

Quest Diagnostics Incorporated

4690 Parkway Drive  
Mason, Ohio 45040  
www.QuestDiagnostics.com



**Written Testimony of Tom Wagner, Chief Technology Officer  
MedPlus Inc., a Quest Diagnostics Company**

**Before the HIT Policy Committee, Governance Workgroup**

**September 28, 2010**

**Panel 3: Experience of Implementers of Health Information Exchange**

September 28, 2010

## **I. Introduction**

My name is Tom Wagner and I am the Chief Technology Officer of MedPlus Inc., a wholly-owned HIT subsidiary of Quest Diagnostics Incorporated. In this role, I am responsible for the strategic direction, product governance and overall product execution for all of our customer connectivity solutions including the Care360 Product Suite, Centergy Data Exchange Services, NHIN Direct, Patient Exchange Services and ChartMaxx product lines.

I would like to thank John Lumpkin and the members of the HIT Governance Workgroup for the opportunity to testify today on behalf of Quest Diagnostics and MedPlus regarding our experience with governance in implementing a national network.

My testimony will focus on establishing a governance model that is built upon a foundation of trust, privacy and security, and will include recommendations for best practices.

### **A. Organizational Introduction**

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 is a HIPAA-covered entity that provides clinical and anatomic laboratory testing services for over 150 million patients on an annual basis as ordered by thousands of physicians and over one-half the hospitals in the United States.

The company also provides electronic connectivity for laboratory services, electronic prescribing and Electronic Health Records (EHR) through its MedPlus subsidiary to over 160,000 subscribing physicians via our Care360 network. It also develops and provides electronic medical record (EMR) vendor applications, leads development of some of the nation's largest health information exchanges (HIEs), and enables our laboratory information systems to interface with hundreds of hospital laboratory information systems and public health agencies. Due to the criticality of laboratory information in the clinical diagnostic process, it is necessary for our national network to provide immediate accessibility of laboratory information for all Quest Diagnostics' stakeholders with "24 x 7" accessibility, 365 days per year. The support of this highly trusted network requires many foundational components including a strong and established governance structure, cultural and organizational support, highly sophisticated and scalable technical infrastructure, and appropriate privacy and security policies.

MedPlus has been developing and supporting clinical and administrative applications since its inception in 1991, providing solutions that serve physician practices, hospitals and integrated delivery networks (IDNs) and regional/community HIEs. MedPlus provides interoperability solutions supporting HIEs (three funded through NHIN Exchange), IDNs and over 170 hospitals and 70,000 physician offices.

## **B. Stakeholder Landscape**

Our stakeholder composition includes the breadth of our customer base including a broad range of healthcare entities. Representatives from our customer segments participate in our governance process via formal focus groups, stakeholder sub-teams, on-line forums and specific meetings. Their contribution to our governance model is highly valued and critical to its success. Our stakeholders include representation from the following markets: ambulatory physicians, hospitals, health plans and EMR vendors.

## **C. Governance Process**

The Governance Process for our Care360 Network is managed through a refined portfolio management process that incorporates feedback from focus groups covering a number of stakeholder sub-teams (i.e., physician, hospital/IDN, health plan and EMR). The core Quest Diagnostics' team is comprised of healthcare experts, clinicians, legal, business and technical participants that work to understand stakeholder needs and manage priorities based on a blend of business priority, user satisfaction and operational performance and resilience. Our governance process also contemplates government and industry requirements supporting laws such as the Clinical Laboratory Improvement Amendments (CLIA), HIPAA, and HITECH and our own corporate policies consistent with our business practices and our medical and lab domain expertise.

## **II. Trust**

### **A. Governance Mechanisms for Trust**

Our governance process requires a standardized approach that provides flexibility to meet the needs of our external stakeholders, which are largely comprised of the ambulatory clinical community, hospitals, IDNs and HIEs, EMR vendors, as well as our internal stakeholders. The changing landscape necessitates that we understand and adapt to evolutionary industry trends such as the proliferation of HIEs, emerging Accountable Care Organizations (ACOs), growing EMR adoption, new patient initiatives and evolving payer-based incentive plans.

We have striven to gain our stakeholders' trust, which is based on our integrity and our ability to effectively and efficiently accomplish their objectives. In turn, we offer our stakeholders a solid partnership, strong leadership and open communication. Fulfilling stakeholder goals may pose challenges when they have competing objectives. It is our position that we must be flexible to meet the needs of our stakeholders while also driving a standard, industry approach to contain costs and allow for broad adoption.

Building trust does not result from governance alone; instead, it is driven by an organization's credibility that flows from its ability to properly execute its strategy. An effective governance process should align measurement systems, create balanced scorecards or similar frameworks, define aligned incentive programs, and build execution goals into the process itself. We have

September 28, 2010

found the following values beneficial to support an effective governance process:

- **Develop a Collective Vision and Realizable Goals:** We seek to establish clear goals for the network through a collaborative, multi-stakeholder process. Engage stakeholders in creating the vision and collaborate on the desired goal. This process aligns stakeholders at the onset and sets expectations to build trust as the relationship matures. As an example, Quest Diagnostics works annually with our stakeholders to create “strategic themes” through stakeholder sub teams. These themes drive our overall priority and associated execution.
- **Provide Transparency:** We have been impressed with the transparency within the NHIN Direct model. NHIN Direct has regular venues and Internet capabilities that allow stakeholders visibility into the progress within each of the teams. NHIN Direct’s use of teams, venues and technology has proven to be an innovative, cost-effective way to provide transparency and gain the trust and alignment of stakeholders.
- **Involve Stakeholders Often:** We engage our stakeholders at various levels, ranging from their serving as expert partners and consultants to their involvement in direct operational input. This synergy creates high value in our products while empowering our stakeholders and building trust. For example, we conduct physician focus groups to solicit advice on over-arching strategic concepts as well as specific operational or usability requirements. We also have a web-based Care360 On-Line Community where clinicians and MedPlus representatives participate in open dialogues.
- **Gain Proper Perspectives:** We also conduct stakeholder focus groups to understand their perspective, their business and their needs. This process allows for confidence building and for the opportunity to tailor strategy to be responsive to their business needs. Quest Diagnostics utilizes the established focused groups.
- **Receive Support for Industry Standards:** Quest Diagnostics is a member of the American Clinical Laboratory Association (ACLA), a trade association working to create industry standards such as the ACLA Test Compendium Framework (eDOS), and providing industry input on LOINC and HL7 connectivity standards. Alignment of standards within our industry is essential to strengthen our collective as well as company credibility.
- **Clarify Relationships Through Contractual Agreements:** Contractually, Quest Diagnostics utilizes Business Associate Agreements to establish rights and obligations and level-set mutual expectations. All business relationships are reviewed by an executive team at Quest Diagnostics.
- **Ensure Quality through Certification:** We have established a National Certification process to certify our EHR vendor partner products and validate the proper display of laboratory result representation based on CLIA standards. We focus our national

September 28, 2010

certification process toward ensuring that the integrity of clinical data and the support of regulatory requirements satisfy CLIA.

- **Strong Technology Management:** We design product “roadmaps” to communicate our product direction based on stakeholder input and according to our governance model. Roadmaps are timely communicated so that stakeholders reasonably foresee modifications. Strict adherence to Service Level Agreements (SLAs) for data delivery, monitoring and control level-set both parties’ expectations and are essential to build end-user trust. Measurement techniques (i.e., a customer availability index) provide the capability to evaluate our responsiveness and identify areas for improvement.

## B. Privacy and Security

Within the framework of our services, we have adopted privacy policies and security practices that we believe are consistent with emerging industry trends.

- **Security Policies and Communication:** Quest Diagnostics maintains an enterprise-wide Information Security Program to assist our business operations in developing policies and practices, and to provide information security compliance and audit support to the business operations.
- **Senior Management Oversight Board:** Quest Diagnostics Security Council provides governance on matters relating to IT Security, integrity and risk to Quest Diagnostics information and infrastructure as well as the information our customers entrust to us by assessing threats and implementing programs to address potential exposure.
- **Consent Management:** The need to educate patients and to enable informed consent is an important component of our privacy policy. For example, with respect to patient consent as it relates to direct patient care, our Care360 application allows for a patient “opt-out” policy, so patients may choose not to participate in our exchange. Until there is a more defined consent management model, we will continue to support the opt-out policy as we believe that it allows for patient and physician control while streamlining overall administration.
- **Direct Patient Accessibility:** We base our policies concerning direct patient accessibility on various commercial patient platforms. Our patients have access to their results through a number of PHR means to include those external to the company such as GoogleHealth and Microsoft HealthVault.
- **Role-based Security:** Quest Diagnostics has implemented comprehensive access controls that follow the principal of minimum necessary, based on role-based access rights.

September 28, 2010

- **Authentication:** Quest Diagnostics authenticates users via in-person customer communication (through our sales force). Stakeholders are notified through in-person validation and communication when they are credentialed and ready to access our network as made possible through our national footprint of sales and implementation representatives.
- **Authorization:** Authorized persons can access our system with unique user names and passwords provided through the authentication process. We do allow single sign on capabilities to allow third-party products (i.e., EMR vendors) to securely integrate our capabilities into their products.
- **Protocols for Breaches:** While we strive to maintain the privacy of patient information, we have established communication protocols in the event that a breach should occur, consistent with required regulations.

### C. Issues and Recommendations

- **Patient Privacy Issues and Public Trust:** Limited guidance exists as to how patient-specific data can be used beyond direct patient care. This is especially concerning as some HIEs are considering selling data to support a sustainability model. Until policies exist to clarify the responsibilities of entities and the appropriate use of data beyond patient care, it is our belief that patient data should not be used beyond direct patient care purposes. Quest Diagnostics' policy is to only use patient-specific data for direct patient care, and not for secondary purposes. Since building public trust is paramount to our purpose, our third-party agreements stipulate that stakeholders that participate in our exchange will adhere to this policy. Consideration should be given to establishing national standards around this issue. We will continue to review our policy as standards mature.
- **Increase Public Awareness:** Open communication and transparency is critical to building trust. Broader public awareness of the value and use of healthcare data and associated governance policies is essential to gaining credibility. The NHIN Direct process is a model for establishing transparency and allowing stakeholder empowerment. Consideration should be made to a similar process to establish national governance policies.
- **Emphasize Adoption and Utilization:** The governance of a national health network should take into account actual utilization and adoption. Pragmatically addressing the real need of stakeholders, creating an approach that can be applicable to a vast set of stakeholders, and allowing measurement targets around adoption and utilization are all ways to keep adoption and utilization in focus. We support NHIN Direct because it is a working example of a model built with a keen emphasis on ensuring adoption and utilization.

September 28, 2010

- **Resolution of data use and privacy issues:** The largest fragmentation of healthcare stakeholders occurs around disputes over data ownership and use and privacy issues around patient access and rights. These issues divert attention from achieving the overall goals of entity governance process. National standards that consider the needs of all stakeholders, including national laboratory providers that have unique challenges would enhance overall interoperability and lower barriers that inhibit trust between stakeholders.
- **Legacy Migration Improvements:** Smaller clients present a challenge as they are most reluctant to upgrade their IT solutions after the initial deployment. As we require vendors to upgrade their connectivity to adhere to newer rules and regulations, lack of end-user motivation and incentive to upgrade will create holes in the interoperability chain. Suggestions would include defining some type of incentive/penalty for upgrading, or requiring established time limits or the sunset of legacy versions.

### III. Interoperability

#### A. Expectations and Suggestions for Interoperability

Quest Diagnostics performs and reports on 13% of all laboratory diagnostic tests ordered in the United States. Our business creates terabytes of highly valuable laboratory information that can be used for clinical care and reimbursement, as well as case management, quantitative analysis and syndromic surveillance. As a result, our data is in high demand from multiple stakeholders.

As the number of HIEs, ACOs, physician office EMRs, patient initiatives and payer-based incentive plans grow, an increasing number of parties want access to our data. Each of these entities has a need for individual laboratory data results, but may have differing objectives for that data. Since each of the entities is “governed” by its own directives, this often creates collisions with our established governance policies, technical solutions, and privacy and security policies. One would anticipate that a federal governance model would have greater complexity and difficulty that may inhibit adoption of a one-size-fits-all solution

Although a national governance model around interoperability should involve and empower stakeholders, effective governance relies on strong program management responsible for oversight and leadership. Program management must be accountable to the governance body, comprised of independent individuals with no conflicts of interest and empowered to make trade-offs and create the necessary foundation for sound decision making. Additionally, an effective program management structure must include individuals with strong leadership skills and diplomacy, who are also bona fide subject matter experts in the core areas around exchanges and interoperability.

September 28, 2010

Additionally, the ONC should influence interoperability with the following considerations:

- Recognize and prototype HIEs that are: 1) successfully interoperating with partner HIEs either through mutual adoption of standards or by joining forces to promote interoperability; and 2) demonstrating sustainability and practical application.
- Award funds primarily to HIEs that have demonstrated open standards, good partnership techniques and have a sustainable model.
- Leverage existing models that have a proven national ability to interoperate. Companies like Quest Diagnostics have been successful with interoperability because it is core to our business and, as a result, we have connected a significant number of disparate systems over the past 10 years to provide standards-based, secure, scalable solutions.
- Provide incentives to smaller ambulatory offices to subsidize standardized interface pathways to drive interoperability since the benefit of interoperability often does not attribute to those bearing the cost.
- Define and govern the deployment of interoperability standards that are practical and can be easily adopted in the industry.

#### **IV. Accountability, Enforcement and Oversight**

We have participated on both sides of the governance model. As a national exchange, we have driven our own governance. As a participant in an HIE, we have been subject to the governance decisions promoted within the HIE.

As a leader of governance, we have found that allowing open participation and involvement builds trust. Large teams are more difficult to manage and necessitate a strong core leadership team that is empowered with decision-making authority. It is important to ensure that all stakeholders have some degree of representation in order to garner support and address issues holistically. Vetting should be based on building manageable sub-teams, with a cross-cutting of the industry. The core team should be responsible for approving participation.

In conclusion, I want to thank you for the opportunity to discuss our experiences with governance for trust, interoperability, accountability, enforcement and oversight. I welcome your questions.

Sincerely,

Tom Wagner  
Chief Technology Officer  
MedPlus, Inc.