

April 5, 2011

Subject: SBIR Phase-I Proposal Entitled:

“New E-mail and Data Exchange Protocol for Electronic Medical Records and Healthcare Information Systems”

Reference: SBIR Solicitation “PHS 2011-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])”

Dear Sirs:

Mamomail Inc. is pleased to submit the subject proposal for your consideration in response to the referenced solicitation.

You may assign this application to the following:

Institutes/Centers:

National Center for Public Health Informatics - NCPHI/CDC)

Scientific Review Groups:

Alliance Management and Consultation

Disciplines Involved:

Exchange of Electronic Health Records

The reason for these requests is that the proposal addresses the feasibility of an email protocol for system-to-system exchange of electronic medical records with the security, privacy and reliability necessary to meet the HIPAA criteria.

Sincerely,  
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## Specific Aims

This NIH SBIR Phase I project proposes an innovative adaptation of existing email infrastructure that meets the security, privacy and reliability criteria of HIPAA for system-to-system exchange of data for electronic medical records. Many physicians are hesitant to migrate to an EHR system due in part due to the complexity of these protocols and the lack of established connectivity. Also, despite numerous studies advocating the use of email in healthcare, there is a singular lack of business service models and technologies in the marketplace that can facilitate exchange of electronic medical record, at the provider level and the patient level.

The overall project goal is to demonstrate the feasibility of developing an email data exchange system that would provide a pervasiveness and intuitiveness option while meeting the HIPAA criteria, and the requirements of HITECH. It would facilitate the migration to EHR systems, increase the use of email for physician to patient communication, and improve healthcare by helping drive efficiencies.

In Phase I, we propose to demonstrate that healthcare data can be properly exchanged, where "proper" is defined as: (1) the healthcare data to be transferred is automatically encrypted by the sending system and decrypted by the receiving system; (2) the receiving system filters incoming emails for a protocol-specific tag that identifies the email as containing healthcare data and specifies the required action to be taken upon receipt; (3) the receiving system will authenticate the message and validating the sender and (4) the receiving system identifies the healthcare data and take action designated by the protocol-specific tag (such as routing the data to an appropriate folder to be extracted later by the EHR).

Toward this end, five technical objectives are proposed.

**Demonstrate Ability to Identify and Separate EHR Emails:** Demonstrate an ability to correctly identify and extract email bearing EHR data from among all incoming emails.

**Demonstrate Encryption/Decryption and Authentication:** Demonstrate the ability to authenticate the sender and receiver and to encrypt and decrypt the email.

**Demonstrate Separate Destination In-Box Sorting:** Demonstrate an ability to route EHR-bearing emails to a unique email in-box per instructions from the sender.

**Demonstrate Electronic Medical Record Data Extraction:** Demonstrate the ability for reliable extraction of EHR data from an email and its transfer it to the associated EHR system.

**Demonstrate Special Instruction and Action Tags:** Demonstrate through the use of embedded tags established, and in some cases custom rules for the purpose of providing special handling instructions of the email. These codes can be either created by the user, system, or be established as an agreed upon standard. For example, the creation of category or subcategory in boxes, the removal of particular boxes at scheduled dates and times, rules for emails and attachments such as restriction of further forwarding or removal from the designated location.

The focus of this research is on the development of a novel approach to using email based EHR system-to-system communication protocol; this method further has potential to be applied in other industries, including the banking and financial services sector, e.g. the actual monthly statements can be securely emailed and automatically integrated to the personal financial application of the users, and other data communication intensive industries where there are many to many communication end points.

We propose to research and develop a system that will adapt email systems and expand its utility to options in the healthcare field capitalizing on its ubiquity and intuitiveness, thereby expanding it for uses beyond the current art of simple messaging.

RESEARCH STRATEGY

SIGNIFICANCE

This SBIR Phase 1 proposal is for an innovative adaption of email for system-to-system exchange of data, in particular, electronic medical records delivered to a secure and unique e-mailbox and their special handling and display actions, that meets the security, privacy and reliability criteria of HIPAA and help the healthcare industry meet the meaningful use requirement of the HITECH Act. We propose an email method for: a) the secure, private and assured delivery to EHR systems; b) the encryption, decryption, and authentication of the sender, the receiver and the data; c) the identification, categorization and proper handling of its data and attachments; d) enabling the integration of such information directly into the EHR systems; and e) *special embedded tags and rules for the purpose of providing special handling instructions of the email and attachments.*

The healthcare industry and the government seek to increase the use of electronic medical records both at provider level and the patients to drive efficiencies and improve patient care. Also, numerous studies strongly advocate email for the physician to patient communication. However, even as email is ubiquitous and intuitive, its use very low throughout the healthcare space.

*Currently the Health Information Exchanges (HIE) are listed as the primary sources for the interconnectivity for the exchange of data. But the full interconnectivity is still many years off. Our method is complementary, and not a substitution, to the HIEs by allowing the physicians' EHR systems to achieve interconnectivity via the email protocol. Physicians do have the need to communicate directly and often they do so through the patients, e.g., by giving a CD or they will fax records to each other. Many physicians are not on HIEs and even if they are, they have to be in the same HIE to seamlessly communicate as the HIEs are not integrated. But, the ubiquitous email offers a very practical platform to exchange HL7 documents that can then be easily incorporate into the EHR system.*

*As of this publication, we have not found a company that provides an email based solution and approach in any manner similar. There are no other companies, in or out of healthcare, putting everything together about delivering records over the email protocol in a secure, verified, categorized and organized manner. The currently available solutions and services specializing in email are only about encryption and email management. The only other transport solutions are FTP and direct connection.*

*The 2009 ARRA represents a significant opportunity for the industry that will fuel marketplace changes, foster innovations and new approach to problems and new business alliances over next few years and these dynamics will help new companies to launch and offer new solutions.*

Some potential barriers are the technical complexities to design and fit our system to the variety of EHR systems in the marketplace. However, there are open sources systems such as VA VISTA and the Open EMR that can be target initially. We anticipate being able to form relationships with EHR companies such as Allscripts (a VistA solutions provider). Another possible barrier is if there are any limitations due to HIPAA, HITECH (Health Information Technology for Economic and Clinical Health Act), and CCHIT (Certification Commission for Health Information Technology) that would prevent us from transporting healthcare information by email.

*(Portions that are new or substantially modified from the first submission are in italics.)*

## INNOVATION

*The current proposal is a novel email protocol, dubbed Secure Private Email Exchange (SPEE), which defines an email interface, a security encryption algorithm, an authentication protocol, a standard set of action tags (e.g., XML tags) and the concept of the system controlled separate secure mailbox. The objectives are to demonstrate secure-private exchange and automated seamless integration of data via email with an EHR system. This project will include understanding and working with EHR systems for the demonstration proof-of-concept; building the software and system and testing. This research focus is the EHR system to system communication; however, it can provide a proof of concept for the important consumer PHR uses.*

Most common data-exchange protocols include asynchronous messaging, web posting, and batch FTP. In the healthcare space, data is exchanged almost exclusively via two methods: 1) batch FTP, which has implications for file encryption while in motion, decryption during processing, re-encryption while at rest, and determination of a secure storage solution for processed files; and 2) direct messaging, which involve development and installation of custom software at the site sending and the site receiving the message. In many cases to set up communication link with a new physician or a clinic, these forms are difficult or impractical to implement, especially for secure data exchange and secure processing where the future usage and relationships needs are unknown.

For example, there are a large number of physicians' offices who have EHR systems but have no affiliation with a larger organization healthcare provider (i.e. hospital or hospital systems). Their practices simply do not have the ability to set up and maintain a secure FTP site or develop and monitor a direct system-to-system communication link.

Similarly, large organizations that do not communicate regularly might find the complexity and cost of integrating with other providers prohibitive. An affordable, easy to implement alternative is needed to help compliance with the HIPAA meaningful use regulations.

### *The Differences and Advantage of the Proposed Protocol over FTP and Direct Messaging*

*The assumption is that there is a need for direct doctor to doctor communication because of the lack of broad acceptance of HIEs. Therefore, the doctors have the needs to communicate with each other in order to improve patient care.*

### *FTP Overview*

- 1. Doctors are not familiar with FTP and its complexities.*
- 2. In order to use FTP, one needs the server name and the credentials, i.e., the ID and the password.*
- 3. The doctor has to know how to use the FTP software to send a file, e.g., to zip it and send it.*
- 4. Further, the current EHR systems do not have FTP capabilities built into them to allow the doctor to doctor exchange. Therefore, FTP is not practical.*

### *Direct Connection Overview*

*With direct connection, the user must know the server name, know how to create the file and to post the information either on a web page or configure the user's system to send the information to a particular IP address, which has to be configured as well to receive the information. Each sender and recipient EHR system must have been configured this way. This process is necessary for each of the initial link between the doctors and generally requires a technician to configure the settings, which could change time to time. These complexities and cost limit the acceptance and the reach of direct connection.*

*With our method, the user-sender will create the document in the EHR and to send will require only the recipient doctor's email address.*

The overall project goal is to demonstrate a new alternative and complementary communication channel using an established and ubiquitous technology: email. Our hypothesis is that an email data exchange method that meets the security, privacy and reliability criteria of the HIPAA and is transparent and intuitive to the providers and the consumers will help the **healthcare** industry meet the meaning use requirement of HITECH; facilitate electronic medical records use and exchange among physicians; and increase the use of email for physician to patient communication. In addition to these healthcare innovations, we will research a new approach and expansion on the current art in system-to-system communication as well as highly novel uses and expansion of the email art.

## **TECHNICAL BACKGROUND**

This research focus is the EHR system to system communication. We propose a novel email protocol, dubbed Secure Private Email Exchange (SPEE), which defines an email interface, a security encryption algorithm, an authentication protocol, a standard set of action tags and the concept of the system controlled separate mailbox.

**SPEE Central Credential Server and Keystore.** In order to maintain proper auditing and security, a central location for registered clients must exist to validate the SPEE functionality requested by each user, provide for encryption key generation, key storage and periodic key exchange.

Client user data received as part of registration or service requests is handled according to applicable PHI privacy standards, e.g. HIPAA. The purpose of the client data is to control access to SPEE functionality: access to actions for routing, labels, and other embeddable values are mapped and managed at the user role level. User roles are assigned per client. Roles can be combined to group levels simplifying assignments across departments, companies, or industries, including the definition or support of industry standards. The privacy of the patient medical record will be protected. It will be encrypted The only party who can open the email and decrypted is the person who is the intended recipient or their EHR system. The SPEE tags also have many other uses, the research proposes an XML specification that describes the meta-data envelope, EHR data packet, attachments, and dynamic and potentially infinite special handling instruction and actions such as expiration date of the email, preventing the forwarding, list of approved viewer or EHR system.

Encryption key management ensures the security required for complete communication and data privacy. Keys generated according to standards such as the government-adopted AES are stored and managed for SPEE clients. The SPEE trusted certificate, used to encrypt communications between the SPEE Central Server and sender/recipient end points, provides the security to support periodic key exchanges. Such exchanges increase the security of the overall solution, minimizing vulnerability if a specific end point is compromised.

The SPEE markup tags consist of an XML specification that describes the meta-data envelope, EHR data packet, attachments, and special instructions. *(Tag Exhibit from the first submission has been removed. We have attached it in the "Other Attachments" as a possible reviewer interest and FYI.)*

The issues of abuse of the system, risks of attack, and maintenance of the systems are same for any other interconnected systems including those used in healthcare. In order to get into the SPEE mailbox, it has to be authenticated. This is what prevents the abuse of the system and successful attack. The solution will be no different with regard to security and privacy of existing secure email transmissions like ZixMail. Solutions such as ZixMail provide an additional security layer for email to be as secure as any other such as secure FTP and secure Https.

## The SPEE Interface

The design and the interface of the software will be put together out of this research. There is no need for any separate user interface as it will be a plugin on an email client or be integrated into the EHR system. One of the advantages of the proposed approach is its integration into the user's EHR interface or email client's interface. If a user wishes to send the electronic record via SPEE Email system, users will have that functionality as part of their EHR system.

### APPROACH

In Phase I, we will test system-to-system integration on a single mocked-up computer. The EHR system produces HL7-compliant records, as mandated by CCHIT regulations. For Phase 1, we will assume only CCHIT compliant EHR systems will be in scope.

**Inception/Planning Phase (3 weeks).** In this phase, the focus is to scope the system adequately as a basis for validating initial projections of effort and cost. The primary high-level use cases describing the conceptual uses of the email system are developed to establish the boundaries of the problem space and the scope of the solution. The project plan and risk management plan are also created. This set of documents is used at the phase gate to determine:

- Agreement on scope and cost/schedule estimates
- Sign-off on requirements for the effort as representing in the high-level use cases
- Validation of estimates and schedules
- Sign-off on high-level architecture
- Validation of resource availability to complete the effort

**Elaboration/Design Phase (3 weeks).** In this phase, the focus is on domain analysis and applying sufficient resources/effort to mitigate risk identified during the Inception phase. In this phase the optional email system functionality is scoped for inclusion in the final deliverable, or deferred to a later release. Use cases are elaborated to produce sub-function use cases. Most modeling diagrams, use cases, and business rule documentation are developed during this phase. The phase gate at the end of this phase is satisfied by the following set of deliverables:

#### Part 1:

- Pareto-complete use case package, including bubble diagrams, use case descriptions, and business rules
- Software architecture description document that satisfies the key user-goal and sub-function use cases
- Revised development plan
- Prototypes that demonstrate basic assumptions and mitigate identified risks.
- Determine the appropriate APIs and functionalities to run a series of test cases.

#### Part 2:

- Develop the test cases that will have the most utility. Such as: transferring blood results from one physician to another, transferring immunization results from one physician to another, transferring patient vitals (weight, height, blood pressure, family history, etc.). These are the cases that are required for meaningful use compliance as defined by the ARRA.

**Construction Phase (10 to 16 weeks).** In this phase, the focus is on developing the system components. The behavior and functionality described in the use cases and business rules are built. In an Agile environment, iterations may be developed in an effort to divide the use cases into manageable segments that produce demonstrable prototypes. This phase produces the first external release of the software.

As part of the test plan, each interface is tested in phases. In the first phase, we transmit small representative file exchanges between systems. This phase of testing ensures that network connectivity and file formats have been implemented correctly. In the second phase, we perform end-to-end testing with a specific subset of data.

This testing will ensure that communication initiated from end points:

- Correctly authenticate and access the allowed functions

- Transmit the encrypted communication from the sender end point to the receiver end point
- Match the embedded instructions to the appropriate tags and actions
- Capture the time in transit and other metrics
- Transmit basic communication paths and audit logging

This phase of the test also includes confirming, via reporting and visual inspection, that communications are routed and handled correctly.

**Testing and Debugging Phase (1 to 2 weeks).**

- *Functional Testing*
- *Performance testing the baseline to determine the potential throughput under the test conditions, e.g., the number of emails sent and their rate of incorporation by the test EMR system such as Open EMR*

**STATEMENT OF WORK**

Mamomail will endeavor to demonstrate the feasibility of exchanging healthcare data *and email and the special handling instruction tags via email integrated within EHR systems* in a manner that complies with all HIPAA regulations.

**WORK BREAKDOWN STRUCTURE**

**Task 1. Develop SPEE EHR Integration component .** Mamomail will build a limited SPEE integration component; since EHR systems do not currently possess this capability. The basic functions needed for Phase I are an ability to extract data from the EHR system and the ability to put data back into the system: Determine how to extract data using the existing EHR interface. Determine how to place data using the existing EHR interface.

**Exit Criteria.** This task will be complete when an interface with sufficient fidelity for the Phase-I simulations has been created and is ready for use.

**Task 2. Create Simulated Exchange Data.**

Get an EHR System

Understand the APIs in order to understand what the EHR System can do in terms of integration.

Determine what transactions will be sent from the EHR System; i.e., what test transactions to send from one EHR system to another.

Research the creation criteria and required data/format for the medical record documentation.

**Exit Criteria.** This task will be complete when a data package has been successfully created and is ready to be prepared for transmission.

**Task 3. Prepare Data For Transmittal.** Mamomail will develop the transform logic for the Mamomail SPEE (Secure Private Exchange Email) interface.

Determine integration points and depth of integration.

**Exit Criteria.** This task will be complete when a data package has been successfully prepared for transmission and is ready to be transmitted.

**Task 4. Transmit Data.** Mamomail will take the data package and encrypt it. The message must be encrypted in a manner such that only the recipient's private key can open it.

Determine who the receiver is.

Encrypt using the key.

Send the email.

The SPEE local application also sends the sender's key to validate the sender.

**Exit Criteria.** This task will be complete when a data package has been successfully encrypted and transmitted to a receiver.

**Task 5. Receive Data.** The recipient will have to verify and authenticate the sender key through the central Mamomail SPEE. If the key is correct, then it is available for decryption using the recipient provided key.

The SPEE interface puts the data into the appropriate EHR database for its use.

**Exit Criteria.** This task will be complete when a data package has been successfully decrypted and placed in the receiver's database..

**Task 6. Program Management.** Mamomail will provide program management for the duration of the project and comply with all reporting requirements. The PI will manage the program for the technical progress, adherence to schedule, and compliance with budget. He will also be responsible for setting scientific direction and evaluating technical progress. A senior technical director will be responsible for day-to-day activities. Mamomail shall comply with all reporting requirements.

**Exit Criteria:** This task will be complete when the technical effort has concluded, and all contractual requirements have been satisfied.

#### **CRITICAL MILESTONES**

A most important milestone is to demonstrate technical feasibility. The venture capital industry is extremely hesitant to provide seed funding for untested and radical concepts. With a successful proof-of-concept demonstration, we expect more favorable interest, including from existing solution providers and potential customers and begin to create a buzz around our innovation in and out of the healthcare industry.

#### **DELIVERABLES**

The main Phase-I deliverable is a Final Report, along with the associated SF 298. The report will summarize the work performed and the results achieved.

#### **ADDITIONAL EXPLANATION TO THE TECHNICAL BACKGROUND AND STATEMENT OF WORK**

##### **INTEROPERABILITY WITH VARIETY OF EHR SYSTEMS AND MEETING HIPPA AND CCHIT REQUIREMENTS**

*CCHIT governs the exchange of information electronically. Our Secure Private Email Exchange (SPEE) technology will be compliant to current CCHIT requirements. No existing commentary from CCHIT indicates that, in the future, email will not be acceptable if it meets security and privacy requirements.*

##### **THE ACCESSIBILITY OF THE PROPOSED APPROACH WITH PROVIDER-USERS**

*We have advisors who will introduce us to physicians and EHR systems. We anticipate being able to create test cases from physicians or a clinic using Open EMR or VISTA. This research purpose is to build the system, gather test data and feedback from test cases.*

##### **UNRELIABILITY OF EMAIL DELIVERY**

*Any unreliability of email delivery is rooted in network connection error, which would pose a problem for EHR system interconnectivity. The underlying assumption is network will be available. Any SPEE will reside at a level on the email stack higher than spam filters – i.e., the only other piece that can pose a problem are the spam filters, however, spam filters can be programmed to allow the SPEE tag pass through or SPEE can be integrated with the spam filters to do the authentication at the same time as the filtering.*

##### **SYSTEMS TO BE USED FOR THE PROPOSED RESEARCH**

*We will use Open EMR and VISTA for the research. VISTA is the largest integrated HIS in the world and is available at hundreds of healthcare facilities across the country from small outpatient clinics to large medical centers.*

*It is difficult to obtain pre-commitment for a research project as the providers do not wish to promise cooperation prior to actual research being approved. But we have advisors and contacts in the healthcare industry including RHIOs and EHR system providers.*

*We are using existing export and import functions within the EHR systems to export and import HL7 documents, which are already standard. Therefore, we do not need to write custom queries to extract and place the EHR data into EHR systems.*

### **THE VALUE PROPOSITION OF THE INNOVATION**

All stakeholders in the healthcare industry will be able to seamlessly deliver health related documents such as HL7 or CCD or any other formats that may be created in the future, to other stakeholders who may not have integrated technologies - i.e., EHR systems that cannot communicate with each other; the lack of existence of a central HUB for medical records or an individual (referring physician, staff, etc.) who lacks access to that HUB or is not part of an Health Information Exchange; or the patient who does not have the facility to get records electronically from the provider, as mandated by the meaningful use of the ARRA. This system will provide a way for integration of those pieces that don't have integration means, and provide a way for a physician to exchange with other physicians or for a patient to receive the EHR documents and information in a manner that they are accustomed to - i.e. email.

### **THE COMPANY/TEAM**

Michael Chung is the founder and the inventor of the method. He has experience in managing technology projects based on concepts that he originated. The other team members are Alexander Pelaez, Michael Peter, and Elliott Simon. Steve Ritacco is owner of KeptPrivate, a security oriented web email service that offers a web email client accessible over an SSL connection and will be an advisor.

The origin of the company comes out of Michael's earlier direct marketing knowledge and early Internet based entrepreneurial endeavors. Michael was seeking to solve the problem of delivering direct marketing messages to consumers via email. Direct marketing, which is targeted but essentially unsolicited communication, is a fundamental practice and a traditional business art. His realization was to separate such unsolicited emails from the general personal inbox, to allow the user the choice to open the mailbox containing the marketing communications and to offer greater transparency and hopefully appropriate quid pro quo in order for the user to voluntarily engage with the mailbox.

Recently, we saw the opportunity and potential uses of the Mamomail technology and the separate secure mailbox methodology for the healthcare space. This research in the Healthcare space can lead to commercialization in other industries.

The team comprises of: Alex Pelaez, the Senior Technical Director to the program. Alex has nearly 20 years of working experience for a variety of technology companies. He has developed expertise and knowledge in healthcare as a Senior Director for Enterprise Architecture at Emblem Health, a 3.7 million member health insurance company for over past 5 years. He developed health care technology classes at Hofstra University Zarb School of Business where he is an Adjunct Professor. In addition, he is pursuing his PhD degree in Information Systems at Zicklin School of Business, Baruch College (CUNY) where he is an Adjunct Professor of Information Technology. Mike Peters, software programmer, is a senior technical professional with 15+ years of verifiable success in driving object technology initiatives through all phases of the software development life cycle. Elliot Simon, senior healthcare resource to the program, has a proven track record in planning, operations and project management, as well as excellent relationships with trustees, medical staff, management teams and unions within the industry. Our team of professionals is ideally suited to address the feasibility demonstration proposed for Phase I.

### **THE MARKET OPPORTUNITY**

Email use in the healthcare industry is almost non-existent, from doctor to patient communication to exchanging medical records between providers and in many other areas.

#### Consumer Need

"Electronic communication promises to revolutionize the delivery of health care...Increased opportunities for electronic communication have revolutionized many industries and customer services...but email's promise for improving delivery of health care remains largely untapped.

“...For example, a recent US Harris poll revealed that 90% of survey respondents would welcome the opportunity to communicate with their doctors by email, with 56% of those surveyed stating that ability to communicate with their doctors electronically would influence their choice of doctor. Perhaps more surprising is that 37% indicated that they would be willing to pay for email access to their doctor.

“Between 1% and 10% of the US public communicate with their doctors electronically, most in only a limited capacity...Electronic communications that the public would particularly like to see available include follow up emails after visits to doctors, receipt of personalized medical information, obtaining test reports, and submission of charts for monitoring chronic conditions such as diabetes and asthma. The public also thinks that doctors should use automated systems to help patients better manage preventive care (such as email reminders for impending flu vaccination). Many patients also wish to use email to book or cancel appointments, arrange non-urgent consultations, and request repeat prescriptions.” (Car, J., Sheikh, A.; BMJ; 21 August, 2004)

#### Provider and Industry Need for Connectivity

Adoption rates for EHR are still very low in the United States - “83% of docs don’t even have a digital content yet...90% of Hospitals have no functional comprehensive EHR, those that do are large, usually urban based, and teaching hospitals...” - while, “the government wants all EHRs to share your data across all platforms. (Minnesota has a bill before the legislature right now that would mandate patient information be shared across all EHR systems.)”

“Patients see different doctors for surgeries, emergencies and routine checkups...all doctors should have access to relevant patient medical information in near real-time where and when it needs to be for patient care (to emergency departments, outpatient centers and ambulatory practices)...there are record keeping and mobility issues - coordinating these appointments via paper records is a time-consuming procedure.... The overriding goal of health care reform is to expand access, quality and affordability - and see the key to be healthcare IT...” (The CMO of a leading NYC hospital; Hofstra University HCIT Conference, April 22, 2010)

Physicians are very focused on healthcare quality but lag in access and adoption of new technology options for data sharing. They know about their responsibilities under HIPAA, and a degree of responsibility over the use and security. They are also very concerned about migrating themselves and their staff to digital solutions. An email based data exchange solution could be a helpful attraction to the “paper and pen proficient” physician and their staff.

“The popularity of e-mail is attributable to some of its unique characteristics, namely its ability to allow asynchronous communication and rapid message transfer, making it a hybrid of the telephone and the written letter. As it is used, e-mail is a more informal means of communication than the letter, but more rapidly transmitted. Like a letter, it can be sent or read by the recipient at convenient times, avoiding “telephone tag.” In addition, it is “self-documenting,” providing a lasting copy for future reference. Thus, it is no surprise that pediatric patients and their families share the desire to use e-mail to communicate with their pediatricians. E-mail would seem to offer physicians and patients obvious benefits for facilitating communication. Therefore, it may seem somewhat surprising that there has been relatively slow adoption of e-mail as a patient communication tool by pediatricians and other physicians. There are many reasons for this, including but not limited to concerns about maintaining the confidentiality of e-mail, physician concerns about the potential volume of e-mail correspondence, and potential legal issues.” (“E-mail Communication Between Pediatricians and Their Patients” Robert S. Gerstle, MD)

#### **CUSTOMER NEEDS ADDRESSED**

The needs of the medical community and the healthcare space are complex, varied and challenging. They range from migration issues such as the reluctance of the many physicians to adopt the new medical technologies and processes, to the hugely dispersed geographic and varied demographics of the US population. “There’s not a one-size-fits-all for doctors offices, clinics and other health care facilities...many...health care customers are waiting for more clarity from the government...And different

specialties require different things on the back end.” (Gary Sims, CEO of IT solution provider Advanced Technical Solutions).

In our own market research, we are hearing that many physicians who have started using the EHR systems report productivity losses of 30% to 50% - and are considering reducing patient visits and/or to ask for higher fees. This is due to the challenging migration issues from paper to digital, and the new procedures and data collection requirements by the compliance agencies. However, as the email is a well known and simpler tool, it can play a valuable role by reducing the complexity during the migration phases.

“Through the American Recovery and Reinvestment Act of 2009, the Centers for Medicare and Medicaid Services will pay physicians \$44,000 (Medicare) to \$64,000 (Medicaid) over five years, beginning in 2011, for deploying and ‘meaningful use’ of certified EHRs. This is expected to drive up to 90 percent of U.S. physicians to EHRs in the next decade, according to a Congressional Budget Office review.”

However, in our research we found that even with all these incentives, many practitioners, especially the smaller practices, do not want to invest the time to migrate nor yet see net advantages. Use of email can lower the costs and user barriers.

Further, many Americans prefer to control their data. The government and the industry are hopeful that this could lead to improved care and lower costs as patients can self direct their care. This requires wide distribution and exchange of information that is very suited for email based solutions.

The broad targetable user segments are: Patients, Physicians, Payers and the Public (regulators and agencies). Each of these constituents can use our proposed solutions. One of the top market needs is to communicate and exchange data through all the platforms and we believe that the relatively easier and faster to deploy email solutions can play a prominent and greater role.

Our early commercial focus will be on the individuals (patients) and the single to small practice physicians. These will be hardest for the current HIT providers to reach, network or integrate into a common system into. There are some 900,000 physicians in USA (about 300,000) practices.

Our project also envisions permitting information being securely transmitted between providers outside the institutional/practice EHR: physician to physician, physician to private lab or imaging center in a system much better protected than standard email (with attachments). While a private practice may have an EHR, much labs, imaging centers, pathology consultants, etc. have an EHR, and probably will not. But they have important electronic files and data, both clinical and other financial/social information of the patients.

Microsoft Health Vault is providing free PHR services to members and very interested in capturing data and popularizing the free PHR service and could adopt an enhanced email solution for their members. For system to system uses, Microsoft currently has two of the three components: MS Exchange for email client and Microsoft BizTalk Server (connects systems inside and across organizations, to exchange data and orchestrate processes requiring multiple systems). Our solution can be the third component that will transport medical data over the email networks.

#### **ESTIMATED MARKET SIZE**

It is a broad market – the healthcare industry is 16% of the U.S. economy and is growing larger. “...the 1.2 billion-dollar market for EHR is expected to grow nearly 400% in the next eight years...” This may be underestimated. At a recent conference, healthcare experts were speculating that the demand for HIT professionals could increase 200% to even 500% in the next 7 years, from the current 108,000 in USA.

A segment such VA VISTA users alone could be a significant commercial opportunity. “By 2003, the VHA was the largest single medical system in the United States, providing care to over 4 million veterans, employing 180,000 medical personnel and operating 163 hospitals, over 800 clinics, and 135 nursing homes. About a quarter of the nation's population is potentially eligible for VA benefits and services because they are veterans, family members, or survivors of veterans.” (Wikipedia) Therefore, VISTA is a representative of sorts for the

USA population. Also, they are supported and backed by the government and their users could become commercial customers.

“The report estimates that the global market for Healthcare IT market was valued at around \$11 billion in 2008. US Healthcare IT Market Boosted by the American Recovery and Reinvestment Act will Continue to Remain the Largest Market...The US is the key economy driving growth within the global Healthcare IT market. It contributed 37% towards the global Healthcare IT market in 2008. The contribution is expected to increase to 48% by 2015. The US Healthcare IT market is forecast to grow in double digit rates for the next seven years to exceed \$10 billion...” (The Future of the Healthcare IT Market to 2015 – Healthcare Reform in the US to Boost Growth. Global Markets. 2009)

#### **ANTICIPATED IMPACT ON JOB CREATION AS A RESULT OF THIS INNOVATION**

Healthcare and IT are the two largest job creators in the economy today. We anticipate a significant amount of job creation to manage our services. Zix Corp., which is primarily an email based solution service, reports about 83 employees in their encryption division – ranging from sales, to customer and tech support. We anticipate that most of the jobs will be USA based, due to the HIPAA compliance and the individual privacy desires.

We have the potential to export our technology to other nations to complement their existing centralized medical data systems. For example, in Canada where the national health insurance has been in place for many years, the patients routinely still go and pick up and deliver their paper based medical files and hand carry from one doctor to another. Further, the proposed research can be applied to other industries, such as: advertising, general notices and communication, for use with enterprises and large organizations.

Email can be an ideal alternative data exchange solution where the end points are one to many or many to many. And email enhanced with our innovative adaption can be adopted in a variety of industries. For example, banks and other services can regularly email electronic versions of the statement containing confidential information directly to the consumers' personal finance management tool where the data is automatically extracted and loaded to the application. Even perhaps in select military applications.

#### **COMPETITION**

We have not to date found a company that provides the solution and the approach that we are proposing. There are no other companies, in or out of healthcare that puts everything together about delivering records over the email protocol in a secure, verified, categorized and organized manner. In healthcare, the currently available solutions and services specializing in email are only about encryption and email management – such as Zix Corp.

#### **CRITICAL MILESTONES**

A most important milestone is to demonstrate the technology and demonstrate product. The private venture industry is somewhat hesitant to fund seed capital for untested and radical concepts. With the demonstration, we expect more favorable interest, including from existing solution providers and potential customers and begin to create a buzz around our innovation in and out of the healthcare industry.

#### **FINANCING AND REVENUE MODEL**

We are hopeful that many of the healthcare venture capital investors would be interested to back the technology and business model or have alliance opportunities with existing major HIT providers. HIT solution providers could license our solutions and integrate into their EHR solutions (e.g. practice management applications). There are many dynamics going on in the industry currently, IT companies such as mindSHIFT Technologies are entering the healthcare space by acquisitions and most do not have an email based solution beyond the encryption and management services.

We may look into forming research and business collaboration relationships with other SBIR grantees that are in the HIT/EHR space. In a NIH SBIR directory, there are several companies offering their interests: Cambridge Solutions Corporation; Dimagi, Inc. (focused in third world EHR services, and email can be particularly effective where there are lack of centralize infrastructure); Information Security and Assurance Corporation (recipient for 20 grants); Leap of Faith Technologies, Inc. (...received eleven SBIR Grants, which

have enabled the development of new technologies for health communication.”); Medical Office Online Inc.; etc. – none are focused on an email solution.

### Examples of Commercialization and Potential Revenue:

#### Healthcare:

- Licensing the software to EHR software and system providers; valued added resellers.
- Directly to independent medical practices.
- To Federal government for various uses from general data communication to dealing with compliance data gathering.

#### General Industries and Other:

- Finance: Banks and services can pay a small rate based on each email sent.
- Advertisers: Marketing emails can be sent in a valued added email format and thus increase appeal to the consumers.

### **IP PROTECTION**

We are patented in China, Korea and pending in USA. We have additional email related patents pending.

### **ADDITIONAL FUTURE HEALTHCARE SPACE GOALS**

To integrate the solution into existing popular EHR systems: For hospitals and large practices - such as VA's VISTA, ECLIPSE Practice Management Software / Billing Software and Epic. And from EHR side: Allscripts, Athena, and other CCHIT certified EHR systems - and to exchange/send the email within the same system but from different user accounts

To explore non-electronic medical record uses, in the healthcare space: sending information and data outside to Public and other agencies; (optionally) to different user devices and interfaces; and the multiple stakeholders (payers, regulatory agencies, RHIOS, etc.); to have them integrate the general SPEE email into their work and process flows.

To promote use of email to deliver information and improve communication (such as physician to patient general emails ) to the patient in a secure manner, so they can see it and handle it; an email client plugin.

(End of Commercial Potential and Company/Origin Section)

**(This is removed in the resubmission.)**

**SPEE Tag Exhibit (An expanded-scope version).** The SPEE markup tags consist of an XML specification that describes and instructs the meta-data envelope, EHR data packet, attachments, and special instructions.

	<MamoXML>		
(Envelope)	<EncryptionKey>	.....	</EncryptionKey>
	<DigitalSignature>	.....	</DigitalSignature>
	<Sender>		
	<Address>	.....	</Address>
	<SenderEmail>	.....	</SenderEmail>
	<SenderPhone>	.....	</SenderPhone>
	<IpAddress>	.....	</IpAddress>
	</Sender>		
	<EHRInformation>	.....	</EHRInformation>
	<Recipient>		
	<Address>	.....	</Address>
	<EmailAddress>	.....	</EmailAddress>
	<Category>	.....	</Category>
	</Recipient>		
	<Patient>		
	<ID>	.....	</ID>
	<EmailAddress>	.....	</EmailAddress>
	<CcEmailAddress>	.....	</CcEmailAddress>
	<Category>	.....	</Category>
	</Patient>		
(Data)	<Cardiology>		
	<BloodPressure>	.....	</BloodPressure>
	<HeartRate>	.....	</HeartRate>
	</Cardiology>		
	<Pharmacy>		
	<Rx>	.....	</Rx>
	<Dosage>	.....	</Dosage>
	<Refills>	.....	</Refills>
	<DispenseAsWritten>	.....	</DispenseAsWritten>
	</Pharmacy>		
(Document)	<HL7>		
	<Data>	.....	</Data>
	</HL7>		
("Special Handling /Delivery" – SH&D)	<DateActive>	.....	</DateActive>
	<DateEnd>	.....	</DateEnd>
	<PriorityLevel>	.....	</PriorityLevel>
	<SubjectLineImageLabel>	.....	<SubjectLineImageLabel>
	<EmailClassification>	.....	</EmailClassification>
	<SH&DInstructions>		
	<MustDeliverDateConfirmation>	.....	<MustDeliverDateConfirmation>
	<OpenConfirmation>	.....	</OpenConfirmation>
	<RestrictForwarding>	.....	</RestrictForwarding>
	</SH&DInstructions>		
	<ViewingInstructions>		
	<ApprovedViewer>		
	<GoogleHealth>	.....	</GoogleHealth>
	<MicrosoftVault>	.....	</MicrosoftHealthVault>
	<VaVistA>	.....	</VaVistA>
	</ApprovedViewer>		
	</ViewingInstructions>		
	</MamoXML>		© 2010 Mamomail

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