not widgets. Two tests by two different labs for the presence of the same genetic characteristic for the same intended use may easily be quite different in methodology, reliability and accuracy; if represented in the GTR as the same test being performed by two different labs, one costing more than the other, providers or patients could be led to select the less expensive test even though its reliability and accuracy are questionable and the other test is reasonably priced and is clearly

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reliable and accurate. Price-based test selection under such circumstances could easily result in higher downstream costs due to less accurate and reliable test results leading to substandard patient care and poorer health – an outcome the GTR should seek to avoid.

Rather than potentially discourage voluntary participation in the GTR by including price as a data element, the GTR should direct price inquiries to the applicable laboratory or payor for a personalized response.

ACLA fully agrees with another key point made by a member of the expert panel recommending that NIH carefully consider the elusive and difficult concept of clinical utility in the design of the genetic test registry. The point was well made that clinical utility is distinct from analytic validity and clinical validity. Regardless as to how it is considered and defined, it will be difficult to provide clear guidance for clinical utility data submission to the registry. Clinical utility may best be left to experts in the field of genetics and physicians to determine how the tests can be applied for the benefit of patient care.

We look forward to working with NIH as it continues this process. If you have additional comments, or need further information, please do not hesitate to contact us.

Sincerely,

David Mongillo  
V.P. Policy and Medical Affairs