

**U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information
Technology**

Privacy and Security Tiger Team
Health Information Technology Policy Committee

Consumer Choice Technology Hearing

June 29, 2010
Washington, D.C.

Private Access, Inc.
Written Public Testimony
Robert H. Shelton

Good afternoon Dr. Blumenthal, members of the Privacy and Security Tiger Team and staff, and thank you very much for this opportunity to testify today on behalf of Private Access, Inc.

The issue you have asked that I discuss is critically important to the vision that every person in this room holds – namely of a more open, more responsive, less costly, more effective, and more sustainable healthcare system. From my perspective, this goal can only be achieved if we are able to successfully bring to bear in healthcare the most advanced information technologies we see applied in a number of other industries. And yet this goal – perhaps more so than within any other industry – relies on our building “trust worthiness” as a fundamental and widely accepted attribute of the health information system that each of us cares about deeply.

I am Robert Shelton, founder and CEO of Private Access. We are an early-stage company that is developing a consumer-centric technology platform to enable individuals to do two things simultaneously: First, to create and manage privacy protections for their confidential health information. And second – just as importantly – to permit their confidential information to be efficiently located and shared for the purposes they consider beneficial.

In other settings, I have spoken about the inspiration for my founding Private Access, and perhaps we may wish to explore that today. But for the purposes of my prepared remarks, suffice to say that Private Access is building a technology-enabled service to respond to the insight that consumers have remarkably strong wishes for the seemingly contradictory desire for both privacy and data accessibility. Sometimes they want information to be tightly protected and shielded. And at other times, consumers want their information to be far more accessible, searchable, and effectively used to improve their health outcomes and reduce their costs.

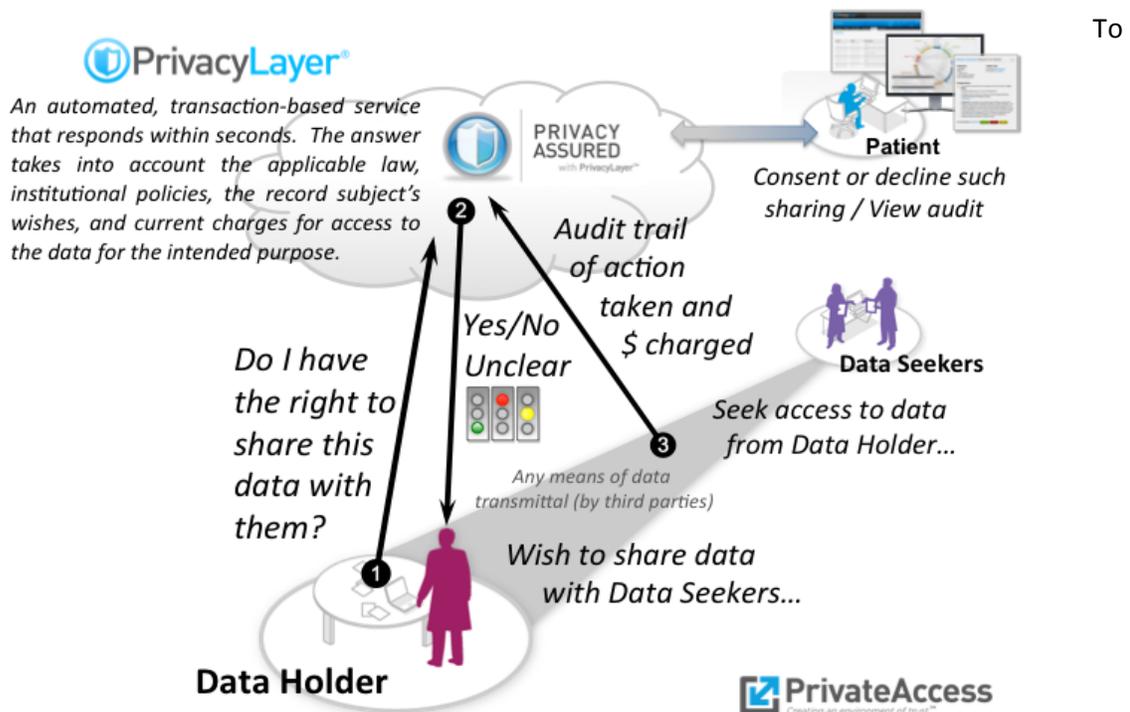
This dichotomy is particularly true for persons with potentially stigmatizing conditions. In addition to my role as CEO of Private Access, I have for the past 7 years served as Chairman of a national non-profit organization addressing several of such conditions, and have seen this first-hand. I know patients whose privacy sensitivities are so intense that they don't even disclose their medical condition to members of their own immediate families, who ask that there be no return address on our organizations' mailings, and who request that their doctors omit certain information from their medical charts that they fear will adversely affect their insurance coverage or their ability to serve in the U.S.

military. And yet, I also know these very same persons acutely want their information to be more effectively used to improve their outcomes, to advance important medical research so that more effective treatments can be developed more rapidly, and to make it easier to receive services.

In the broader context of health information technology, I know that you are aware of the substantial body of research that informs us that a significant number of people have considerable anxiety about potential vulnerabilities related to electronic health records. A 2009 study prepared for AHRQ based on the results of 20 focus groups found “near universal agreement in all the groups that if medical data are to be stored electronically, health care consumers should have some say in how those data are shared and used. [...] Most participants believed that health care consumers individually should be able to set limits on the use of their medical information.”¹

We think that Private Access’ technology, which enables consumers to quickly and inexpensively exercise greater control over their confidential information, could play a useful role in addressing just this sort of consumer expectation; and in so doing, in helping to advance the overall national objective of protecting privacy while advancing health IT.

Private Access allows individual patients to establish specific and dynamic privacy directives and consents for their confidential health information and records. Data Seekers – those who wish to have access to these records – can then locate and access the specific information made available by Data Holders based on the patient’s privacy consents and prevailing law. These consents are stored and managed through a technology platform we call PrivacyLayer®, which is illustrated in the figure shown below:



¹ AHRQ (Agency for Healthcare Research and Quality), “Final Report: Consumer Engagement in Developing Electronic Health Information Systems,” July 2009, pages 29-30.

date, Private Access has invested nearly \$8 million in building the first generation of the PrivacyLayer® system and in launching this in a series of commercial Beta releases that began earlier this year in connection with live patient data and an initial use case built around accelerating clinical trials recruitment. On the basis of this work, we are now moving to the next stage and preparing for a series of broader commercial releases on behalf of clients and as we deploy additional functionality.

It has been said by some that a robust system of highly granular patient consents and detailed accounting for disclosures is impossible or will be unacceptably costly, and yet on the basis of our development efforts to date, I would beg to differ. On the other hand, it has been said that a consent management system is easy to provide. To this assessment, as well, I would with all due respect, wish to object.

In our case, Private Access has engaged a full-time dedicated staff of database architects, systems analysts, software designers, developers, and programmers – informed by privacy counsel and technical writers – working on this system for over 3 years. To date, we have written more than 600,000 lines of code, addressed a number of important issues from the ease of the graphical user interface, to the adequacy of legal disclosures in obtaining informed consent, the latency of response time by the rules engine, and the ontology on which privacy directives should be based. All of these achievements have represented major challenges, and yet we have made substantial progress and attained extremely positive consumer feedback and acceptance.

Let me provide you with a few examples to clarify how the PrivacyLayer® system can be used. Let's say that I am a Private Access account holder, and that I am very concerned about my online healthcare privacy. In this case, I might set my preferences so that my consent directives are very narrow, permitting only the disclosure of personal health information required by law, such as information disclosed to a health insurer.

On the other hand, I could choose to set my preferences quite broadly. In this case, I might allow my spouse, my adult child, and all physicians in a practice group I designate, to have – in addition to what is permissible by law – complete access to my records, including personally identifiable information and, at the same time, allow cancer researchers to search for and access partially de-identified information that I have chosen to make available under a system generated pseudonym.

I could also set my privacy preferences to allow researchers or others the right to contact me directly (and anonymously) through Private Access; later permitting them to ask me for access to my records or to communicate with me about potentially becoming involved in a clinical research study. Critically, given the way that the system is designed, I wouldn't have to make an initial, one-time, blanket decision to allow or disallow research, or other uses involving my health data. Rather, Private Access would establish a confidential communication pathway that would allow me to make those decisions once they arise, based on the knowledge I have at that time.

Further, I could segregate my information and give my orthopedist information on all of my health information except for my psychiatric records; and my psychiatrist access to all of my information except for the report on my knee surgery.

As I mentioned above, Private Access's initial products were released in commercial Beta earlier this year. By design, these initial products are focused on clearing the privacy hurdles associated with clinical trials recruitment. Thus, in the current deployment, users fill out detailed questionnaires specific to their condition, and then set their privacy directives to allow or disallow various levels of search and/or contact by clinical researchers. We look forward to sharing a brief demonstration of this system, which takes under 5 minutes and that I think may bring to life for you a number of the attributes and functions I've described. I look forward to responding to your questions and describing our intended next steps in our development roadmap if this would be of interest.

As we develop our offerings further, the PrivacyLayer® technology can be employed in a variety of HIT settings, ranging from electronic health records to bio-banks, to health information exchanges and social media systems. We today are working with clients and implementation partners in each of these industry segments.

I could not possibly be testifying here today were it not for the diligent efforts by a large number of dedicated people. This includes the members of our technology team, our collaboration partners at Pfizer and Genetic Alliance, and investors who have believed in and supported our efforts.

We are here today by the shared belief of all of these persons and firms that what we are doing can make a positive difference. I wish to again thank you for the opportunity to address the panel this afternoon and, should this be your wish, to exploring the possibility of working with you in the future.

Private Access has made, and intends to continue making a major investment in this niche of privacy-enabling technology. I got started in this long before it was popular or required by HITECH or any other statute to do so. I did so because I believed then – and I believe even more fervently today – that when the issues of trust-worthiness of the system to handle confidential and highly sensitive information are systemically addressed, then the era of data liquidity and the attendant benefits we aspire can come from this, can and will take place.

We welcome your questions and your feedback.

**Consumer Choice Technology Hearing
Cutting Edge Consumer Choice Technology Panel**



Responses to Questions Posed in Advance by the Workgroup

1) *Describe how the technology implements the patient's consent and the specific choices given to the patient.*

The idea behind the Private Access technology is that consumers should be provided with a unique, trusted environment where they can establish and manage their consents regarding health information or other confidential information.

Through Private Access, patients set up secure accounts where they can establish consents and make their privacy preferences known about some or all of their personal health information. These consents can be given to an individual (such as a primary care doctor, a single researcher or a family member), to an entity (such as a hospital, a pharmacy chain, or a payer), or to groups of entities (such as “all NIH researchers,” “all doctors,” or “all marketers with new heartburn remedies”).

One of the challenges we faced in designing the user interface for the system was making it easy to use, and in effect masking the considerable complexity of managing highly granular privacy settings and providing adequate disclosure about what each setting means. We have pioneered a unique graphical user interface that is built on testimonials by trusted guides that each user can select, and from whom they can select different levels of privacy concern and corresponding settings. We've received a very positive response to this from consumers, to date over 75% of who have rated the Private Access system as “easy to use” or “highly intuitive”.

2) *How far along is the technology in terms of implementation? What steps or technological advances need to be made in order to implement the system in the health information exchange?*

We've recently launched our technology in commercial Beta with the specific goal of the application employing PrivacyLayer® being to accelerate clinical trials recruitment. We achieve this by inviting patients to make their interests in research known by establishing their consents for such in advance at PrivateAccess.com. This data is only available to the individual or group that to whom the individual granted Private Access. But for this (or these) researchers, the otherwise confidential data can then be searched to identify pertinent characteristics, and the individual contacted about enrollment in relevant studies and trials through our companion search engine for researchers, called RecruitSource®.

By design, the use case we selected in implementing the system thus far was designed so that the legal issues were asymptotic, meaning that they move from being at one extreme, in which the data cannot be shared (e.g., without patient consent) to the other extreme, in which this consent is in place and therefore the Data Holder has everything he or she needs to share the data with the (approved) Data Seeker. As additional use cases are built, the

“adjudication engine” that calculates state and federal, institutional policy, and the patient’s privacy preferences, will need to be expanded and its functionality extended.

Additionally, in order to implement this system for all health information exchanges, Private Access needs to complete development of APIs (Application Programming Interfaces) that will allow the Company, with the Data Holders’ permission, to index (not hold) data from all Data Holders where health information for Private Access account holders is stored.

3) *What are the advantages to your approach to obtaining patient consent?*

There are four primary advantages to the Private Access technology.

The first is that the PrivacyLayer® platform and privacy rights adjudication engine are “in the cloud”, which means that these services can be accessed by all consumers, Data Seekers and all Data Holders.

The second is that we have designed the system to be consumer-centric and user friendly. We utilize the above-referenced trusted guides to recommend privacy settings depending on whether users are “highly concerned about privacy”, “moderately concerned” or “not concerned at all”. To date, this approach appears to convey helpful recommendations in an easy to understand format that each patient can use or prepare their own settings from scratch.

Third, consents stored at PrivateAccess.com are dynamic. Patients can log into their accounts and change their settings at any time.

Finally, once APIs are available, Private Access can welcome other software developers to build or modify their health applications to access the PrivacyLayer® platform and use our database of patient consents and privacy adjudication engine.

4) *Is the technology scalable so that small and medium-sized providers could implement it?*

Yes. Individuals, small and medium-sized providers, as well as large networks can use the applications Private Access has built. Our architecture, ontology and business model contemplate building out the platform as a service bureau. As Private Access develops APIs to establish connectivity to multiple data repositories of varying sizes, our underlying architecture can be scaled up and customized to the data environment to assure security and responsiveness according to user expectations.

5) *Is the consent technology interoperable with other systems? (i.e. Can the patient’s preferences be passed to other HIEs?)*

Yes, broad interoperability is achieved, and is sustainable, through a number of mechanisms that are integrated within our solution. These mechanisms include standards-based medical record format data interchanges, published API’s, custom systems integrations and, in some circumstances, we contemplate the deployment of proprietary appliances behind the fire-wall of Record Holder entities.

Regardless of the method employed, the Private Access technology platform has been

architected to accept inquiries by Data Holders relative to patient consents, permissions and privacy preferences. These Data Holders may be large health information exchanges or single practitioners; hospitals, labs, pharmacies, PHRs or any other repository of personal health information and other confidential data.

6) *If the consent is not currently interoperable, what are the barriers that stand in the way of this?*

None. The Private Access ontology anticipates full interoperability with all existing privacy standards and ontological expressions. The only “barriers” to achieving our goal of full interoperability with all entities, operations and systems within the industry result from our current stage of development, and the time, limited availability of resources, and priority we place on this milestone within the implementation of our development roadmap.

7) *What resources are necessary to implement the consent system in its current form? What further resources would be necessary to offer further consent choices?*

Since founding Private Access in 2006, we have assembled a core team of database architects, systems analysts, software designers, developers and programmers. Given the nature of the project, these technical personnel work closely with privacy counsel, artists and technical writers. Our senior architects, particularly our CTO, are experienced in large scale, commercial social media and networking, e-commerce platforms, media and entertainment and health care systems with large volumes of users, transactions and activity within highly secure, high-uptime environments.

In order to fully realize the comprehensive vision we have for the PrivacyLayer® platform, and Private Access’ complete product suite to be fully realized and sustainably accessible by all patients, Data Seekers and Data Holders, the principal constraint is, once again, time and the availability of development capital. Our company develops and operates from a highly detailed and comprehensive product and technical development roadmap. We update this roadmap frequently to reflect any changes in conditions and newly identified opportunities.

8) *How many users does the system serve currently, if applicable, and how many will it serve when it is fully operational?*

We recently concluded the initial beta release phase of our service with several of our active clients, and have now transitioned both of these deployments successfully into commercial implementations within a live production state. Based on the pilot requirements of our client’s program, our solution was introduced through a phased-release program to a limited population, which resulted in approximately 1,000 Private Access account holders registering with our service. Our initial email campaigns, when conducted by a trusted intermediary such as a patient advocacy organization known to the consumer, generated an adoption rate of more than 40%, impressive by any measure for an beta release of a new web-based solution. Of the users responding to a subsequent survey, over 90% indicated that they would recommend use of the system to family and friends.

The technology platform specified within our current product and technology roadmap is architected to support volumes of up to 25 million users within the next 3 years. Our architecture is designed to be robust enough to handle commercial levels of activity and

high volumes of concurrent requests and user sessions, without material degradation in performance or experience. One prospective client, located in Europe, recently approached Private Access relative to internationalization of our solution toward enabling clinical trials recruitment to take place on a global scale. Our current platform has been designed to enable, with further development, this level of scalability and extensibility, to meet future opportunities.