

**NYC DOHMH's Primary Care Information Project Testimony
to the
Clinical Laboratory Improvement Advisory Committee**

Laboratory Interfaces

February 4th 2009

The Primary Care Information Project is pleased to present this testimony to the Clinical Laboratory Improvement Amendments Committee. The Primary Care Information Project (PCIP), a bureau within the New York City Department of Health and Mental Hygiene, currently oversees the largest community Electronic Health Record implementation in the nation. There are now over 1000 providers using a prevention-oriented EHR, with another 1500 in the pipeline. PCIP partnered with a vendor, eClinicalWorks, to create a fully integrated EHR that supports preventative care and chronic disease management. This EHR includes clinical decision support that encourages preventative care and has the ability to transmit aggregate measures for public health evaluation. In addition to significant development changes, PCIP also provides implementation support, quality improvement consulting, and a host of other services to ensure that physicians are able to incorporate the EHR into their practice and reap the benefits of its full potential. PCIP has achieved a 99% success rate for physician adoption of this EHR.

Electronic lab interfaces are integral to our project. Laboratories play a critical role in healthcare with lab data representing 60% of the medical record and informing 60-70% of medical decisions. Labs are even more vital to the PCIP, as much of our clinical decision support and aggregate measures are reliant on lab orders and results. For example, key measures and decision supports have been established for lipid control and A1C control, but cannot be fully functional without EHR-interpretable laboratory results.

Unfortunately, electronic lab interfaces have proved to be one of the greatest barriers encountered in this project. Through great effort on the part of our EHR vendor, commercial laboratories, and the PCIP's dedicated staff, we have managed to provide electronic lab interfaces to approximately two-thirds of our practices over a period of two

years. It has proven nearly impossible under current processes to ensure that practices have an electronic laboratory interface at the same time that they go “live” on their EHR. Many of these practices waited months before they had an electronic interface, and subsequently needed to create complicated “workarounds” in the interim. On average, implementing, testing, and validating a lab interface for a PCIP practice takes about 10-14 weeks. Frequently we have heard from lab companies and other stakeholders that the CLIA regulations in their current form are partly responsible for the difficulty around lab interfaces.

Electronic health record adoption and quality reporting are key elements of the Obama Administration’s health care reform agenda, and a necessary feature of 21st century healthcare. Updates to CLIA regulations must take into account support for electronic health care communications while maintaining the rigorous standards that ensure lab orders are properly received and executed and that results are accurately obtained and communicated. We urge this committee to evaluate the current regulations in light of electronic health records and health information exchange.

We understand that the American Clinical Laboratory Association spoke to this committee in 2006. We echo their call for a change in the CLIA regulations that will support the electronic transmission of lab data. A change in the CLIA regulations will recognize that lab orders and results flow in a myriad of ways: from laboratories to the ordering physician, from the physician to other clinicians, health plans, clearinghouses; or from laboratories to Regional Health Information Organizations, the governance structure of health information exchanges. As CLIA is currently constructed, the flow of this data is encumbered in at least two ways.

1. CLIA as currently constructed, holds laboratories responsible for the format of the result viewed by the clinician. In an electronic context, laboratories should be help responsible only for verified delivery of the standardized message content to a clinical information system. The format for display of laboratory results is highly conserved within the user interface of a given EHR product. It may be appropriate for CLIA regulations to

also require validation and certification of how electronic health record products render the information received by clinicians.

2. CLIA as currently constructed, requires laboratories to test and validate each individual interface, a laborious and time consuming process, which, in many cases, is redundant, since a single “master interface” connecting laboratories and EHR vendors can ensure standardized and consistent delivery of laboratory information. Updated CLIA regulations should recognize such “hub-to-hub” interfaces, allowing for more streamlined approval of each new practice being added to the “master interface.”

In addition to these changes in the CLIA regulations, we propose the Committee also undertake a review of several other issues that impede the electronic exchange of critical laboratory data in a 21st century healthcare environment. We believe the CLIA Committee can be influential in the development and eventual regulatory requirement of laboratory standards that will ease the widespread adoption of EHRs and electronic laboratory interfaces.

- Requiring the implementation and use of LOINC codes in laboratory results
- Endorsement of a standardized coding system for laboratory orders
- Provision of electronic compendium updates to health care partners

We would be happy to provide additional detail regarding these suggestions. Thank you for this opportunity to present on our project and on electronic laboratory interfaces. I’m happy to answer any questions at this time.