



American
Clinical Laboratory
Association

Statement of
The American Clinical Laboratory Association
Before
The House Energy and Commerce Committee
Subcommittee on Health

Presented by: Alan Mertz, President

March 16, 2006

Re: legislative proposals that would promote
electronic health records and a smarter health
information system

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Chairman Deal, Ranking Member Brown, and distinguished subcommittee members, thank you for the opportunity to testify today on behalf of the American Clinical Laboratory Association (ACLA) representing national, regional, and local laboratories. My name is Alan Mertz, President of ACLA, and I appreciate your interest in legislative proposals that will accelerate the widespread adoption of the electronic health record. ACLA members have an extensive history of providing the nation's hospitals and physicians with leading-edge health information technology (IT) streamlining laboratory test requisition and speeding the delivery of test results.

The Health Information Technology Promotion Act of 2005 (HR 4157) proposes several needed improvements to facilitate the diffusion of health IT throughout the United States. These changes will help promote better outcomes for patients. Among the improvements are new Anti-kickback Safe Harbors and Stark Law exceptions; a study of, and subsequent authority to preempt some state privacy laws; and the replacement of ICD-9 diagnosis codes with ICD-10 codes.

Laboratories play a critical role in healthcare delivery by allowing for the rapid and timely utilization of health information by providers. Laboratories and the medical information they provide are the heart of the medical record. Laboratory data represent 60% of the medical record. Diagnostic tests comprise only 5 % of total hospital costs and only 1.6% of Medicare costs, but they influence a much larger portion (as much as 60-70%) of clinical decision-making that improves care and decreases cost. Virtually every health care community (i.e. Regional Health Information Organizations or RHIOs) that is trying to develop an electronic health information infrastructure is looking to laboratories first. A recent nationwide survey by the eHealth Initiative found that, of those who have electronic health information exchange efforts under way, 60% plan to exchange laboratory information within six months to support quality, safety and efficiency goals. In a survey of hospitals, the number one IT function in the majority of hospitals today is the electronic order entry and review of results for diagnostic services.

The reach of laboratories into physician offices and hospitals vis-à-vis the provision of this hardware and software has served as a 'catalyst' in the evolution of health IT. For example, Quest Diagnostics Incorporated, a member of ACLA, has business relationships with approximately half of the physicians and hospitals in the U.S. Quest Diagnostics Incorporated receives 40% of orders and sends 60% of its results via the internet. Similar means of laboratory connectivity are offered by other ACLA's other members.

The federal government, quality organizations, the Medicare Payment Advisory Commission (MedPAC) and others recognize that laboratory data are the essential building block for assessing quality care and will have a critical role in pay-for-quality initiatives. Laboratories can and have been used to measure a provider's performance as a critical component of health care delivery; however, this contribution cannot be realized without incurring additional cost that must be recognized and reimbursed. In a detailed study of practice and laboratory connectivity, the eHealth Initiative recently recommended incentives that could be provided for including electronic laboratory data as part of pay-for-performance reporting. One example from the report would be to provide short term incentives, based on the volume of laboratory messages processed, up to a monthly dollar limit per clinician that would encourage implementation of interfaces. Incentives such as these can be an important driver of adoption of new technologies. By providing incentives encouraging the transmission of laboratory test requisition and results reporting, the healthcare system will actually save money through reductions in duplicative testing, better coordinated care and decreases in morbidity and mortality.

Because of the value that laboratories convey in the data they transmit, they have pioneered the provision of secure, streamlined IT solutions to order and transmit laboratory tests. This is a critically important and highly valued function. So important that since 1995 laboratories have had a limited exception under the Stark Law to provide "items, devices, or supplies that are used solely to...order or communicate the results of tests or procedures for such entity."¹ This is a fundamental capability for laboratories to render services to providers and a critically important function that must be maintained. Clinicians place a high value on being able to order laboratory services and receive laboratory results electronically because it improves legibility, decreases error rates, produces more timely results (including STAT testing), and allows the monitoring of redundant or duplicative testing. The result is improved clinical outcomes, and improved clinical care efficiency with the long-term benefit of reduced healthcare costs.

We recognize physicians, hospitals and other providers routinely cite the fear of legal action/debarment from Medicare as one of the biggest deterrents towards adoption of health IT. Accordingly, HR 4157 establishes a new exemption for the provision of health IT and related training. ACLA believes this legislative proposal, if enacted, would help to address some of these concerns and prompt further adoption of the health IT; however, ACLA believes such an exemption should be crafted carefully to diffuse the technology while guarding against abuses. By doing so, providers will continue to compete on the services they are providing and not, for instance, the size of a monitor. However, in any law or regulation laboratories must be among those entities permitted to offer these items or services because of the critical role laboratories have, and continue to play in facilitating health IT adoption in the health care community. ACLA was particularly perplexed with HHS' Office of the Inspector General's recent notice on the establishment of new Stark Law exceptions and Anti-Kickback Safe Harbors which proposes to exclude laboratories from the newly created exemptions.

¹ 42 USC 1395mm(h)(1)(C)

ACLA also supports the legislation's federal preemption of state laws that contradict the Stark Law exceptions and Anti-Kickback Safe Harbors established under the bill. Today, there are several states whose 'Stark' laws are complicated and have different requirements than the federal law. Similar to the privacy issue (which I'll talk about shortly), the problem is not just that these state laws are more stringent, but that there are many different standards. The differences in these state laws fall into several categories, e.g. the scope of the exceptions to the prohibition or the scope of what is considered a 'designated health service.' By creating a federal preemption, Congress can help address the fear and confusion many providers continue to have as they contemplate adoption of various health IT solutions.

Another of the much-needed changes that HR 4157 addresses is the need for federal preemption of state laws related to the security and confidentiality of health information. HR 4157 requires a study of: 1) the degree to which laws vary among the states; 2) between state laws and HIPAA; 3) how such variations adversely impact confidentiality and the electronic exchange of health information. Upon enactment, Congress will have three years to pass legislation establishing uniform federal standards and preempting state laws with regard to confidentiality and privacy. If not, then the Secretary of HHS is permitted to adopt regulations based on the results of the study.

ACLA supports this provision because the patchwork of state privacy laws is an impediment to health information exchange. For example, LabCorp, a large national laboratory, has been invited to participate in two of the eight regional Medicare Health Support pilot programs (previously known as the Chronic Care Improvement Program) authorized by section 721 of the Medicare Modernization Act. Chairman Deal, LabCorp has been invited to participate in an effort with CIGNA HealthCare in your home state of Georgia as well as a program operating in central Florida being operated by Green Ribbon Health, LLC. These entities will offer self-care guidance and support to chronically ill Medicare beneficiaries to help them manage their health, adhere to their physicians' plan of care, and ensure that they seek the medical care and Medicare-covered benefits that they need. LabCorp's role in the pilot programs would be to transmit laboratory data to CIGNA HealthCare and Green Ribbon Health for those beneficiaries who voluntarily participate in the program. This information would then be used to help monitor the conditions of participants and ultimately, improve their outcomes.

Unfortunately, despite the well-intended efforts of these programs, more restrictive state laws in Florida and Georgia governing the release of lab results have prevented LabCorp from transmitting these important results to Green Ribbon Health or CIGNA HealthCare until its concerns about the application of those laws to these requests have been addressed. More specifically, the Florida and Georgia laws preclude providing test results to anyone other than the ordering physician or provider (or to a person specifically authorized by the ordering physician). In this case, had there been a federal preemption of state laws we would be talking about the successes/failures of these program and not 'red tape.'

HR 4157 also addresses the needed replacement of the International Classification of Diseases, 9th edition, Clinical Modification (ICD-9-CM) diagnosis and procedure billing

codes with ICD-10-CM/PCS codes. ICD diagnosis codes are used by inpatient and outpatient providers for billing and reimbursement. Under the Medicare program, laboratories are paid by including ICD-9 codes on their claims to provide medical necessity. These ICD-9 codes are provided by the physician to the laboratory and are subsequently attached to a claim and submitted to CMS. Today, as many laboratories will attest, problems persist with physicians not providing the appropriate ICD-9 codes in order for laboratories to get paid. Currently, ICD-9 provides approximately 13,000 diagnosis codes. Take into account that ICD-10 provides 120,000 diagnosis codes, and one can see the potential for massive delays in reimbursement for laboratories and many other providers and thus the need for an extended phase in of the new system.

To give you an example of the difference between ICD-9 and ICD-10 consider how a physician would document an accidental sports injury. Under ICD-9, a diagnosis of a sports injury caused by striking against or being struck requires a single code: E917.0, described as "Striking against or struck accidentally in sports without subsequent fall; includes kicked or stepped on during game (football, rugby), struck by hit or thrown ball, struck by hockey stick or puck. Under ICD-10, a similar diagnosis requires one of 24 codes, meaning that the physician must document the causation (see attachment).

ACLA recommends that the implementation period for the transition to ICD-10 be changed from a two-year phase in period to a five-year period. Doing so would provide adequate time to reprogram all health care providers' and payers' computer systems to accommodate the new, longer ICD-10 codes. In addition, considerable time and expense will also have to be spent on client education and testing of the new systems. During this 'transition period' it should be permissible for providers to bill using either the ICD-9 or ICD-10 standards.

In conclusion, ACLA supports the Health Information Technology Promotion Act's new Anti-kickback Safe Harbors and Stark Law exceptions, the bill's proposed preemption of some state privacy laws, and a replacement of the ICD-9 with ICD-10 with a five-year transition period.

I'd like to end on this note. It has been said that every effort in the health care public policy arena aims to improve three different aspects of health care: better, faster, and cheaper. Nothing to date has been able to meet all three objectives – some systems provide two of the three but always at the expense of the third. I believe health IT is the answer. Health IT will make health care better by improving outcomes; faster, by facilitating not only the delivery of information but the coordination of care; and cheaper, by reducing the costs of doing business, be it a reduction in duplicative testing or by saving precious time previously spent on data entry.

Mr. Chairman, thank you for the opportunity to share ACLA's perspective on ways to promote electronic health records and a smarter health information system. We are ready to work with you on this important and vital legislation. If you have questions or need any additional information, please do not hesitate to contact us.