American
Clinical Laboratory
Association

July 8, 2016

Mr. Stephen Posnack
Director Office of Standards and Technology
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Standards and Interoperability Framework Initiative – Task Force
200 Independence Avenue, S.W.
Suite 729-D
Washington, D.C. 20201

Dear Mr. Posnack:

On behalf of the American Clinical Laboratory Association ("ACLA") we wish to express our continued support of the Meaningful Use rules and the laboratory Implementation Guides that help facilitate better patient health. One of the key aspects of facilitating ordering of laboratory tests is the electronic Directory of Services Implementation Guide (eDOS IG) developed by the member organizations of ACLA over 6 years ago and updated by the ONC Standards and Interoperability Framework Initiative (S&I Framework). We believed then, as we do now, that this Implementation Guide will improve the clinician experience because of the additional diagnostic information that will be available to them if the Electronic Health Record (EHR) vendor takes advantage of all the meta data provided. This in turn, will improve the clinician's ability to research diagnostic tools to assist in their diagnostic investigation thus improving patient care.

The complexity of many EHR systems has created a situation where limited components of the test are uploaded, thereby providing the bare minimum of information. Often only those tests necessary for the majority of the services the clinician provides are loaded into the database, probably the top 80 to 100 tests and their components. No additional tests are available on-line for the clinician to add as additional diagnostic insight to the individual patient's need. Providing the additional tests as resource opportunities for research to the clinician would greatly improve the potential patient outcomes. Additionally, the eDOS IG supports interim updates, which allows rapid deployment of new diagnostic tests, for example BRCA for breast cancer.

We firmly believe that the reason to limit the number of tests uploaded into the EHR system is due to the cost per test to build the limited set of data elements. The complexity of cross referencing one test within the EHR system is believed to take 2 to 3[1] hours even with the minimal number of data elements. Updates are anticipated to take the same amount of time, and are not always done in a timely manner. When tests are obsoleted and replaced with improved tests, there have been instances where the obsolete tests have been ordered by the clinician because the updated test is not in the EHR for several days or weeks. The impact is that every patient is then put on a pending list waiting for a response from the clinician to validate what test is acceptable to the clinician as an alternative. This could delay the sample

[1] Estimate average provided by ACLA membership.

from being processed; therefore, impacting the completion of the test performance and ultimately patient care. Often the reason for the delay in updating the EHR database may be that the clinician's staff struggles with finding 2 to 3 hours to perform the necessary updates.

The upload of the electronic eDOS data will still require medical review before applying the changes. Since this is validation of the proposed changes, it will likely take 30 minutes or less. Using 30 minutes as the target, this reduces the time per test by 75%, but it is likely it can be reduced to less than 5 minutes as users get better at the review process.

It is estimated that annual on-going maintenance will require the update of at least 10% of the tests annually or approximately 1 to 2 tests each month.

For simplicity the following assumptions are made:

- The hourly rate is $27.00[2].
- For manually managed database
  - 2 hours to manually create and update the test
  - On average approximately 200 tests are typically ordered by the clinician
  - 10% of tests require maintenance annually
- For eDOS IG supported database updates
  - Review of tests to approve cross reference will take approximately 30 minutes to review at a rate of 2 per hour
  - On average approximately 200 tests are typically ordered by the clinician
  - 10% of tests require maintenance

	Initial Development	Annual Maintenance	Cost for first 5 years
Current manual Process	$10,800	$1,080	$15,120
With eDOS	$2,700	$270	$3,780

Using the figures above, the estimates below were derived using the 2015 statistics for of Certified EHR providers from the ONC website[3], and assuming each practice has 2 laboratory interfaces per practice. For the purpose of the Provider estimate below, two assumed scenarios are included: 1) assumes10 providers/practice and 2) assumes 20 providers/practice.

	Estimated 10 providers per group practice			Estimated 20 providers per group practice		
	Initial Development	Annual Maintenance	Cost for first 5 years	Initial Development	Annual Maintenance	Cost for first 5 years
Current manual Process	$3,226,083,120	$322,608,312	$4,516,516,368	$1,613,041,560	$161,304,156	$2,258,258,184
With eDOS	$806,520,780	$80,652,078	$1,129,129,092	$403,260,390	$40,326,039	$564,564,546

[2] Based on median average Practice Manager Salary from Payscale.com.

[3] Total Providers Reporting the EHR Vendor as Primary (Health Care Professionals and Eligible Hospitals) from EHR-vendors-count-dataset.xlsx, extracting the reporting period dated 2015.

For the hospital estimate, assumes 2 lab interfaces per hospital.

	Initial Development	Annual Maintenance	Cost for first 5 years
Current manual Process	$299,635,200	$29,963,520	$419,489,280
With eDOS	$74,908,800	$7,490,880	$104,872,320

Each EHR system has at least two or more laboratory interfaces and, without eDOS, the same costs exist for each non-standard interface. With the adoption of eDOS standard, development cycles and costs can be reduced by implementing a standard interface. The EHR vendor can also incorporate the eDOS into their standard system offering independently from creating a laboratory orders and results interface.

An additional advantage of an eDOS implementation is that tests offered by the laboratory that are not part of the normal ordering pattern of the clinician, could be part of the search feature of the EHR. While a subset of tests in the test compendium may not be directly orderable from the EHR, they can at least be made available to help the clinician in diagnostic research without having to take extra steps to access the full directory, thereby improving the outcomes for the patient.

For the reasons outlined above, we strongly believe there are significant benefits for the adoption of the eDOS Implementation Guide for the electronic delivery of test compendiums. Thank you for your consideration of these comments.

ONC may use this information in its continued work to promote interoperability and increased utilization of health information technology. We are also sending with this letter a spreadsheet excel file, titled "eDOS Estimate Spreadsheet 2016-06-17", which documents how we derived these cost savings estimate calculations. The spreadsheet also contains a "Clinical Practice Estimator" work sheet that can be used by a practice manager to estimate their potential cost savings using eDOS to automate the initial load and subsequent updates of the laboratory test compendium into an EHR system.

Sincerely,

Thomas B. Sparkman, R.Ph., M.P.P., J.D.
Vice President, Government Relations

ATTACHMENT

CC: Gabriel, Meghan (OS/ONC) Meghan.Gabriel@hhs.gov, Farrah Darbouze (farrah.darbouze@hhs.gov)