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Quest Diagnostics Statement on the
Pennsylvania Health Information Technology Act (Senate Bill 8)
to the Senate Communications & Technology Committee
March 7, 2012

Quest Diagnostics appreciates the opportunity to provide this written statement to the Senate Communications & Technology Committee (the "Committee") regarding Senate Bill 8, known as the Pennsylvania Health Information Technology Act, which would, among other purposes, establish the Pennsylvania Health Information Partnership Authority.

I. Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic testing, information and services that patients and doctors need to make better health care decisions. Quest Diagnostics operates clinical laboratories certified in accordance with the Clinical Laboratory Improvement Amendments of 1988 and associated regulations ("CLIA"), providing clinical and anatomic laboratory testing services for patients nearly 150 million times each year as ordered by hundreds of thousands of physicians and approximately one-half the hospitals in the United States. The Company provides patients and doctors with access to diagnostic testing services through its national network of laboratories and patient service centers and approximately 42,000 employees, and provides interpretive consultation through its extensive medical and scientific staff.

In Pennsylvania, Quest Diagnostics employs over 3,600 employees at 8 laboratory and IT facilities and 146 patient service centers throughout the state. Quest Diagnostics also is a covered entity as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In Pennsylvania, Quest Diagnostics and its affiliates provide the preponderance of laboratory services to ambulatory patients and to their medical providers, handling over 16 million patient encounters per year. In addition, Quest Diagnostics provides reference laboratory services for many Pennsylvania hospitals. Therefore, the Company is directly affected by the proposed regulation.

In addition to a broad range of clinical and anatomic pathology services, the Company provides healthcare organizations and clinicians with information technology products that improve patient care and medical practice, through its MedPlus subsidiary and its Care360™ suite of products, Care360 Data Exchange, and the ChartMaxx® electronic document management system for hospitals. Through these products, the Company offers access to a large national healthcare provider network, including over 165,000 networked physicians who use the Care360 suite of connectivity solutions to order lab tests, receive test results, share clinical information quickly and securely, or prescribe drugs in over

one million electronic transactions per day. Physicians use Care360™ ePrescribing services at an annualized rate of 16 million prescriptions per year. In December 2010, Care360™ Electronic Health Record (EHR), Version 2010.2 was certified as a Complete EHR by the Certification Commission for eligible Health Information Technology (CCHIT).

II. Health Information Technology and Clinical Laboratories

Clinical laboratories have developed and offered health information technology (HIT) solutions to providers for over three decades, beginning with transmission of data over telephone lines to dot matrix printers in doctors offices and currently through high speed interfaces to sophisticated Electronic Health Records (EHR) systems in physician offices and Laboratory Information Systems (LIS) in hospitals and reference laboratories as well as through centralized, internet accessible data hubs.

Laboratory data represents 60% of the electronic medical record and plays a leading role in as much as 70% of medical decisions. Laboratory data is complex and voluminous, and laboratories, particularly independent laboratories, have invested extensive resources toward establishing electronic ordering and results reporting systems with physician offices. Laboratories also have extensive expertise and experience with the intricacies of establishing electronic interfaces with thousands of physician offices and hundreds of EHR systems.

Laboratories have and will continue to provide a leading role in the electronic exchange of data for health care delivery sites across the country including hospitals, physician offices, and ambulatory care centers among many others. Virtually every health care community that is trying to develop an electronic health information infrastructure is looking to integrating laboratory data first. Laboratory data and technology improves patient care while promoting the highest level of efficiency and affordability. Laboratory providers know from experience that, implemented properly, health IT can provide ready access to timely, relevant, reliable and secure information.

III. Quest Diagnostics' Experience as an Active Participant in Standards Development and Health Information Exchanges

Quest Diagnostics has taken a leadership role in establishing nationally uniform standards for the exchange of health care information, and laboratory information in particular through our work with the Office of National Coordinator for HIT on the DIRECT specification, and co-leading development of a national standard for Lab Results Interfaces anticipated to be recognized by the Department of Health and Human Services for Meaningful Use Stage 2. We also maintain leadership roles with HL7, a standards development organization supporting information exchange, through active participation on the EHR-Lab Interoperability and Connectivity Standards (ELINCS) project, and through leadership of the American Clinical Laboratory Associations Health Information Technology Committee.

In addition, Quest Diagnostics has demonstrable experience in the planning, development, support and growth in a variety of existing regional HIE initiatives. This is exemplified by our vital participation in the Western New York State RHIO, "*HEALTHeLink*" [http://wnyhealthelink.com/AboutUs] as well as Western Pennsylvania's first Health Information Exchange (HIE), "*Clinical Connects*" [http://clinicalconnecthie.com/]

MedPlus, a subsidiary of Quest Diagnostics, has provided leadership in the design, development and testing of the complex infrastructure network required to support the exchange of data within HIEs. Quest Diagnostics, MedPlus supports a nationwide network reaching more than 165,000 physicians who use the Care360 suite of connectivity products. Quest Diagnostics is the only organization selected to support three of the nine original Office of the National Coordinator for HIT Nationwide Health Information Network II [NHIN II] grant awardees. Additionally, Quest Diagnostics, MedPlus has provided services to the Direct Project [http://wiki.directproject.org/], a select team of healthcare IT stakeholders dedicated to the use of NHIN standards to develop specifications for a secure, scalable, standards-based way to send encrypted health information directly to known, trusted recipients over the Internet. Quest Diagnostics and Med Plus also have developed robust analytic reporting structures and a variety of mobile application platforms for the viewing of Quest Diagnostics laboratory results that will accommodate the future of data sharing and views.

IV. Role of Clinical Laboratories in Advising on HIT Standards

Given the fact that laboratory data is such a valuable and major portion of the electronic clinical record, clinical laboratories are uniquely positioned to inform state efforts to bring this technology to health care providers and their patients throughout the country. We strongly believe that for HIT to be established and implemented in a usable way, the laboratory industry must serve as an active participant in the state decision-making bodies for HIT policy to convey our expertise with the transmission and integration of laboratory data into the electronic record. Having the input of the laboratory community will avoid integration of standards or requirements that do not match the operational realities of providing laboratory services, industry capabilities, and billing requirements for these services.

V. Specific Comments on Pennsylvania Health Information Technology Act

Quest Diagnostics appreciates the opportunity to provide our views on this proposed legislation, which affects the company and its employees.

1. Quest Diagnostics supports the "hybrid" model for state oversight.

The sponsor of this bill intends to create an oversight model under which the state does not itself act as the health information exchange (HIE) or gather health information, but

rather creates a policy and standards framework for HIEs. We support this approach. The *exchange* of health information mirrors the *provision* of health care services, in that both are regional in nature. As such, we strongly believe that the state itself should not gather health care information on individuals merely to create a huge database of private information on its citizens, raising privacy and security concerns. Instead, the state should set the rules by which regional HIEs operate to ensure that the information in regional HIEs is secure and will be made available to the physicians and other providers who need or use the data for care of the patient (i.e., for treatment purposes as defined by the Health Insurance Portability and Accountability Act (HIPAA)).

2. Quest Diagnostics supports naming a representative of the laboratory industry to the Board of the Pennsylvania Health Information Partnership Authority (Section 302b).

As noted above, laboratory data represent 60% of the electronic medical record and plays a leading role in as much as 70% of medical decisions. In addition, for decades, laboratories have been involved in electronic transmission of laboratory data and today interface with over 165,000 physicians through electronic health records systems, with thousands of hospitals and reference laboratories through electronic interfaces to laboratory information systems, and to regional HIEs in many states. However, the standards for laboratory data exchange are complex and continually changing. Therefore, we strongly recommend that laboratories be engaged at the board level to make sure that the adopted policies and standards will be feasible and implementable. Our experts, many of whom reside in Pennsylvania, are engaged at the highest levels of standards development with the Office of the National Coordinator of U.S. Health and Human Services Department, with standards organizations such as HL7 and the California Health Care Foundation, and with state health care commissions in a number of states. Therefore, we recommend that the bill be amended to provide for a specific representative of the laboratory industry on the Board, in addition to laboratory representation on several of the relevant advisory groups.

3. Quest Diagnostics opposes establishment of fees for providers who merely provide information to HIEs (Section 303a(10).

Section 303a(10) would provide the Board with authority to "[i]dentify and adopt transaction, subscription and other fees or donations to cover costs associated with implementation and operation of the exchange or for other services provided by the authority." Quest Diagnostics has built a well-functioning and capital-intensive computer-driven infrastructure to quickly, efficiently and flawlessly accept laboratory orders, gather billing information, and transmit laboratory results to ordering physicians. All laboratories are required to demonstrate to regulators that reporting systems function properly and deliver complete and accurate laboratory results to the ordering physician, in accordance with regulations adopted under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). As such, laboratories are responsible at the federal regulatory level for delivery of the laboratory report and

compliance with the CLIA regulations. While we voluntarily may choose to participate in regional HIEs by contributing our data under data use agreements, our voluntary participation with HIEs does not abrogate our regulatory responsibility to provide the complete and accurate medical report to the physician. Thus, if an HIE were to assess fees on a participating provider such as Quest Diagnostics merely for contributing data to an HIE, this would duplicate the costs we already have incurred and continue to incur for providing results in accordance with our CLIA responsibilities. Therefore, we request that the legislation clearly provide that no HIE may charge fees to a provider, including laboratories, merely for submitting data to an HIE. Our recommendation is that fees only be assessed to those entities requesting / consuming information from the HIE.

4. Quest Diagnostics recommends that the legislation clarify that providers such as laboratories may release information to HIEs in reliance on representations from the HIE that its members will only use the information for treatment or other HIPAA permitted purposes. (Section 701).

Section 701 deals with issues surrounding consent of the patient or in some cases the consent of a minor's parents or other responsible parties. Under HIPAA, laboratories are permitted to release personal health information (PHI) to a physician for treatment or other HIPAA permitted purposes. One of the purposes of HIEs is to facilitate the provision of PHI to physicians who were not the original treating physician. We recommend that a statutory provision be adopted that authorizes the release of PHI by a laboratory to an HIE in reliance upon the representation of the HIE that all of its participating physicians have consented through business associate agreements or other lawful means to the HIE's release of stored PHI to other HIE members for treatment or other HIPAA permitted purposes. The statute should contain a waiver of liability protecting any laboratory or other entity that submits data to an HIE, in reliance upon such HIE representations, against any claims, lawsuits or other actions for damages or other losses for any disclosures for which the HIE did not obtain appropriate consent.

We would like to thank the Committee for the opportunity to provide these comments and would be pleased to offer continuing input to the Committee as it moves forward on this important policy initiative that will benefit patients and increase transparency and access to health care information. Please feel free to contact me at 973-520-2920 if you have any questions.

Sincerely yours

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Quest Diagnostics Incorporated