Medical Strategic Planning, Inc.

Date: July 12, 2014
From: Richard Dick, PhD, Chief Medical Informatics Officer, Medical Strategic Planning, Inc. (MSP)
To: The Honorable Fred Upton, Energy and Commerce Committee, 21st Century Cures initiatives
RE: Comments requested and due by July 22, 2014 cures@mail.house.gov

Medical Strategic Planning thanks the bipartisan efforts of Congress for the opportunity to speak to the **Reboot Healthcare** and **21st Century Cures** initiative in the Senate and House. These remarks and suggestions provide answers also to questions raised in the **JASON Report** (A Robust Health Data Infrastructure) and also in the December 2010 **Healthcare PCAST Report**, both of which document the general lack of progress in successfully addressing fundamental health data infrastructure problems that have persisted and deterred progress for more than 25 years, in spite of over $20B billions dollars in government appropriations and various policy initiatives, including the ACA.

There is a fundamental problem with the issues that all of these well intended initiatives have raised; they have not surfaced or focused on all of the data representation technologies that could solve fundamental health data problems, rather, they have only focused on those that were commercially known. The ONC (HHS) and government policy makers are clearly unaware of newer, more advanced data representation technologies. This omission has switched the ONC onto the wrong (DBMS) data representation tracks, and derailed progress in obtaining the noble objectives of the Reboot and 21st Century Cures visions. Rather than pursuing achievement of meaningful use (MU), developing a foundational interoperable data representation is the more accurate and rewarding target, because it is a pre-requisite for achieving MU and achieving other crucial goals. MSP is revealing a proven, but new data representation technology that was unknown to the civilian authors of both of the above reports.

MSP submits these comments as a member company of the **Health Record Bank Alliance**, a group founded by Dr. William Yasnoff, MD, Ph.D. and others. Dr. Yasnoff is familiar with the Triad Dataspace technology which MSP is now disclosing / introducing and applying to solve many of healthcare's most fundamental data infrastructure problems. Dr. Yasnoff's comments on Triad Dataspace are attached. MSP's submission is necessarily lengthy because Triad Dataspace requires some study / exposure and contrast to traditional database methods of representing data, in order to understand and conceptualize Triad's impact. In addition to a significant and foundational data representation advance, Triad Dataspace, while empowering semiotic interoperability, will also advance *data security* (reducing breaches), create *quality improvements*, *reduce storage costs*, *improve data integrity*, *enhance usability* and *enable more advanced analytics*. These additional advances will *empower Population Health Management* (PHM); *clinical and research epidemiology* and make possible *assured-quality processes for Evidence-Based Medicine* (EBM) in near-real time. While Triad is a proven technology, it has remained a commercially unknown solution – until now.

By disclosing Triad's existence, MSP's goal is to solve healthcare problems that will benefit all Americans by improving the U.S. healthcare system and actually making it the example of what can and does work, rather than the showcase for how to waste the largest amount of money on a dysfunctional system that ranks poorly in OECD healthcare measures. MSP is inviting the Energy and Commerce Committee to facilitate MSP applying Triad Dataspace™ in the healthcare sector. Doing so will switch the ONC train onto a track that will quickly move our nation in a more productive direction. Triad Dataspace™ technology can resolve (or circumvent) the very healthcare problems that DBMS approaches have created, alluded to in 21st. Century Cures White Paper.

Thank you for the opportunity to submit this information. If the committee wishes to learn more, please contact the company's CEO, Art Gasch, who, at the request of a CMS manager, will be conducting orientation sessions in the Baltimore, MD area in September 2014. MSP invites Chairman Upton and/or other committee members to attend that ½ day presentation. Please contact Art Gasch at MSP for further details. MSP would be available to testify before the Energy and Commerce Committee about this advanced. Proven technology, which was developed for certain national interest applications, and how it might now be carefully applied in addressing the fundamental health data infrastructure problems which these important Reports (Reboot / JASON / PCAST) have so significantly noted.

Sincerely,

Richard S. Dick, Ph.D., Former Study Director and Senior Staff Officer – Computer-based Patient Records Committee, Institute of Medicine (IOM)
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June 2, 2014

Letter of Recommendation for Triad Dataspace™

As both a physician and PhD computer scientist, I am pleased to have the opportunity to write in support of the widespread use Triad Dataspace™, a new and different approach to automated data storage and retrieval. Its substantial and important advantages over conventional data storage software, including lossless compression, secure encryption, and automatic pattern discovery, make it especially attractive for health and medical applications.

Triad Dataspace™ replaces typical object-oriented, relational, entity-relational, associative, Hadoop and other conventional storage approaches with a novel, self-adaptive information structure called a 'dataspace.' A Triad Dataspace™ is an unstructured mathematical storage 'space' with no a-priori schema, which builds its own information structure as data is presented to it and stored. All record fields are normalized and expressed in a topological (universal) representation, which is a double-blind encryption of the original information. The resulting information structure has novel properties. Besides autonomous structure discovery and double-blind encryption, it allows near-real time query and data lookup even as the amount of stored data becomes huge. It is extremely secure and requires far less storage space than commercial databases, and can enforce access control permissions at the individual data item level with complete audit trails of all access. The properties of Triad Dataspace™ make it an excellent fit for any large health or medical dataset, including Population Health, HIEs, ACOs, Health Record Banks, and cloud-based EHRs. More details about Triad Dataspace™ technology are available at www.triaddataspace.com.

My understanding is that Medical Strategic Planning (MSP) is the first company to bring the Triad Dataspace™ system, developed for use by the intelligence community, into commercial healthcare markets. Since the deployment costs quoted by MSP are 50-75% less (on a per exabyte basis) than other database technologies now in widespread use, *it is a potential game changer for healthcare applications.*

Having been responsible for the work at the U.S. Department of Health and Human Services that led to the President's creation of the Office of the National Coordinator for Health Information Technology in 2004, my consulting practice includes a variety of public and private sector organizations facing very difficult informatics challenges. I now strongly recommend that my clients with large-scale healthcare applications (either new or ongoing) seriously consider utilizing Triad Dataspace™ to reduce costs and increase the capabilities and effectiveness of their systems.

Please note that my recommendation is not based on any affiliation with or financial arrangement with MSP, and I very rarely write letters such as this. However, in this case, my independent evaluation is that Triad Dataspace™ represents superior technology with tremendous potential to improve and expand the effective and economical use of large-scale health and medical databases.

Discussion and Recommendations – 21st Century Cures initiatives

In the 21st century, health care innovation is happening at lightning speed. From the mapping of the human genome to the rise of personalized medicines that are linked to advances in molecular medicine, we have seen constant breakthroughs that are changing the face of disease treatment, management, and cures. Health research is moving quickly, but the federal drug and device approval apparatus is in many ways the relic of another era. We have dedicated scientists and bold leaders at agencies like the NIH and the FDA, but when our laws don't keep pace with innovation, we all lose.

If we want to save more lives and keep this country the leader in medical innovation, we have to make sure there's not a major gap between the science of cures and the way we regulate these therapies.

That is why, for the first time ever, we in Congress are going to take a comprehensive look at what steps we can take to accelerate the pace of cures in America. We are looking at the full arc of this process – from the ***discovery*** *of clues in basic science, to streamlining the drug and device* ***development*** *process, to unleashing the power of digital medicine and social media at the treatment* ***delivery*** *phase.*

It is in the spirit of this worthy objective and mission statement, MSP is submitting these comments and disclosing Triad as a new technology to help the Congress achieve its objectives. As a member of the HRBA, MSP is in general agreement with Dr. Yasnoff's submission on behalf of HRBA, but MSP's perspectives are somewhat broader, so MSP is making this separate submission that elaborates how MSP's new technology addresses fundamental problems with data representation, security and interoperability that are required to move the nation's healthcare agenda forward before it can achieve MU goals.

In the interest of brevity, please refer to both the **JASON Report** submitted to AHRQ this year, and the **PCAST Healthcare Report** submitted to the President in December 2010. While these two reports were compiled by two distinct groups of commercial technology experts, *their conclusions are remarkably similar*. A brief synopsis of the problems they identified are listed below.

Synopsis of JASON and PCAST Report Conclusions:

From the **PCAST Report**:

1. "Despite great promise, almost 80 percent of physicians…lack even rudimentary digital records. Where EHRs do exist, they are… limited in functionality and have poor interoperability. *As a result, the ability to integrate EHR information and exchange it… is the exception…"* The **JASON Report** confirms this is still an issue four years later.
2. "Most current health IT systems are proprietary and have proprietary data formats that are not directly exchangeable*… making it difficult for data to be disaggregated, indexed, searched, and assembled to provide accurate information to treat a patient..."* The **JASON Report** confirms this is still an issue four years later.
3. "Legitimate patient concerns exist about privacy and security, *making patients uneasy about participating in health IT systems."* The **JASON Report** confirms this is still an issue four years later.
4. "Even the few successes, upon closer examination, highlight the limitations of current approaches… and are generally… *not designed for the exchange of data with a heterogeneous and geographically diverse set of other organizations..."* The **JASON Report** confirms this is still an issue four years later.
5. "What is needed is a simultaneous focus on… universal data exchange… *The critical issue is to facilitate … and disseminate an infrastructure for locating patient records, while rigorously protecting privacy and security."* The **JASON Report** confirms this is still an issue four years later.

Limitations of Commercial Expert Panels

Because all solutions tried to data have been database management systems – DBMS solutions, our progress has remained unchanged. *To a large extent, DBMS properties are the source/cause of essentially all the problems listed in both reports*.

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*MSP believes that the goals called for by the ACA legislation and the problems stated in the **JASON Report** can only be overcome if Congress mandates adoption of better data representation technologies, that will actually empower interoperability, one of which has existed in national interest domains for almost three decades.*

It is clear from the **JASON** and **PCAST Reports** that both task groups were *unaware of Triad Dataspace™ technology*, and therefore could not take it into account in making their recommendations. This is understandable because these committee members were *chosen from commercial companies, and such companies are unfamiliar with the national interest applications for which Triad Dataspace™ was developed or the technologies that ultimately solved such problems.* MSP is now making Congress aware of the existence of Triad Dataspace™ technology, without disclosing its national interest uses.

Unlike databases (DBMS), Triad Dataspaces™ provide a solid foundation for a completely new solution to the healthcare interoperability and other problems cited in the above reports. Triad™ is not a database solution; it is completely different.

Triad Dataspace™ is an advance in data representation, which MSP's CTO (Kenneth Happel) has developed previously. What public information there is about commercial applications of Triad™ exists at www.TriadDataspace.com and MSP suggests committee members peruse that site. Mr. Happel and MSP as a company, wish to see the technology used to benefit people, as well as to protect them. Information breakthroughs (whether Triad or others) have been hinted at in a Wired Magazine article.

> "Mar 15, 2012 - The National Security Agency's immensely secret… heavily fortified $2 billion center project in the Utah desert should be up and running in September 2013. Chief Scientist and Head of its Information Technology program continues, *"The NSA made an information breakthrough several years ago…"*[1]

Triad is known inside national interest circles. An early disclosure of Triad Dataspace™ technology was highlighted in the Keynote speech "***Forces for Change***" delivered by Bob Williams, *Director of the National AeroSpace Plane (NASP) program*, at the First International Conference on Hypersonic Vehicles *in 1986.* Mr. Williams was at that time *Special Assistant to the Commander in Chief of the US Southern Command* (USSOUTHCOM) *Technology and Requirements*. Williams stated, "*Hyperknowledge™, (the Triad Dataspace™ precursor technology) is one of the ten technologies that will produce fundamental change as we enter the 21st century.*" Triad Dataspace technology has indeed produced change, just not in commercial markets. Healthcare will be the first opportunity for Triad to be applied here.

That Triad Dataspace™ technology has remained commercially unknown for almost 3 decades is a testimony to its significance to U.S. national interest applications.

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[1] http://www.wired.com/2012/03/ff_nsadatacenter/all/

CONCERNS ABOUT CONTINUED FUNDING OF FAILED DBMS APPROACHES

Given the existence of Triad Dataspace representation technology, and the *repeated failure of DBMS solutions going back 25 years to Community Health Information Networks (CHINS),* MSP recommends *that further funding of in any DBMS-based healthcare solutions be immediately halted for the 8 bulleted reasons listed below.* So long as U.S. healthcare policy continues to fund DBMS approaches*, the nation's progress in achieving desired objectives will remain stifled and crippled by a flawed data representation problems introduced by the use of DBMS solutions.* The Reboot (Senate) and 21st Century Cures (House) initiatives both need to consider "Second Information Age" nature of Triad Dataspace™ technology, to supplants the need for databases.

Isn't it time to fund, or at least pilot a different approach that overcomes the problems associated with DBMS technologies? Triad Dataspace opens up Second Information Age solutions to use in the commercial healthcare sector that can move the nation much closer to achieving its goals.

Why Database Management-based Solutions Cripple Healthcare

DBMS, in all their flavors (e.g. relational, entity-relational, object-oriented, HADOOP and others), *create the very problems that now stifle the healthcare advances sought by the ONC, AHRQ and Congress*. MSP believes there is little dispute about the following summary of DBMS technology characteristics.

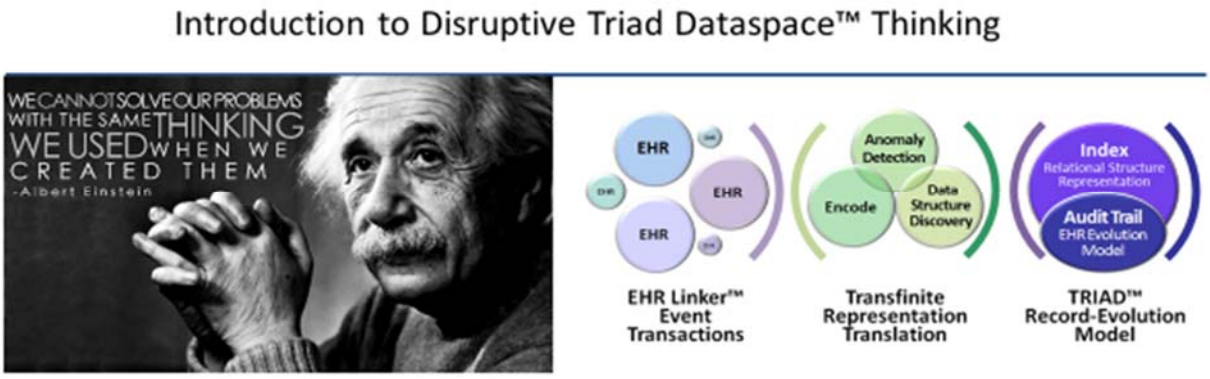
- ***DBMS was designed for and works best in CLOSED knowledge domains***, where all of the facts and relationships are known in advance, and can be properly expressed in the database schema. However, *healthcare is an OPEN knowledge domain*, in that all of the relationships between life and death, health and disease, illness, treatment and outcome are NOT known in advance, and in fact are being sought by aggregating the information being stored;
- ***DBMS lack secure (encrypted) representation* as a *native format or data type***. (If used at all), Encryption is always added onto DBMS data types. *Because DBMS operations work on non-encrypted data only, if encryption is used in a database, the data must be first decrypted before it can be processed.* This can consume a lot of CPU overhead, which is why encryption is generally NOT used in commercial DBMS solutions. *As a result, DBMS sites containing personal health information (PHI) data (including the www.healthcare.gov) can be protected only by their firewalls, and user authentication, which can often be breached*;
- ***DBMS lack a single common/universal data representation*** that supports data migration from legacy systems or real aggregation and fusion of migrated information. *This complicates interoperability among legacy systems, requiring interface engines which are complex and costly*;
- ***DBMS lack atomic (item-level) data structuring, accounting, and audit trails*** *of all transactions, and all attempted transactions by authenticated (or unauthenticated) users*;
- ***DBMS lack near-real time query and data retrieval response for all queries*** that *contain non-indexed fields*, and *query response drops* as *data mass grows or data collected has more non-indexed fields*;
- ***DBMS require substantial multi-variable scaling and other pre-processing* (a second step) *before population-level data analytics*** *to uncover causative factors in the data mass*. Therefore, *as data mass size grows, data analytics* (to uncover and recognize: 1) fraud, 2) desirable medical outcomes, 3) emerging disease epidemics), *becomes less responsive and certainly does not remain near-real time. This creates data center upscaling issues and ignites the quest for processing speed;*
- ***DBMS are storage footprint wasteful***, thus *limiting the opportunity to reduce storage c*osts needed because of growth in data mass stored per patient as genomic and other large data mass becomes common for each patient. This is entirely related to the multiple data types (integer, floating point,

string, image, blob, date, and so on) and handling/storage of duplicate identical records in databases. Connect Direct, with its XML-tagged data is particularly wasteful of storage space;

- ***DBMS have no inherent method to enforce patient permissions****, nor to provide item-level audit trails* as recommended by DHHS for PHI storage systems. [2]

In the **JASON Report**, one committee member who paraphrased **W. Edwards Deming**, was quoted as saying (on page 13), "*If you invest in automating bad things, you just make bad things happen faster*."

Albert Einstein put it most succinctly – *"We cannot solve our problems with the same thinking we used when we created them."* Yet, that is exactly what national policy has been attempting to do for 30 years, and it hasn't worked. *Triad Dataspace™ is not based on the thinking that created healthcare's problems – rather it is the solution to them!* This begs the question – *If databases thinking has created the problems in healthcare, they can't be used database concepts to solve them, so why do we keep trying to do this?*



[2] Completely overlooked by planners is the fact that if item-level audit trails, as recommended by DHHS are kept, over time, the size of the audit trail, exceeds the size of the stored data. In conventional DBMS products, this means a substantial increase in long-term storage costs.

A Legislative Primer on *Second Information Age*

This Legislative Primer is included to remove any "threat" associates with this "new" technology, and to provide a layman's basis for understanding it, and how simple, inexpensive and non-disruptive it would be to apply it to the existing healthcare situation as it exists today.

Triad Dataspace™ technology was generalized by Ken Happel, MSP's Chief Technology Officer, *who has been involved in its uses since it was discovered*. Mr. Happel extrapolated the general case of the fundamental mathematics, opening the door to national interest uses. Many advances have been made since that happened. MSP is the first company *commercially licensing use* (while retaining control *of) Triad Dataspace™ technology outside of national interest applications.*

Triad Dataspace™ is the first commercial product *from the Second Information Age*. Triad Dataspace isn't a new form of DBMS (database), so it doesn't launch any discussion about, "Whose database is best?" among database vendors, because ALL databases are the wrong solution. Triad is a *self-structuring method* to *sparsely represent and securely store* information *by data anomaly that simplifies retrieval and interoperability; that is a complete and proven alternative* to DBMS technology. Triad *excels in OPEN knowledge domain applications* like healthcare because a Triad Dataspace does not need to be pre-informed of the information structure of the data it is going to store; instead it discovers it as the data is stored! No database does this – all have a-priori schemas. Triad has many other novel features that no databases offer.

First, unlike DBMS solutions, ***Triad™ operates as an asynchronous process***, which means that while it can run on (synchronously-clocked) computers, it can also be *implemented in ASIC firmware* and *run at speeds much greater than current CPU clock speeds.* This opens the door to *embedded Triad chips in medical devices and sensors*, which can vastly improve medical sensors and noninvasive monitoring in general. Triad *can also be implemented in optical network devices* in Triad data centers that operate at near fiber optic speeds – much faster than current CPU-Slice clock speeds. This will *significantly boost cloud-based data throughput while lowering their costs* dramatically.

Second, ***Triad organizes information by its differences (anomalies),*** which is *very useful in identifying and reducing healthcare fraud*. The JASON Report cites (page 5) the "*cost of fraud in the range of $60-100 million dollars.*" The JASON Report concludes (Page 5): "*Even the partial recovery of fraudulent billing for duplicate claims, unbundled services, and services not rendered would more than cover the cost of implementing a new architecture.*"

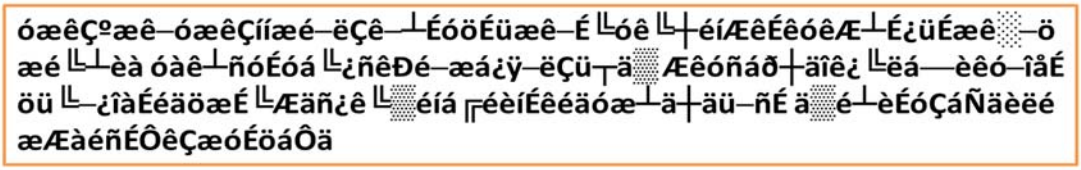
Costs of conversion from DBMS-based solutions to Triad-based solutions will produce saving from fraud reduction and breach reduction that far offset the cost!

Fraud is simply the tip of the reducible-cost iceberg. **PHI breach and identity theft** (and the costs to mitigate them) are estimated to have cost healthcare about $21Billion dollars – given the cost of fines plus the cost of $235/patient record breached to mitigate it. *If Triad had been widely used, most PHI breaches wouldn't have occurred!*[3] *Triad reduces breach by the encrypted nature of the way it stores all data on all non-volatile storage media.*

Third, ***Triad's universal, native representation is a natural double-blind encryption***. It is inherently HIPAA-compliant, and *remains HIPAA-compliant even if the Triad representation is exposed, accidently discarded or stolen on hard drives, laptops or tablets. The image below is an actual example of what would be*

[3] This makes theft of a laptop, or an improperly erased hard drive, of even an interception of a data center-to-data center transmission, no longer a breach of PHI data.

available to a person if a theft or breach occurred. Since it cannot be deciphered, it remains HIPAA compliant no matter who possesses the encryption. *Breach of information is different from possession of encrypted information – which if undecipherable. Undecipherable information is useless and remains secure*.



No DBMS technology currently in existence has a double-blind encryption as its universal, single native representation of information, but Triad Dataspace™ does.

In a Triad-enhanced Health Record Bank (T-HRB) data center, *data is always encrypted*, *even during data analytic data query operations* – an important security feature that no cloud data center using DBMS technology provides. In a T-HRB, there are always THREE barriers to breach:

1) The firewall; and
2) Multi-factor authentication of the person(s) using the system;
3) Triad's *double-blind* encrypted universal representation is secure.

DBMS solutions can't offer the third barrier to breach, which is why there have been so many data breaches to date and will continue to be as long as this obsolete technology is embraced.

Envision all of the nation's PHI data stored in Triad Dataspace's double-blind encrypted format. Stealing it becomes useless if data stolen can't be deciphered! Triad protects PHI data in ways that no database can; and does so WITHOUT degrading data center operations.

That's important if Americans are going to have confidence in the security of their personal data stored and the government's ability to prevent its theft or their identity theft. *To date, the government has done an abysmal job of maintaining security BECAUSE of the type of solutions it has funded, starting with the www.healthcare.gov website, which should have never been built on database technology*.

Fourth, ***in Spite of encryption, Triad expedites query processing***, which is key for 1) population health management (PHM), 2) data mining/analytics, and 3) near-real time Evidence-Based Medicine (EBM).

Query processing WITHOUT first decrypting the data, (called homeomorphic lookup), is a Second Information Age property, not available from First Information Age DBMS products.

Since cloud-based health record banks are constantly performing queries for epidemiological and research purposes, a conventional cloud data center is constantly exposed to its internal network and only one firewall breach away from being exposed to every hacker, criminal organization or foreign agent. To date, American DBMS healthcare technology funding has created a treasure-trove of easily-hackable data, and has undermined cyber-crime prevention efforts by creating low-hanging fruit waiting to be plucked.

Triad brings "double-blind" encryption to healthcare, and licensing/routing it through MSP's T-HRBs data centers assures it is NOT able to be coopted for criminal purposes.

HOMEOMORPHIC (QUERY-WHILE-ENCRYPTED™) LOOKUP EXAMPLE

In general, *Triad Dataspace renders "searching" obsolete. Triad does lookups by calculation processes not searching operations. Calculation is much faster than brute force record searching of huge data masses*.

Suppose data is being encrypted and stored about a haystack in a Triad Dataspace and in the process a needle is discovered. It wasn't expected to be in a haystack so no place in the pre-defined schema of a conventional database would have been reserved for it, and even if it had been, that "field" would not have been indexed.

However, In Triad Dataspace, since a needle has different properties (it's made of metal, has a fixed length, and isn't bendable or compressible) than any of the hay (made of straw, varying lengths, bendable) found to date, Triad recognizes it as an anomaly (compared to the hay) and creates a branch of the stored haystack information tree, for storing needles. This is the storage-by-anomaly concept.

Suppose a screw were later also found in the haystach. A screw is an anomaly also because screws 1) aren't like hay, and 2) they aren't like needles either. Triad now expands its self-adaptive information structure (schema) to include "screws" because they also represent a new anomaly to what has been previously encountered. So the haystack now has three major branches in its adaptive, self-structuring schema, each associated with what was actually found in the haystack, not what someone thought (in advance) might be found there in advance.

Now let's make the problem real. Instead of one haystack, there are 2,000 (EHR, CPM, LIS, RIS, whatever) haystacks in 2,000 different haystack (legacy) silos, with 2,000 different teams of people entering the data, and there are 2 billion examples of hay inventoried. That introduces an interoperability issue of all the haystack inventory systems communicating with each other.

Now the question is posed, "Are there any 'needles' in the haystacks?" The question isn't posed by showing any of the Triad systems an example of a needle; e.g. this is a "needle", are there any of these in the inventory?

Let's assume that all the haystack inventories are in systems that have Triad Dataspace as their information representation (although that doesn't have to be the case).

Each Triad Dataspace can calculate where the "needles" would have been stored if it was found previously and stored, and then simply check that storage location. If it's empty, there were no needles. If it's not empty, there is a list of the location of all of the needles. Note the word "calculate", not "search". One never searches in a Triad Dataspace (unlike a conventional DBMS). Each Triad Dataspace can process this same "needle" query, and each can simply calculate and check if any needles exist. So the same query works perfectly when made to each inventory silo separately (by showing it an example of a needle).

Now suppose that all 2,000 silos are connected to one central Triad Dataspace (that is being constantly updated in near real time). That repository has the aggregated and fused information structures of the entire 2,000 individual repositories in the one, encrypted datatype/representation. It finds ALL of the needles in ALL of the separate haystacks. This is semiotic query lookup interoperability. Triad has it, without "interface engines," but databases don't in spite of $20 billion in federal funding to achieve HITECH requirements for interoperability.

Finding all needles (or screws or whatever) is very fast. It doesn't matter how big the haystack is (or how many haystacks there are), because ALL occurrences of needles are always stored in their own part of the

haystack information structure. Welcome to one way of visualizing the adaptive, self-structuring information model of Triad Dataspace and its unique homeomorphic data query/information lookup processing.

Databases only offer indexing and only for some field anticipated in advance to be useful. But in healthcare, which is an open knowledge domain, we don't know in advance which combination of fields will be "useful" and therefore which ones to index in advance. Indexing is established in the database schema before the first record can be stored in the database. Fields not anticipated to be occurring frequently, are typically indexed.

Suppose the owner of one of the 2,000 databases replies, "I've found a needle, and I will change my database schema to include needles. The first task will be to re-processed every record recorded to that point, because they now have empty needle fields, that need to be updated. That can take a while.

What about the 1,999 other databases, who have no idea one database has encountered a needle? In fact, they aren't even aware of the 1,999 other barns and haystack inventories being independently conducted. So they don't change their database schemas, or reprocess all their records, because they haven't found any needles, or if they have, they are buried in some "catch-all" field called "other." Updating the schema of one database make it less compatible with all the others. While the one DBMS system can answer how many needles in your haystack, in all likelihood, the other 1,999 can't even process the query! *That is the state of query interoperability in healthcare today because of database limitations. Does it make any sense to perpetuate this information representation model?*

Suppose the needles are diseases, or symptom(s) of diseases, or abnormal clinical pathways. The normal in healthcare is that people are healthy and disease is the exception. More people don't have cancer than have it. The key is to finding the anomalies that may be causative of the cancer, is to differentiate the anomalies of people with cancer to healthy people. These anomalies might be genomic damage, RNA transfer, metabolic pathway changes, protein pathway or protein synthesis anomalies, or all of the above.

Anomalies are important in healthcare but DBMS's don't organize information by anomaly, but Triad Dataspace does. Triad can easily calculate the combination of properties/features/measurement that distinguish the two different patient populations, and indicate what changes in those parameters would move the anomaly population to overlay the normal population. MSP refers to this as "assured quality processing," because it's available in near-real time. Databases don't offer that, but evidence-based medicine, and population health management require it.

Fifth, ***Triad Dataspace is more scalable than DBMS solutions*** *and can support a national-level MPI (Master Patient Index)*. Triad packs more data in less physical space, and therefore, scaling up to the national level with Triad costs less than scaling up database storage to the same degree. Triad storage costs are anywhere from four to 2,000 times less expensive that database-organized storage. See table below.

	Number of Attributes Per Record	Number of Records	Original File Size (bytes)	7Z Final File Size	7Z Reduction Ratio	Triad™ Reduction Ratio	Triad™ Final File Size	Triad™ Improvement over 7Z
File 1	4	30	810	472	1.7	188	4.3	2.5 times
File 2	4	42	1,141	757	1.5	260	4.4	2.9 times
File 3	4	250	6,784	1,515	4.5	1,090	6.2	1.3 times
File 4	4	1,000	103,000	31,000	3.3	3,265	31.5	9.5 times!
File 5	19	1,200,000	45,225,000	8,484,000	5.3	23,000	1,966	370 times!

In the above example, database did NOT include medical images, only structured medical text information

Triad ALWAYS uses raw storage space (on any media – fixed drives, SSDs, in memory) more efficiently than the multiple data types used by DBMS systems. The table above shows how much more efficient Triad is compared to the best First Information Age compression technologies like 7Z or PKZip.

Note that **File 5** above was processed by 7Z, *achieving 5.3 times storage footprint reduction*. However, when expressed in Triad Dataspace universal, encrypted representation, the *Triad storage footprint reduction was 1,966 times* or 370 times better than achieved by 7Z! Triad is *100% bit lossless and fully isomorphic* (meaning no information is discarded)! This level of storage efficiency is unknown in the commercial DBMS products, and it is *commonly believed that such reduction in footprint cannot be achieved.* In fact, *it can't be achieved* in First Information Age storage representation; but with *Second Information Age data representation – it can be achieved, and MSP's Triad demonstration achieves it*.

Look at **File 1**, of less than 1,000 bytes. 7Z reduces it 1.7 times, but Triad reduces it 4.3 times. The MSP Triad demonstration system generated these results*. Triad always does a better job at reducing storage footprint than 7Z, sometimes a lot better (when data source size is greater).*

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*The **JASON Report** posed the question, "How will storage space be conserved when the data mass per patient (due to genomic data) is growing larger?" The answer is Triad Dataspace, and the representation advance it represents is the only answer found to date.*

Triad Dataspace is not just efficient at storing structured numeric and text information, it surpasses JPG2000 lossless for storage of images, yet like jgp2000 lossless, Triad is *100% bit lossless and fully isomorphic* – no image information content is thrown away! There is no bitloss in how Triad stores images.

Envision automation of certain labor-intensive, error-prone lab studies (such as WBC screening) that could be automated by Triad doing a preliminary screen and detection and guiding technicians to where WBC anomalies exist on the slide. That's most likely where the cell changes will be seen. A single cell anomaly causes the test to become positive, so Triad could greatly speed up finding abnormal results – thus saving technician time and money.

Triad Dataspace can reduce storage costs by over 90% for structured text and numeric data and by 66% or more for medical image data in most cases. This has profound cost reduction implication because healthcare data must be stored for decades in some cases.

COST OF HEALTHCARE DATA CENTERS COMPARISON

$5M spent on storage in a SCIF T-HRB data center holds as much structured information as $223M spent when the same data is stored in a conventional data center using DBMS technology.

Suppose a data center uses hard drives (obviously, SSD or even large memory arrays could be substituted). In one 10-rack bay, four hundred fifty 6-Terabyte drives that would provide 1.8 petabytes of storage space at a cost of approximately $223,000. However, with data in Triad's universal representation, up to 3.6 Exabytes of PHI data could be stored in that 1.8 petabyte physical storage space, consuming less than 10 sq. ft. of data center space. For the same 3.6 Exabytes of PHI storage in a conventional data center would require 2,000 bays occupying 10,000 sq. ft. of bay area, and cost over $223 million for hard drives alone, *not to mention much larger UPS systems, backup generators, air conditioning, shielding, building construction and other capital and operating costs*.

The **JASON Report** raises questions about how storage cost reduction can be someday achieved. MSP can demonstrate it in less than 12 month as part of a $6M T-HRB feasibility project, which we invite the government to fund.

The 21st Century Cures report asserts, "that Biomedical research and innovation, particularly at the molecular level, is happening at lightning speed alongside of, and supported by, equally breathtaking advancements in digital and personalized medicine, including the use of sensors, genomics, health information, and other technologies. Congress must proactively ensure that our nation's laws and regulations keep pace. We want to solicit ideas on how Congress can effectively and responsibly do so, and thus, as detailed below, seek input, answers, and feedback on the discovery, development, and delivery cycle."

It goes on to ask, "While global research and discovery is a positive development, the U.S. must maintain its leadership role. How can we make sure that is the case? How much of the contributions should come from public and private sources? How can public-private partnerships further the discovery process?"

Remember, an individual's genome data can require up to 1 terabyte of data per sample, when stored in a conventional database. A person might have two or more instances of such data (one from normal tissue areas, and one from cancerous tissue areas). Triad would store only the anomalies in the cancerous sample of the genome, saving enormous storage space, because Triad would have a smaller storage footprint for the normal genome sample. Instead of consuming $99 for a 2-terabyte drive for one patient, suppose that 100 patient's data could be stored in the same 2-terabyte space in Triad format. What would that mean to Cancer Research Institute budgets? How would Triad advance analysis of protein synthesis in cancer research, if the cost of storing and analyzing the raw data were dramatically reduced?

The nation's healthcare infrastructure costs can be reduced forever by choosing a Triad Dataspace data storage solution today – because healthcare data has to be stored for decades or more!

The 21st Century Cures paper states, "Communication about how certain treatments are working in certain patients is happening through a multitude of media around the globe. These conversations between and among doctors, patients, researchers, and scientists in academia and industry should be facilitated. This includes the free flow of data, research, and results related to what a therapy or combination of therapies does or does not do well and in what types of patients. We need to harness the power of the Internet and social networks."

The most effective way to learn what works is to create an information infrastructure that allows what works to be measured! Triad is such an infrastructure because it organizes information by patient and patient group anomalies, across hundreds and thousands of data anomalies, just as it did for the needle in the haystack. And Triad does it in near-real time where the information can still be useful in affecting a beneficial outcome. See point 6 below.

Sixth, *Triad calculates correction vectors in near-real time for an individual patient parameters compared to the closest matching cluster of patients that had a beneficial (or the desired) outcome* – creating an "assured-quality"™ process. Assured-quality is the heart of MSP's T-HRB Population Health Management business strategy, *which differentiates it from all DBMS-based system solutions*. DBMS quality assurance solutions are generally limited to *after-the-fact statistical quality assurance calculations*.

MSP believes Triad's ability to perform assured-quality corrections/interventions could save lives and improve healthcare delivery, if widely adopted.

DATA ANALYTICS FOR POPULATION HEALTH MANAGEMENT AND ASSURED QUALITY PROCESSES

Triad *improves and expedites data analytics and quality measure (or fraud) searches for Population Health Management in population-level data masses – by making the search space more manageable and the execution of queries much faster*.

Query processing is the heart and soul of data analytics. Analytics *postulates a combination of features that MAY be causative of some outcome (desired or undesired) and then queries the entire data mass* to determine correlation coefficients. This submission has previously explained why Triad processes queries in near-real time, independent of data mass. The major benefit when performing data analytics, predictive analysis and population health management of patients who have chronic healthcare conditions is that with *Triad Dataspace there is now a technology that can support assured-quality processes,[4] such as EBM.*

EBM depends upon getting data while it can still be applied to the healthcare delivery process in time to affect a more beneficial outcome for the patient being treated.

Seventh, ***Triad transforms problem statements of certain types of (NP) hard problems****, to a form in which they can actually be solved in practical time frames.*[5] The solution of NP hard problems in healthcare relates to microbiology, genomics data representation, pharmaceutical and molecular bonding representation and natural language processing used to structure freeform text so it will become queryable.

The 21st Century Cures document states, "Finally, recent analyses have shown that the cost of developing a new drug now exceeds $1 billion—double the costs in the early 1980s—and that it takes upwards of 15 years from initial molecular targeting to bring a drug to market. Are the economic incentives and policies currently in place sufficient to encourage robust investment and promote innovation? How can we make sure that biomedical research and product development continues and attracts venture capital?"

MSP simply states that Triad allows the approach to these problems to be restated in a manner that renders some solvable in practical time periods without the use of quantum, super or massively-parallel computers. MSP has a White Paper on how Triad can reduce drug development costs and bring new capabilities to model microbiology, and clinical pathways.

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[4] An assured quality process is one that if followed to its conclusion will minimize the impact of change or random process in achieving the outcome of the process. Assured-quality is much closer to the original thoughts expressed by Demming, than today's DBMS after-the-fact, statistical quality assurance detection, which can never positively impact the care of the patients that the data was collected from.

[5] Triad achieves solutions where multi-typed DBMS representations become combinatorially-explosive; because Triad limits the growth of the data combinations (solution space), by identifying and excluding entire subset of the potential solution space where the solution cannot exist. This reduces the number of choices (size of the solution space) from (2^{n-1}) choices (when using database representations) to ($2^{n-1}/2^n$) choices when using a Triad Dataspace representation. It is a huge breakthrough and effective gain in computing power.

MSP Recommendations to Congress

In Summary, these seven properties of a Triad Dataspace revealed here are generally unknown by commercial database vendors, who don't believe such solutions are possible (which is one reason why they haven't discovered them).

The 21st Century Cures White Paper asks, "How can we harness our nation's desire, human capital, and technological know-how to get to the bottom of what may cause Alzheimer's and other deadly diseases or conditions? How can we incentivize, coordinate, and accelerate research for diseases or conditions we know relatively little about? … Over the past several years, that number decreased to 15. In 2010, more biotechnology companies were formed in China than in the U.S."

The answer is by storing the structure of the information in a way that links it with what is already known and organized so all contributors that learn things can integrate their new "facts" into a single, aggregated and fused information structure that a wide variety of researchers can easily query against it. This is exactly what databases don't do, and what Triad Dataspace excels at.

There is no logical or rational basis for thinking that a DBMS representation solution applied since the 1970's that have failed repeatedly, will suddenly work because it receives more funding. Until ALL technologies are considered, the ONC needs to ramp down telling commercial entities what to build and help them by discovering better ways to express what is already known.

Regulatory over-reach is the single most significant factor in why the U.S. is falling behind other nations in basic research and understanding of disease, and why it is lagging in new commercial ventures that explore creative ideas that are dismissed by larger organizations.

Given the lack of awareness of Second Information Age technologies, and the ONC's previous driving of the entire healthcare industry along the lines of propagating DBMS solutions, *continuing down this same path will be extremely short-sighted, expensive and unproductive.* It will actually stifle and undermine the progress that the 21st Century Cures initiatives seek to achieve.

MSP agrees with **JASON Report's** Recommendation 2.1 and feel that all **four goals** (1) interoperability, 2) patient privacy protection, 3) access for clinical care, and 4) access for research/academic purposes) - *can be most cost-effectively and rapidly achieved by using Triad Dataspace technology;*

A Strategy to Advance Data Fusion and Interoperability

In regard to Recommendation 2.2 (Page 7), *MSP believes that **JASON** and **PCAST** committees and the industry need to rethink interoperability, rather than focusing on achieving Meaningful Use (MU) – because achieving MU depends on advancing the level of interoperability. We have the cart before the horse here!*

Using a Second Information Age approach (Triad Dataspace), we can advance the level of interoperability significantly, based upon universal representation, simple aggregation and fusion of the data mass based on chronology of the patient encounter.

Triad brings with it the ability to collect data from all legacy systems, *based upon whatever schema (information model) the legacy systems have used to collect it – by using ODBC/JDBC industry standards*. Triad –

in combination with a *composite clinical data dictionary* (C2D2), SNOMED III and MEDCIN, provide the *ability to handle language, unit of measure systems and ontological equivalence issues to create a single fused, correctly structured data mass that is queryable in near-real time.* Triad initially moves healthcare forward to achieving semiotic interoperability.[6] Achieving semiotic interoperability *without* interface engines (employed by DBMS solutions) is a *major step forward*.

The final step to semantic interoperability is on the horizon when Natural Language Processing (NLP) is advanced by embracing Triad Dataspace representation. That could be within the first 5 years of switching from DBMS to Triad Dataspace representation.

ACHIEVING SEMIOTIC INTEROPERABILITY NOW

Semiotic interoperability can be achieved by deploying a Triad Datalinker (software application) running at a legacy system site. It forwards healthcare data gleaned from the local, legacy DBMS system to *one* T-HRB as a real-time, offsite backup data stream. At the T-HRB this legacy data stream is converted into ONE, universal, secure (double-blind encrypted) data structure that (assuming proper permissions) can aggregate and fuse ALL information from all legacy sources into ONE queryable data mass – providing the *ability to connect anything to anything - with some caveats (see below):*

Caveat 1 - *Data interoperability will not eliminate data truncation incompatibilities* where the DBMS receiving the data *has not allocated in its schema a sufficient field length to contain the information being sent to it*. With regard to target DBMS field size, data *truncation (due to fields defined to be too small to contain structured or numeric data) should be viewed as a DESIGN FLAW of the specific system; not as an interoperability failure*.

This problem is not a *limitation of interoperability* for the use of Triad Dataspace as intermediary universal representation of information is derived from the data itself and Triad will ALWAYS allocate enough storage space to accommodate data without sacrificing data precision)[7]. MSP's *composite clinical data dictionary (C2D2™) technology* solution developed by *Dr. Richard Dick*, MSPs CMIO, (and former study chair for the **Institute of Medicine** committee on Computerized Patient Record systems) fixes that problem, and should be adopted as a national standard, after consensus review of its content.

Caveat 2 - *Data interoperability depends upon a match between the field labels* of the source and target DBMS systems. A field named "Lname" in one **source** database, needs to be correctly associated with a target field of say "last-name" or "last_name" in a **target** database. This problem however is simply *overcome by using a composite clinical data dictionary (C2D2™) technology*. The filled-out/populated (patent-pending) C2D2™ could be published as a set of interoperability standard nomenclature labels, clinical data ranges, with their precisions, and then adopted as a new addition to SNOMED-III and MEDCIN ontologies and nomenclatures. C2D2 provides a guideline for existing legacy application developers to update their data schemas based on C2D2 references.[8] It would also greatly simplify interoperability label harmonization, *eliminating the need for*

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[6] C. Laroque, J. Himmelspach, R. Pasupathy, O. Rose, and A.M. Uhrmacher, eds, Proceedings of the 2012 Winter Simulation Conference SEMIOTICS, ENTROPY, AND INTEROPERABILITY OF SIMULATION SYSTEMS – MATHEMATICAL FOUNDATIONS OF M&S STANDARDIZATION; ... Semiotics identifies which symbols are used (syntax), what the meaning of these symbols is (semantics), and what the intention of symbols is (pragmatics). These ideas have already been mapped to integratability of networks, interoperability of simulations, and composability of models for modeling and simulation applications. New research on model theory and algorithmic information theory support this viewpoint. Applying the finding of mathematics allows to define three different entropies: syntactical entropy that measures the variety of data **representation**, semantic entropy that measures the variety of data **interpretation**, and pragmatic entropy that measures the variety of data **utilization**.

[7] Triad builds its own schema on the fly, so the "size" and "resolution" of the data element is not predefined by Triad and therefore not a limitation as it would be in a database, where the field size would have to be declared in advance.

[8] Once this one-time update was completed, for the majority of clinical interoperability, labels would not have to be matched, because they would be those used in the C2D2 label dictionary, which would include OS-specific alternatives, such as the need for "_" in place of " " or "-" in some database products.

interface engines when legacy DBMS systems are interfaced to Triad Dataspace, or *to each other through a Triad Dataspace bridge repository*.

Caveat 3 – The *boundaries of the chronology (time period) of "an encounter's" parameters need to be clearly defined so that the record boundaries being aggregated and fused can be properly discerned.* That is, if a lab result and blood sample were ordered and drawn during a 15 minute exam encounter, their timestamp is the *time they were drawn during the encounter*, not the time the results become available. The same is true for all other diagnostic tests, the *data is reported at the time it was initiated/drawn, not at the time the results later become available*. Data obtained BEFORE or AFTER this encounter, form other encounters.

Caveat 4 – All atomic components for a medical record entry, have to be present and accounted for. In the case of a drug order, that would include: {the drug label/name, its dose, its package, its language, its administration route and its dosing interval}. Three of these would be provided by the RxNorm ID code, to which language, dosing interval, and administration route would be added to make one COMPLETE drug entry.

A C2D2 allows checking (in this case) if ALL six necessary components exist and have been entered. If not, it would alert the user (in near real time) about whatever parameter was missing-in-action. Defaults on specific entries (like language) can also be set by users, such as ENGLISH or SPANISH.

The same is true for a "Complete Blood Test" (CBT) entry, where C2D2™ would check to see that all required separate tests (RBC, WBC, Platelets and so on) that comprise a CBT were present. More importantly, C2D2 alerts Triad to the incoming data type of each component, so that a quantizer appropriate to each datatype is assigned and ready to quantize the results when they become available.

So long as there is compliance with these 4 caveats, semiotic interoperability can easily be achieved. That enhances interoperability and puts us ONE step away from achieving semantic interoperability - without expensive interface engines.

Given these four (4) caveats, *there is no reason all structured healthcare data could not become interoperable within 12-18 months (the time it takes for existing EHR vendors to incorporate C2D2 into their products).* Compliance with C2D2 could be added as an EHR certification criteria for EHRs seeking ONC approval for MU Stage 3.

Data Integrity Empowered by Anomaly-Triggered Events

Unlike DBMS solutions, a *Triad Dataspace normally organizes data by anomaly and each anomaly can act as a trigger or alert event.* Here are three healthcare examples:

Example 1: *A drug order appears in which there is a* ***mismatch between the drug name and its RxNorm ID***,[9] (due to a bad EHR design or a human error). If the EHR record shows that Plavix was ordered, but the RxNorm code indicates the generic equivalent (Clopidogrel) – there's an inconsistency. The first time it is encountered, it is detected - because all previous (correct) records would have the Plavix ID associated with the Plavix drug label, not the generic ID. When the Plavix label first occurs with the Clopidogrel RxNorm ID, an alert could be triggered and a human operator resolves the inconsistency.

[9] RxNorm, a standardized nomenclature for clinical drugs, is produced by the National Library of Medicine. In this context, a clinical drug is a pharmaceutical product given to (or taken by) a patient with therapeutic or diagnostic content. In RX norm, the name of the clinical drug combines its ingredients, strength, and form.

This inconsistently was automatically detectable because previous correct-records had no anomalies. As Triad encounters the data, the data itself causes *the anomaly, not a fixed schema, nor procedural code embedded in some DBMS product. Triad announces the anomaly it has detected and states the condition that spawned it, seeking the correction before proceeding. That "message" is sent back through the Data Linker (located in the physician office or other point of care) in near-real time to the point of care,* not days later as part of a billing coding session.

Example: Suppose that instead of a dose label ID error, *there is a **drug dose error** (anomaly)*. This should never happen if the EHR schema was properly designed, *because once the drug name should lookup and present only valid dose and packing options based on the RxNorm ID.* If an EHR does NOT reference RxNorm (an industry standard) and allows entry of these elements separately, such errors will be common. To help to assure data integrity and consistency in Triad Dataspace's population-level data repositories (which is important for epidemiological and research query purposes, and to assure semiotic interoperability, proper data aggregation and fusion) such errors must be caught.

Triad catches inconsistencies or errors because they appear as anomalies to previous data correctly entered, and Triad announces anomalies. DBMS products have to be programmed to do that, which means in DBMS products all possible errors have to be anticipated in advance, and procedural code written to handle each case.

Example 3: Suppose that one **dosing interval for the same drug was entered differently** by two EHRs but are logically-equivalent. One EHR has "Take daily," and another EHR "Take Q24". As part of the installation of the Data Linker – the component of Triad that is installed at the provider-site, EVERY field type defined in the DBMS schema is examined, and an appropriate quantizer is assigned to each field, so that the valid entries are properly quantized into a topologically-consistent, normalized representation that Triad uses. As these various examples illustrate, *storage-by-anomaly in Triad Dataspace is a great advantage over the storage-by-similarity in conventional DBMS products.* It is also a key in discovery of fraud patterns in data masses.

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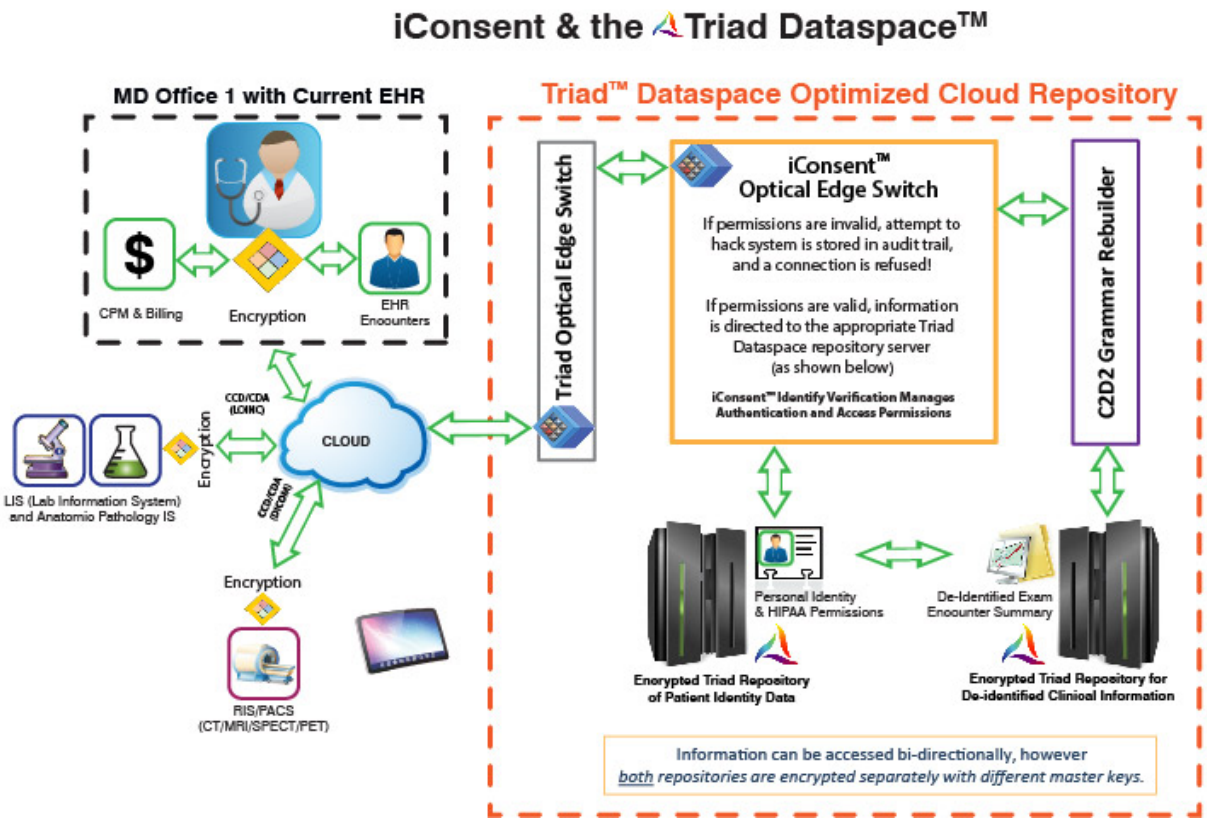
*MSP therefore recommends the adoption of the storage-by-anomaly approach for all information storage structure as a national standard by the ONC. It will empower the discovery of fraud and other discrepancies, WITHOUT the need for separate cadres of rules. This is consistent with **JASON Report** Recommendations 2.2, 5 and 7.*

Universal Triad Dataspace Backup to Fuse and Aggregate Information

The government could achieve much by funding a universal BACKUP of EHR and diagnostic databased-systems using Triad Dataspace as the repository. It would simplify API validations because the issues related to multiple data types, "big Indian, little Indian," and other DBMS data type-related issues would be harmonized with only ONE system. The Triad Dataspace Health Record Bank (T-HRB) view as seen by one user (an MD Office), is shown below.



The Datalinker (Yellow Diamond) interface to Triad Dataspace T-HRB would only have to be changed when a new software release actually changed the SCHEMA of a source/legacy EHR that was contributing data to the backup repository. If there is no schema change, the existing interface continues to function properly.

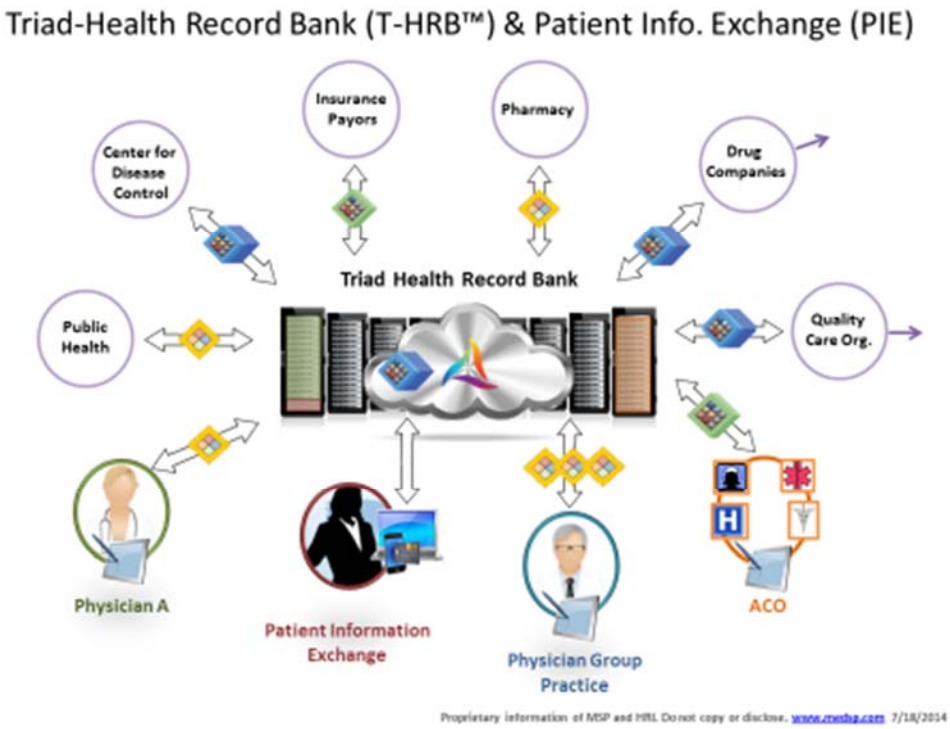
If a new field were added to the EHR schema, the Data Linker would assign the appropriate quantizer to that field, so that its data could be forwarded to the T-HRB. If an existing field's data type were changed, it would be a new quantizer appropriate to its new data type. This could all be managed as part of the already-in-place EHR certification program the ONC has already established, and happen before the EHR change/update went live.

From the perspective of continuous, near-real time BACKUP, all data from all users is stored in a topologically-normalized representation in Triad Dataspace. That is how all users at the source locations "see" data, no matter what format it was originally provided in. They don't necessarily see any of the other users who are also utilizing the T-HRB for whatever purposes – research, analytics, disease registry, public health and so on.

Triad obtains all parameter-based data through the installed Datalinker's ODBC interface[10] (which is available for every DBMS system) should dramatically reduce "*code-a-thon connectivity issues*," and greatly expedite the real, secure and reliable exchange of information between any legacy systems connected to a T-HRB off-site, secured, backup repository, which forms a data migration pathway and mechanism between them. However, the overview (next figure) shows the entire T-HRB and the variety of clients it is supporting concurrently. Each group of clients can be engaged in more than one business model. For example, a physician may be using the T-HRB for offsite data backup (offered by MSP), but may also be participating in a

[10] Call Level Interface (CLI)) drivers supported by virtually all commercially-available legacy database systems, to capture the data schema, and the data stored in commercial databases, as it is being posted. ODBC supports all major databases – Oracle, Microsoft SQL Server, DB2, Salesforce.com, Sybase, Greenlpum, PostgreSQL, MySQL, Informix, Apache Hive, Hortonworks, MongoDB, Alpha 5, Filemaker Pro Web and many others. It supports all Windows, UNIX, Linux and more computing platforms, and supports both 32-bit and 64-bit operating environments. – Wikipedia.

local ACO group with whatever their business model is. The T-HRB simply keeps track of data storage, data accessed, and the billing associated with that, and invoices each user for the services they consume under each of the business models T-HRB is supporting.



The Triad Dataspace approach addresses interoperability that actually leverages existing industry-standard, database API (ODBC) drivers that already exist and are already supported by all DBMS manufacturers. Use of higher level standards like HL7-RIM and CCDA, RxNORM, LOINC and others would be helpful in accelerating the implementation. For the most part they already exist. To achieve this, a Triad Dataspace only needs to know 1) the observed magnitude, 2) data precision required (looked up from C2D2), 3) the parameter name (established when the quantizer is assigned to the data field), 4) its clinical limits range (looked up from C2D2), 5) its units of measure (degrees C, F, mm/Hg, mm/H20, and so on) and 5) its language (which like airline transmissions, in the U.S. at least), could be standardized on English.

Non-Disruptive Implementation Strategy

A comment on Implementation strategy: If a T-HRB was a national standard for PHI data BACKUP only, each EHR would do streaming BACKUP to a T-HRB at a very low cost, say $1-2/day/MD for ALL their patient records and there would be no disruption to any legacy EHRs installed; which would simply continue to operate as they normally do. Triad deployment would NOT be disruptive to the commercial market operations or individual EHR vendor's business models, market shares, or competitiveness. It would be a vendor-neutral, market-neutral insertion to enable consolidated backup system, as depicted below.

At the BACKUP T-HRBs the data from all of these EHRs would be totally normalized, aggregated and fused, and access to it would be controlled by the patient's HIPAA permissions granted at little or no expense to the EHR vendor.[11] Research, public health, disease registries, etc. could be submitted against the BACKUP T-HRB

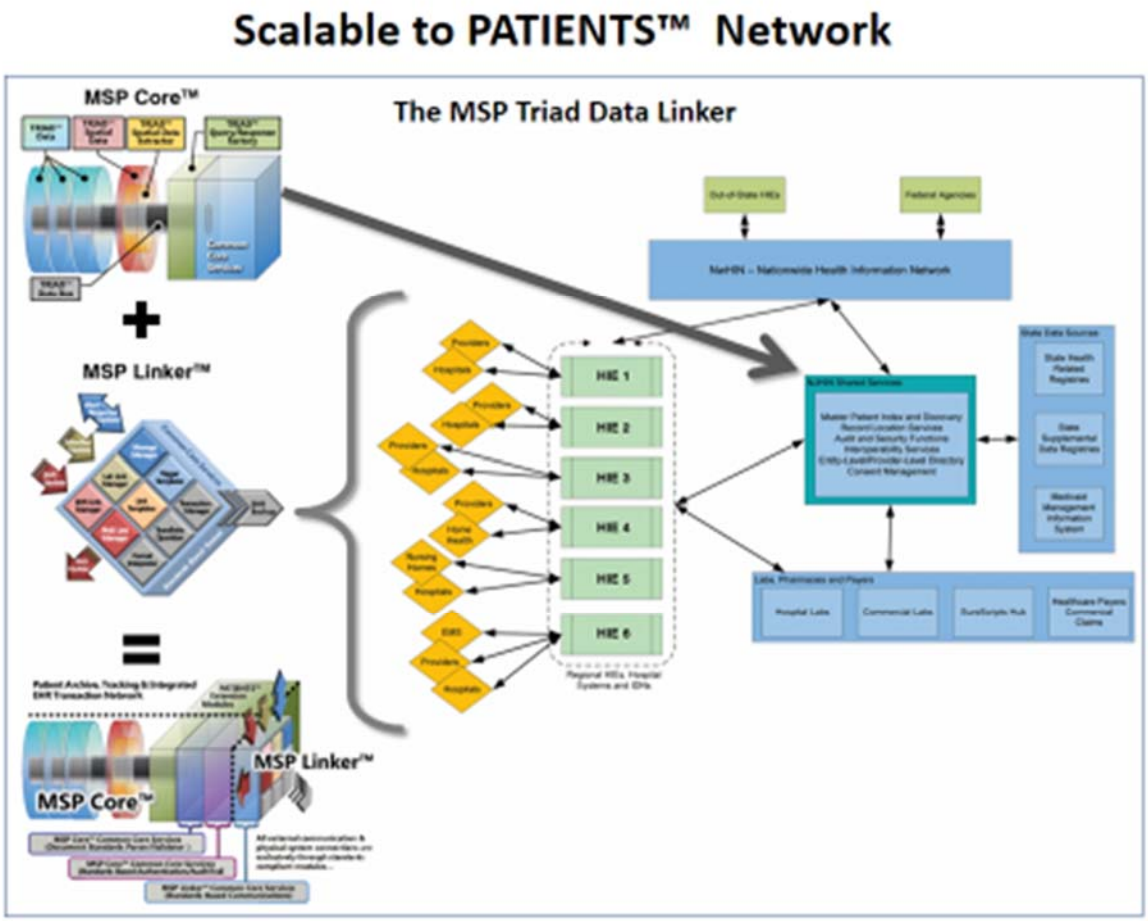
[11] In fact, under the MSP, HAPPI and other business model, it might become a revenue generator to the practice, rather than a cost.

repository (which is a near-real time MIRROR of each provider's EHR content, but expressed in a secure, standardized, normalized, permission-controlled, rapidly queryable format).

This Triad Dataspace BACKUP approach would achieve: 1) all national objectives, 2) return control of data use for research and other purposes to the patient, 3) improve fraud detection, 4) reduce breaches, 5) and not distort market competition among EHR vendor products – a situation in which every one of the diverse healthcare stakeholders WINS! Triad Dataspaces empower just such a national strategy – because it works IN PARALLEL with existing legacy systems and applications, and bring properties that no DBMS storage repository has.

HRB Data Architecture Considerations

MSP retains all intellectual property rights to Triad and manages its evolution in accordance with a consensus of guidance by its licensee community user base. The existence of a standard API to access Triad Dataspace analytics and a BYOG (Bring Your Own GUI) approach to application development, will allow each individual Triad Licensee to control their application development and business model independently, using the Health Record Bank implementation of Triad. The **JASON Report** recommends against one, large, central repository. We concur, but since individual T-HRBs would all share the same data representation, they can each be mirrored in near-real time to a central T-HRB used as a backup repository, where all information would be aggregated and fused, to support query that are national, or population-level in scope. Triad HRBs located in different geographies, and can communicate with each other over a PATIENTS network, each storing data in Triad representation.



Two Triad properties are important here. First, because the native Triad representation is a double blind encryption, mirroring across dedicated fiber on the Internet makes even large transmissions unhackable. Second, since there is only one universal representation, aggregation and fusion among records sent from one Triad T-HRB to another, allows them to synchronize, making it possible for any T-HRB to be visualized as the master backup and all of the others to be sources to be synchronized. This would be particularly as a fail-soft and mitigation mechanism during incidents of regional or national significance.

Regarding Open Standards, **JASON Report** recommendation 4 (Page 6), MSP agrees that ODBC is an open standard, *and is willing for C2D2 to become an open standard, by publishing it and creating a mechanism for consensus updating of its content as new parameters are defined.* MSP also commits to use existing standards that are applicable, such as: like **RxNorm** (for drugs) and **LOINC** codes (for lab results), and so on. MSP could also leverage Connect **DIRECT** as a mechanism of sending content from a source site to the T-HRB that is backwards-compatible with existing systems and its level of security is considered by the client to be sufficient. Note **DIRECT provider-to-provider query** (that does not route and process through a T-HRB), will be supported in Triad Data Linkers, but will retain all of the interoperability issues that today plague DBMS-based EHR solutions.

Research Community, CDC and Public Health Recommendations

Research Applications, Recommendation 7 (page 6) are clearly paramount. *Triad enhances the state-of-the-art in support de-identified and identified use of population level data for research purposes, while maintaining strict patient control of data and privacy* – for the following reasons:

- *Triad harmonizes ALL types of medical data, including images, arrays, numeric, textual, etc. into one, fused, secure, searchable data mass – making them available for research.*

  Implication - We no longer need one repository for vendor-agnostic images, another for genomics and pharmacology, another for freeform text, and another for structured text and numeric information. All of these currently different repositories, collapse map into a single Triad Dataspace! This is a huge cost saver, and greatly simplified legacy system interface and semiotic integration. *DBMS solutions don't offer this today and may be years or decades away from the solutions now offered by Triad Dataspace*.

- *Outcomes analysis can span data from various different legacy systems.*

  Implication - If the diagnostic images are in the same queryable (in near-real time) structure that contains the therapies administered and the outcomes achieved, then practical evidence-based medicine based on assured-quality™ processes has arrived. *DBMS solutions don't offer lookup by image pixel pattern.*

- *Triad inherently works at the item-level, including the enforcement (and tracking of) privacy at the item level. Privacy protection in Triad uses a soon-to-be-patented, iConsent™ approach, that integrates the access permissions into the data mass itself* in such a way that those searching it, who lack adequate permissions, are not even aware that the data exists, and can never reach it. *Databases don't even offer a searchable, encrypted datatype*.

  Implication - *Since patient choices ultimately determine permission attributes, the control of the use of PHI data is finally returned to the patient.*

- Depending upon patient permission, *search of identified data can be granted to researchers, and search of de-identified, population-level data mass is available to academic and private researchers, disease registries, public health agencies and other users.*

  Implication - Therefore, Triad complies with **JASON Report** recommendations on making data widely available for research purposes.

- *Finally, Triad keeps track of (creates an audit trail for) every access to data, documenting who is using the data and for what purposes.* It cannot be circumvented. It can be printed or displayed to the data owner on request. *Conventional database vendors' claim item-level audit trails could not be accomplished with databases. They may be correct.*

  Implication – Triad Dataspace is the first practical commercial system that complies with DHHS item-level audit trail recommendations..

Social Responsibility

MSP is a socially-responsible, for-profit company whose shareholders seek to *empower and serve other healthcare vendors*, and are *committed to the licensing of Triad Dataspace as widely as possible to all interested parties*, so long as MSP maintains control of the SCIFs where it is implemented to protect the intellectual property involved. Maximization of profit is not our driving incentive, but growing and remaining profitable is. The commercialization strategy explained above, achieves many national healthcare objectives, benefits all stakeholders, reduces costs, reduces fraud, and improves security. It will save lives and improve the overall quality of healthcare. MSP can become a key healthcare resource in the same way as IBM is using Watson. Third parties don't control Watson, IBM does. But third parties can leverage Watson freely. MSP offers the same business model.

Triad would be seen as a "black box" technology accessed by a standard API that allows any user to perform certain operations against all (or a subset of) data in the T-HRB repository that the user has patient-granted permissions to access.

This approach is also in the military interests of the United States that Triad Dataspace technology remain protected because of the national interest uses of the technology. *The proposed commercial licensing approach allows every company, and the nation as a whole to benefit from the use of Triad Dataspace technology implemented as a middleware service in T-HRB, while not fully disclosing the technology and thus maintaining its national interest utility.*

In Summary

We have only scratched the surface in this Legislative Primer on how Triad Dataspace technology applies to the challenges posed by the **21st Century Cures** Initiatives White Paper and overcomes the problems catalogued by the **JASON** and **Healthcare PCAST** reports previously published. There is much more, and many benefits undisclosed and not discussed here due to space limitations.

Movement to support Triad Dataspace as a universal representation is the least risky and most effective decisions to move U.S. healthcare forward as it did in the domain for which it was originally designed.

We invite staff and members of Congress to inform themselves on Triad Dataspace, the advance in healthcare information data representation that will finally solve healthcare technology problems in the U.S. It needs to

be carefully applied so as not to undermine it continued national interest applications or advantage potential U.S. adversaries however.

July 21, 2014

The Honorable Fred Upton, Chairman
U.S. House of Representatives
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Upton:

On behalf of the 30 million men, women, and children affected by one of the nearly 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks Chairman Upton and the Energy & Commerce Committee for your continuing support of the rare disease community. We are excited to participate in the 21st Century Cures Initiative.

We welcome the opportunity to comment on the 21st Century Cures Initiative's fourth white paper titled, "Leveraging Technology to Advance the Discovery, Development, and Delivery of Better Treatments and Cures." This white paper requests feedback on how we can leverage existing and developing technologies to accelerate the pace of treatment discovery, development, and delivery.

To address these questions, we have developed the following proposals. We look forward to discussing these ideas with the Energy & Commerce Committee as the 21st Century Cures Initiative continues.

1. Assemble a Task Force on the Standardization of Health Data Collected Outside the Clinic

As the Energy and Commerce Committee recognizes in its white paper, new technological advances are allowing for the collection of patient data at an unprecedented rate. Data collected through wearables, mobile medical applications, health management applications, and other monitoring devices and consumer-focused digital health products are proving invaluable to healthcare professionals in treating patients. This is especially true for rare disease patients. The data collected could also prove valuable if placed in patient registries and natural history studies for research or drug development purposes.

This data may be wasted if it is not collected and stored in a standardized format, thus rendering the data impossible to analyze. Further, a patient's data must be accessible to the patient and the patient's healthcare providers, thus allowing it to be used in shared-decision making.

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To facilitate the standardization and interoperability of patient-reported data, NORD recommends that Congress assemble a task force to study the perspectives and positions of consumer-focused health product innovators (such as application developers or consumer device makers), electronic health record developers, practicing physicians, experts in achieving interoperability, and related federal agencies. This task force should provide recommendations for the standardization of non-clinically sourced data.

2. Ensure the Privacy of Data within all Innovative Patient Data Collection Technology

With the advent of innovative patient data collection technology, the legal and regulatory framework must be updated to ensure patient privacy. The data collected by wearables, mobile medical and health management applications, and other consumer-focused products often includes individually identifiable health information.

To safeguard patient privacy, Congress must ensure these innovative collection technologies adhere to the same privacy standards that established health data collection technologies adhere to. This may require updating the current statutory language to reflect the rapid advancement in health data capturing technology.

3. Modernize the Reimbursement and Licensure Regulations for Telemedicine

Much like the collection of health data, the delivery of health care is rapidly changing due to technological innovation. One innovative delivery model that shows particular promise for the rare disease community is telemedicine. As a member of the Advisory Board of the Alliance for Connected Care, NORD recognizes the importance of being able to access one's physician outside of the hospital or doctor's office.

Telemedicine is especially important to the rare disease community, as many rare disease patients must travel far to see physicians who specialize in their disease or disease area. This distance is often prohibitive in accessing treatment, and can create insurance reimbursement issues as well. In addition, many patients with rare diseases have severe physical disabilities, thus making even a limited amount of travel difficult. Telemedicine allows rare disease patients to receive consultation from their physician in the comfort of their own home, thus greatly improving access to care and to the quality of life of the rare disease patient.

There are many regulatory hurdles physicians must overcome if they are to use telemedicine. First, physicians face steep reimbursement challenges when practicing telemedicine, especially within the Medicare and Medicaid programs, as telemedicine is often only reimbursed for beneficiaries who are living in very rural areas. Public and private health insurance models are also not adequately reimbursing for the physician's consultative services, which makes up the vast majority of telemedicine services.

Second, there is a lack of a standard definition of telemedicine, thus creating different standards across health care practices and insurance plans. This exacerbates access and reimbursement issues, creating vast inequalities in accessing telemedicine across the nation.

Finally, in order to facilitate a greater use of telemedicine, the current medical licensure system must be reformed. Currently, State Medical Boards are responsible for setting licensing standards in each state, thus creating broad variation in application processes, fees, processing times, and requirements. Most states require a physician to be licensed within the state to practice telemedicine there. Thus, physicians who wish to practice telemedicine are required to obtain a medical license in each state where they have patients.

Together, these hurdles make practicing telemedicine extremely difficult, thus greatly limiting access to physicians who may not be geographically close to the rare disease patient. To overcome these hurdles, NORD requests that Congress address the current reimbursement and licensing regulations to facilitate a greater use of telemedicine. For example, Congress could lift geographic restrictions for practicing telemedicine under Medicare and Medicaid, and ensure reimbursement for telemedicine under the Medicare and Medicaid programs.

Thank you again for the opportunity to engage in this exciting and much-needed initiative. We look forward to working with Chairman Upton and the Energy & Commerce Committee as the 21st Century Cures Initiative continues, and we are grateful for the Chairman's recognition of these extremely important issues within the rare disease community.

For questions regarding NORD or the above comments, please contact Diane Dorman, Vice President of Public Policy, at [redacted]

Sincerely,

[redacted]

Peter L. Saltonstall
NORD President and CEO

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Executive Vice President

July 21, 2014

The Honorable Fred Upton Chairman
The Honorable Diana DeGette Ranking Member
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Congresswoman DeGette:

The Pennsylvania Medical Society (PAMED) appreciates the opportunity to comment on the white paper and congratulates you both for your visionary leadership in developing the 21st Century Cures Initiative. PAMED thanks the Committee for providing the opportunity to submit comments regarding the Digital Health Care initiative.

Founded in 1848, the Pennsylvania Medical Society represents 20,000 physicians and medical students in the Commonwealth of Pennsylvania. With an active and dedicated membership, PAMED's mission is to be the voice of Pennsylvania's physicians, to advance quality patient care and the ethical practice of medicine, and advocate for the patients they serve. We promote physician leadership, education, professional satisfaction, practice sustainability, and the public's health. One of our organizational objectives is to develop and advocate for policies and programs that promote the appropriate, patient-centered, physician-led, team-based care as determined by patient need and available resources and position physicians as the ultimate champions of safety, quality and value in patient care. As such, this objective directly aligns with the Committee's efforts around the 21st Century Cures Digital Health Care initiative.

Currently, Pennsylvania is exploring ways to address the various barriers to the practice of telemedicine in the state. PAMED is working with the Pennsylvania Department of Health and other stakeholders to see how the commonwealth can address these and other obstacles facing telemedicine providers. These discussions have included issues such as the requirements for in-person patient contact, professional liability insurance, the cost for telemedicine equipment, and the payment for telemedicine services.

PAMED believes in the importance of the patient-physician relationship. Establishing this relationship provides a foundation of trust, which facilitates the ease in which information is exchanged to improve the quality of care delivered and the overall health of the patient. Therefore, as indicated in the American Medical Association (AMA) policy regarding the coverage and payment for telemedicine, a valid patient-physician relationship must be established before the provision of services.

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Additionally, the regulation of the practice of medicine in each state is essential to the success of telemedicine. Physicians and others practicing telemedicine must retain responsibility for patient safety and the quality of services provided to their patients. Proper regulations that ensure that the patient will receive the same level of patient safety and high-quality healthcare received in an in-person encounter with a physician is key. State Boards of Medicine are charged with regulating the practice of medicine and protecting the health and safety of the citizens in their respective states. As stated in the AMA policy statement, physicians delivering telemedicine services should be required to adhere to state licensure laws and state medical practice laws in the state in which the patient receives services. Physicians should also be required to be licensed in the state where the patient receives services.

Telemedicine will play an essential role in the delivery of healthcare in Pennsylvania and other states. The technology has the potential to improve issues related to the distribution of providers within the state and, most importantly, access to healthcare. Thank you for championing this important effort. The 21st Century Cures initiative will take important steps to answering many of the questions needed to allow states to move forward in their development of policies to support the framework for telemedicine.

Sincerely,

[redacted]

Bruce A. MacLeod, MD FACEP
President

cc: Honorable Joe Pitts
American Medical Association

Comments on the 21st Century Cures: Digital Health Care

July 22, 2014

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide input to the House Energy and Commerce Committee in response to the white paper entitled "21st Century Cures – Digital Health Care: Leveraging Technology to Advance the Discovery, Development, and Delivery of Better Treatments and Cures." These recommendations build on broader input provided by PhRMA on the 21st Century Cures initiative. Your initiative is timely and important, and we strongly support the Committee's effort to identify reforms to accelerate the discovery, development, and delivery of medical and healthcare innovations.

PhRMA is a voluntary, non-profit association that represents the country's leading pharmaceutical research and biotechnology companies. PhRMA members are dedicated to developing medicines that allow patients to live longer, healthier, and more productive lives. In 2013 alone, PhRMA's member companies invested an estimated $51.1 billion in the research and development of new medicines.

PhRMA believes that the emerging digital healthcare infrastructure holds significant potential for identifying opportunities to address unmet medical need; speeding development of treatment advances to meet these needs; helping understand and demonstrate the optimal clinical role and value of innovation; and ensuring this understanding effectively translates to better patient care.

As an association representing science-driven biopharmaceutical research companies, PhRMA strongly supports the potential of digital healthcare data. The growing volume of robust electronic healthcare data creates new potential for generation and use of real-world evidence across the healthcare system. To harness this potential, PhRMA recommends reforms to address some of the key barriers and challenges facing broader adoption and use of digital healthcare tools. These reforms include

- Defining clear, sound policies that allow for appropriate access to healthcare data sets for research purposes and maintain strong protection of patient privacy;
- Ensuring that use of electronic health information includes appropriate context when data sets are released and promotes innovation and market competition by maintaining strong protections for commercially sensitive data;
- Improving health information technology interoperability and healthcare data exchange;
- Leveraging real-world evidence to support the research and development process and promote innovation;
- Strengthening standards for appropriate use of real-world evidence and healthcare data in clinical decision-making, including clinical pathways;
- Ensuring that research based on digital healthcare data is effectively and appropriately translated into better patient care by strengthening transparency and standards for data communication by federal research agencies; and
- Modernizing the Food and Drug Administration's (FDA) regulation of healthcare communications.

PhRMA is committed to working with the Committee to pursue these proposals and appreciates the opportunity to discuss them in more detail.

Appropriate Access and Use of Healthcare Data

The potential for emerging digital healthcare data sets to spur biomedical and healthcare innovation will not be realized without clear, appropriate standards and procedures allowing qualified private sector researchers to gain access to data for research purposes. Such standards can and must be situated within a framework that provides strong safeguards for confidentiality of personal health information.

Reforms in this area should include requiring the Centers for Medicare and Medicaid Services (CMS) to establish a clear, balanced policy on and efficient process for release of claims data sets to address valid research questions by qualified researchers in the private sector. The current policy, under which CMS will not release the data directly to commercial entities, creates a significant barrier to data access for qualified researchers in the private sector in general, and in the biomedical research sector in particular. The policy also inhibits the conduct of important public health research that is vital to improving healthcare quality and value and supporting medical innovation. Providing biopharmaceutical manufacturers with the same access to data as other external researchers will promote research and analysis that strengthens the Medicare and Medicaid programs and improves the quality of care provided to beneficiaries.

In addition, Congress can support initiatives that facilitate the collection, availability, and dissemination of other public and private healthcare data. Such efforts could include supporting the use of state all-payer databases for research purposes, increasing researchers' access to data collected by the Department of Veterans Affairs and Department of Defense, and establishing a central mechanism for collecting data in a standardized format to evaluate the quality of care provided to enrollees in the health insurance exchanges. We recommend that all researchers, regardless of their commercial or institutional affiliation, have equal and timely access to these data sources. The standard for access should be based on the quality of the proposed research, experience and skill level of the researcher, and the proposal's potential to improve program administration or the health of the covered population.

Data Transparency Policies and Commercially Sensitive Data

As policymakers seek to harness the power of digital healthcare data by making it more transparent, it is essential to ensure that this occurs in ways that provide essential context for data sets when they are released and maintains strong existing protections against release of commercially sensitive data.

Without proper context, the release of large batches of public use data may not achieve the intended purpose of helping patients make better decisions about their health care. We recommend approaches that proactively present the user with sufficient context for using and interpreting the data. One example of this approach is a short web-based training course, which describes key data elements and clearly explains any caveats and limitations of the data, similar

to the data use agreement training required by the Agency for Healthcare Research and Quality (AHRQ) for researchers to obtain Health Care Utilization Project files.[1]

PhRMA also emphasizes the need to protect commercially sensitive drug cost data.[2] Disclosure of these sensitive data would undermine the competitive negotiations between health plans and manufacturers. Negotiations between payers and manufacturers have been a key factor in driving lower drug spending growth and are foundational to the success of the Medicare Part D program.[3] Therefore, we strongly urge that rebate and pricing information be kept strictly confidential.

Improve Health Information Technology (HIT) Interoperability and Healthcare Data Exchange

While increased use of HIT and electronic health records (EHRs) offer great promise, gains in healthcare quality and clinical research will not be fully realized until issues of system interoperability and data quality are addressed.

Significant gaps exist in the use of standards for e-prescribing and related EHR functions that both limit the ability of healthcare providers to monitor patient medications and limit the usefulness of electronic healthcare data for research purposes. Opportunities to exchange clinical data should be leveraged to further the availability of robust clinical data sets to improve patient care and support clinical research.

For example, EHRs must be maintained to reflect currently available clinical evidence. Compendia information in EHRs should be updated at least monthly to ensure that prescribers can write for new treatments and include innovations in care decisions. Clinical decision support (CDS) logic built in to EHRs must be more transparent so that providers can be assured that CDS alerts are based on robust and current scientific evidence that reflects medical innovations and can evaluate that evidence in the context of individual patients. The Committee could support the creation of an independent, multi-stakeholder entity dedicated to ensuring that CDS tools, such as those certified for meaningful use, are transparent, evidenced based, and neutral. Further, participants in federal healthcare programs should be required to utilize established standards and technologies for exchanging information about medications in the course of patient care.

Leveraging standards with the goal of making more timely and complete clinical information available in EHRs will improve care, facilitate the rapid adoption of technological advances, and provide a foundation for advanced use of real-world evidence to inform clinical research.

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[1] HCUP Data Use Agreement Training http://www.hcup-us.ahrq.gov/tech_assist/dua.jsp

[2] As outlined in the confidentiality provisions of the Trade Secrets Act (18 U.S.C. § 1905) and SSA § 1927(b)(3)(D)

[3] For example, federal authorities have been clear that the proprietary nature of drug rebates and other pricing elements negotiated between PBMs and drug manufacturers are a key element in keeping pharmaceutical prices lower than if this information were revealed. Additionally, the Congressional Budget Office (CBO) has opined, "the revelation of [manufacturers'] rebates to PDPs would create pressure to reduce those rebates, which would tend to increase costs for both the Medicare program and, on average, for enrollees." CBO has estimated the impact of such disclosure as costing the program up to $10 billion over a 10 year period. Letter from CBO to Congressman Barton and Congressman McCrery (Mar. 12, 2007).

Use of Real-World Evidence

Appropriate use of real-world evidence, by regulators and other health care stakeholders, is essential to realizing the benefits that evidence can have on the discovery, development, and delivery of innovative treatments. Although FDA has demonstrated its ability to make important decision (usually safety-related) based on real-world evidence, that evidence is generally not used for the evaluation of the benefit a drug. Even new or supplemental indications for a product that has already demonstrated safety and efficacy for another use are most often approved based on additional randomized controlled trials, which require significant time and resources.

We support expanding FDA's ability to make decisions regarding therapeutic benefit based on real-world evidence used as a supplement or potentially as a replacement for randomized controlled trials, as appropriate. This would require modest policy changes to broaden the application of the existing approval framework and could be implemented in a step-wise fashion. Enabling greater use of real-world evidence in the regulatory review process would have significant benefit for patients and other stakeholders in the healthcare ecosystem.

In addition to the use of real-world evidence in the regulatory review process, payers and policymakers are also increasingly looking toward new data sources like real-world evidence to support healthcare decision-making and shape incentives for clinical practice. A lack of standards may result in the misuse of that evidence. To ensure patients continue to have access to innovative treatments and services, Congress should ensure communication and use of real-world evidence in federal health programs is transparent, methodologically sound, and patient centered. To help achieve this, Congress should

- Ensure that real-world evidence and comparative effectiveness research (CER) communicated by public programs be patient-centered, support patient and provider shared decision-making principles, and not impose "one-size-fits-all" treatment recommendations.
- Ensure the establishment of a transparent and open process by which real-world evidence and CER are incorporated into CDS tools to ensure alerts are based on robust and current scientific evidence.
- Ensure that as CMS develops and implements payment and delivery system reforms that rely on real-world evidence, it ensures transparency and openness, empowers physicians, supports patient-centeredness, and ensures patient access to innovative, high-quality care.

Modernize FDA's Regulation of Healthcare Communications.

Patients expect that their medical professionals receive the latest scientifically accurate and data-driven information about the medical treatments they prescribe. However, the FDA's limitations on the ability of biopharmaceutical companies to share data and information about prescription medicines restrict the ability of healthcare professionals to access authoritative and regulated information.

The FDA's regulations regarding companies' ability to share truthful, non-misleading medical and scientific information are outdated. These regulations do not even mention the Internet, much less facilitate or allow robust use of social media in a manner akin to the FDA's own use

of such communication tools.[4] At the same time, FDA's regulations and enforcement policies generally prohibit biopharmaceutical companies from proactively sharing useful information about the medicines that they discover and develop. Moreover, FDA's current draft guidance on how companies may share information using the Internet and social media would be expected to decrease the ability to share scientifically accurate, data-driven information with healthcare professionals and patients.

Biopharmaceutical companies have the most complete and up-to-date information about the medicines that they research, develop and manufacture for use by patients. However, companies are often unable to proactively share valuable information about their medicines, especially for information that is not contained in the FDA-approved prescribing information, with physicians and other healthcare providers.

To get the best possible health outcome for patients, FDA should revise its regulations to allow companies to share truthful, scientifically accurate, and data-driven information with healthcare professionals, including

- Real-world evidence and comparative analyses based on EHRs;
- Claims data and other non-trial data;
- Evidence related to product use in patient subpopulations;
- Pharmacoeconomic information that sheds light on the economic value of medicines; and
- Evidence on medically accepted alternative uses of medicines for indications not included in the product label.

The 21st century medical ecosystem requires that all participants – researchers, practitioners, companies, and payers – engage in robust discussion about the optimal uses of medical treatments.

[4] *See, e.g.*, FDA, "#FDA approves #Cyramza for stomach cancer" *available at* https://twitter.com/FDA_Drug_Info (Apr. 22, 2014).

The Primary Care Information Project (PCIP), a bureau within the New York City Department of Health and Mental Hygiene (NYC DOHMH) works with over 15,000 health care providers through innovative programs designed to support the use of health information technology (HIT) to improve care quality. PCIP is also the home of New York City's designated Regional Extension Center (REC), NYC REACH, and provides extensive training and technical assistance support to providers seeking to achieve meaningful use. PCIP's staff of quality improvement specialists makes over 4,000 visits per year to providers in the REC and other programs, conducts dozens of seminars, webinars, and trainings, and disseminates several newsletters and digests on key topics in health IT and care delivery to over 16,000 individuals. PCIP also works on several innovative projects to access, analyze, and use EHR-derived data to support quality improvement at the provider and practice level as well as to support the efficient and effective deployment of public health programs and resources.

PCIP's position at the nexus of public health and primary care enables us to observe and comment on the barriers and facilitators influencing the transformation of our health care delivery system. Our innovative work on a variety of methods to utilize clinical data to support improvements in health care delivery further facilitates our understanding of how data, particularly big data, can empower patients, providers, and care delivery systems to move towards a learning health system.

Despite major advances in recent years towards electronic data capture and sharing, health data remains trapped in the silos of the health care system. We applaud and echo the committee's statement that "New technology and data can shift our health care system from a reactive one defined largely by its silos into a predictive and integrated care continuum." However, the 'big data' needed to support this shift must integrate across the care continuum, stitching together multiple data sources to create a complete picture of health and medical care. Health information exchanges (HIEs) may hold the key to making this idea into reality by developing the infrastructure needed to link data across the continuum of care. Open-source approaches to distributed health querying may form the next link in the chain, offering a feasible, efficient, and cost-effective way to investigate, analyze, and use available data to drive the systemic shift in the health care system towards a predictive and integrated care continuum. In our comments, we highlight challenges we have observed and suggest factors Congress may be able to influence in order to smooth the progress of technological innovation for better health.

As noted in the white paper, data sharing among electronic health records (EHRs) holds great promise for informing health care delivery. However, current mechanisms for data sharing are not seamless; there are several barriers to the exchange of health information that persist across care settings, Health Information Exchanges, or HIEs, act as a central exchange and data repository through which providers can upload health data for their patients and access information uploaded by other providers. Through use of HIEs, a system for facilitating data sharing has been brought to fruition in a few exemplary cases. However, in many more locations around the country, the HIEs have not yet achieved their full potential. Several factors contribute to this state of affairs, and the result is that despite engaged and active stakeholders, the current landscape is one in which clinical data is not easily or frequently shared. The potential benefits of sharing data and communicating across care delivery locations are well understood; we applaud Congress's efforts to address the barriers standing in the way of data sharing amongst health system actors including providers, payers, and patients. These barriers include

interoperability, the business case for and long term viability of HIEs, and patient consent structures. Opportunities for Congress to act to break down barriers and facilitate a legal and regulatory environment that fosters innovation while ensuring protections for patient privacy include supporting open data initiatives, driving interoperability, and reviewing provider liability and patient consent frameworks with an eye towards the changing landscape of healthcare delivery.

Interoperability, or the ability to seamlessly share data across different EHR systems, is a topic much discussed by the Office of the National Coordinator for Health Information Technology and other government agencies involved in HIT. Several initiatives, both national and regional, have made great progress towards identifying and supporting certain data and exchange standards. However, HIT vendors can and do use any of a variety of standards and as a result, most EHRs do not communicate and work together with other EHR systems. Similarly, Continuity of Care Document (CCD) content is not fully implemented in a sufficiently standardized manner despite initial progress made in Stage 1 of Meaningful Use. As the mechanism for data submission to HIEs, the content and format of CCDs greatly affects the efficient operation of an HIE. This lack of concordance on standards represents a major commercial barrier to the exchange of information, whether via HIE, between EHRs, or for research and evaluation purposes.

The concept of legislating data standards is particularly complex, in large part due to the rapidly evolving technological landscape. Furthermore, the Committee states that the goal is to foster innovation, rather than mandate specific technologies. Therefore, we suggest that Congress could drive progress towards interoperability by exploring existing levers to incentivize vendors and developers to work towards a common goal. Such levers include the development of innovative health delivery system models that incorporate features that will require interoperability. For example, the expansion of the Accountable Care Organization model continues to drive development of interoperability functions as needed for ACO functioning. Other pay-for-value reforms, such as the Hospital Readmissions Reduction Program, have the potential to further drive coordination among competing organizations, particularly if Congress incorporates such requirements into the system redesign process. Other mechanisms by which the federal government can ensure progress towards interoperability could include drivers towards standardization of CCD content through the creation of an analogue to HIPAA 5010 Companion Guide.

Finally, Congress could also support changes in the EHR certification process to require standardization of data output. While the EHR Certification process established as part of the EHR Incentive Program has driven overall EHR development towards a common goal, we note numerous circumstances in which additional action through the Certification process could drive EHR development to more broadly support the goals stated in the white paper. These include vendor development of within-EHR consent management systems, and use of standardized data extraction standards.

Long term viability of Health Information Exchange:

The data captured in a patient's EHR is a reflection of one patient's health and medical care; the data captured in an EHR for a provider's entire patient panel is a reflection of the health of that provider's community. At a population level, the unprecedented availability of detailed data on the delivery of

health care via EHRs offers an equally unprecedented opportunity to assess health system functioning, analyze and study trends, and identify opportunities to implement positive change in healthcare delivery and population health. For an individual provider, the availability of this data offers the opportunity to share data across the health continuum and potentially deliver more coordinated and effective care to patients. However, current mechanisms for data sharing are not seamless; barriers to exchange of health information persist across care settings.

A health care provider/health system's data represent a competitive advantage; providing access to the system's information represents a value transfer from the health system to the HIE. Clear, effective business cases have not been established for health care delivery organizations, payers, or providers to participate in HIEs. In the absence of perceived remuneration, organizations and providers alike have little incentive to share their data. Furthermore, due to the fees charged by HIEs (sometimes referred to as Regional Health Information Exchanges or RHIOs), care providers must pay significant amounts of money to participate in an HIE, but the value of doing so may not be apparent to the provider. While potential benefits from HIE participation certainly exist, in many cases the value does not accrue to the health care provider. Cost savings due to use of HIE typically accrue to the payer, while the costs incurred for participation in HIE accrue to the provider. We suggest that Congress consider mechanisms for re-aligning the incentives for HIE participation; some proportion of cost savings associated with HIE utilization could be funneled into underwriting the costs providers incur by participating in HIE.

An additional barrier to HIE participation on the part of organizations as well as individual providers is the uncertainty regarding liability related to HIE participation. Anecdotally, providers are concerned with two circumstances in which they may potentially be liable: first, if relevant clinical information is available on the HIE but the provider does not make use of that information; second, if incorrect information is available via HIE and the provider acts on that incorrect information. We suggest Congress incorporate awareness and recommendations regarding these liability issues into future action regarding HIE participation.

Open data initiatives: Congress should continue to support the widespread open data initiatives which would require publicly funded health IT programs to support the disclosure of de-identified datasets for public health surveillance and medical research advancement. This philosophy is embodied in the Office of the National Coordinator's Standards &Interoperability Framework's recently completed initiative, Query Health[1], which identified existing standards, tools, and security approaches for enabling existing organizations to use EHR information across a distributed network of participants. The NYC DOHMH has pursued this approach successfully over the last seven years as it has gathered disease surveillance information across hundreds of EHR-enabled participants to support its public health mission.[2]

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[1]Klann JG, Buck MD, Brown J, Hadley M, Elmore R, Weber GM, Murphy SN. Query Health: standards-based, cross-platform population health surveillance. J Am Med Inform Assoc. Published Online First: 4 April 2014. doi:10.1136/amiajnl-2014-002707.]

[2]Buck MD, Anane S, Taverna J, Amirfar S, Stubbs-Dame R, Singer J. The Hub Population Health System: Distributed Ad Hoc Queries and Alerts. J Am Med Inform Assoc. 2012 Jun 1;19(e1):e46-e50. Epub 2011 Nov 9.

Patient Consent: Buy-in from the patient community is essential to the success of health data exchange initiatives, and patient must be confident that their health information will remain confidential and secure. Currently, patient consent for HIE is determined at the state level. Current procedures for patient consent create great uncertainty where patient information may cross state lines, and further creates a burden on individual providers to ensure informed consent is documented where needed. We have noted recent indications from the Substance Abuse and Mental Health Services Administration that the need to balance patient privacy with consent mechanisms that support electronic exchange of health information is being considered, and strongly support Congressional consideration of the same issue. In light of the rise of HIE and the national shift towards electronic management of health data, we suggest Congress review national standards for patient consent across various categories of health information. Movement towards clear, comprehensive national patient consent policies would support patient privacy by ensuring protections are applied consistently while simultaneously assisting providers in utilizing HIE to improve the coordination of care for individual patients.

SIEMENS

Healthcare

July 22, 2014

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
Member, House Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

Dear Chairman Upton and Representative DeGette:

On behalf of Health Services (HS), Siemens Healthcare, thank you for the opportunity to provide input to the House Energy and Commerce Committee's *21st Century Cures – Digital Health Care* request for comment. We applaud the Committee for this thought-provoking initiative and for challenging the industry to consider these serious issues.

HS is the healthcare information technology (HIT) division of Siemens Healthcare, with worldwide headquarters in Malvern, Pa., employing about 5,000 individuals worldwide. Holding a leadership position in healthcare IT for more than 40 years, HS is helping healthcare organizations achieve desired outcomes every day through the development and implementation of our HIT solutions. In addition to providing in-house IT solutions for healthcare organizations, HS is a leading cloud services provider in healthcare, hosting systems for more than 850 organizations and operating one of the industry's most sophisticated healthcare network operations centers.

We have an interest in developing answers to the questions you pose as a leader in HIT but also as individuals who are all participants in the healthcare system.

Much progress has been made over recent years – the potential of electronic health records systems is now recognized as a catalyst to ensuring better outcomes from what is the most expensive healthcare system in the world. The 2009 ARRA/HITECH Act successfully launched the rapid deployment of electronic health record systems. With the "meaningful use" program winding down, however, Congress now should pivot to taking stock of the program's results and identifying what policies are required to sustain the momentum. We feel strongly that continued government prescription of product functionality on system developers hinders innovation. HIT products should be built according to market and customer needs. We are concerned that policy approaches such as annual government-required certifications move HIT in the wrong direction and diminish the innovative spark that spurs technological advances.

For decades, the US healthcare system has relied on organizational processes and structures that supported fee-for-service payments, competition among providers and often difficult

relationships with payers. Now, as we undertake unprecedented transformation, we urge Congress to focus the industry on initiatives that improve care coordination and collaboration, quality, transparency, and cost efficiency.

Clinical Evidence Based Best Practices

We urge Congress to support innovation that leverages the potential of big data and the electronic health record to advance the body of clinical evidence. With 92% of hospitals using certified EHRs[1], it is time to move beyond collection of data to manage the individual patient to leveraging the information to improve quality and outcomes. The widespread adoption of HIT and, specifically, electronic health records means that vast amounts of data are now available to analyze protocols and develop best practices. We believe that taking advantage of the deep well of information now available is actually key to a personalized medicine approach. By providing predictive model guidelines, it will support clinical decision support for the individual. Delivering best practice guidelines to care givers means that more informed care is possible and that such care can be more effective and more efficient.

Population Health Management and Care Coordination

In the US, it's worth noting that 45% of healthcare costs are driven by 5% of the population -- the sickest individuals. And, the next tier of patients, covering those considered to be at the 20 to 30% risk level, consumes 35% of healthcare costs [2]. With the advent of accountable care, the system is primed to take advantage of care coordination to manage whole populations of patients who have chronic diseases in common. This has particular benefits for the most vulnerable patients, especially the elderly and those in remote rural areas for whom ready access to healthcare resources is problematic.

To do so effectively, we must be able to identify the patients, implement care plans, and share information with both patients and care givers across multiple and disparate IT systems. We urge Congress therefore to remove the barriers that hinder the full capabilities of these strategies. These include accelerating broadband capabilities in remote areas and supporting telemedicine policies that incentivize coordinated care across state boundaries. Additionally, we encourage Congress to encourage private sector collaboration in support of mature interoperability standards to ensure the exchange of discrete, meaningful data among providers. We also recommend that reimbursements policies be aligned to enable patients to have in-home connectivity to their healthcare providers in order to become fully engaged in their own care.

Regulatory Framework

We recognize that the development of a HIT risk-based framework is a difficult problem to solve and we believe it is a journey not a destination. Healthcare is far from perfect today, thus we should not drive for perfection but drive for improvements. We applaud the bipartisan support from this committee for legislation that promotes more tolerance for risk. We believe the best

path forward to make progress for HIT without adding unnecessary risk or stifling innovation can be achieved by first taking the time to learn from our recent advances.

Overall, since HIT products and the needed infrastructure are still evolving, we should first focus on establishing a learning environment that represents all stakeholders in the healthcare system. With analysis of recent experiences, we can then build the foundation for an HIT regulatory framework. We suggest that a methodical approach to building a Health IT framework from learnings will enable an oversight framework that is beneficial and sustainable for the entire Health IT ecosystem. With many different aspects to be considered, learnings should be cautiously reviewed and as a whole in order to understand the benefits and impacts. This endeavor is key to the future of Health IT and should not be subject to an arbitrary timetable. Instead we urge Congress to focus on a private/non-profit center with the support of federal agencies for learning from which we can build the foundation for an HIT regulatory framework.

Again, on behalf of Siemens Healthcare Health Services, we thank Congress for continuing to take on the challenge of transforming our healthcare system into a sustainable, effective and efficient system that delivers care of the highest quality for all our citizens.

Sincerely,

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[1] ONC Data Brief No. 16, May 2014, Adoption of Electronic Health Record Systems among U.S. Non-federal Acute Care Hospitals: 2008-2013, Dustin Charles, MPH; Meghan Gabriel, PhD; Michael F. Furukawa, PhD

[2] *The Volume to Value Revolution*, Oliver Wyman, 2012. Updated 2013

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Telecommunications Industry Association
21st Century Cures: Digital Health Care
Comments on Questions Posed in the White Paper
July 22, 2014

I. Introduction

The Telecommunications Industry Association (TIA) hereby submits comments in response to the white paper "21st Century Cures: Digital Health Care."

TIA is a trade association representing nearly 400 global manufacturers, vendors, and suppliers of information and communications technology (ICT), and engages in policy efforts specific to health ICT to promote a modern healthcare system that leverages innovative technologies to transform the way care is delivered and consumed. Many of TIA's member companies develop, manufacture, and supply health information technologies and medical devices, producing the tools that allow patients and health care providers to connect virtually anytime, anywhere. TIA would like to thank the Energy & Commerce Committee for this opportunity to comment.

Advances in technology have drastically changed the way healthcare is delivered and consumed, connecting patients, health care providers, and medical professionals virtually anywhere, to help facilitate ongoing care and treatment wherever and whenever it is needed. In order to realize the full potential of 21st century health care, we must have in place effective policies that promote ongoing investment and innovation to development these transformative technologies, and a regulatory framework that provides clarity and predictability instead of barriers that stifle progress.

II. The Health Care System of the Future Should Realize the Potential of Telehealth and Remote Patient Monitoring

A modern, 21st century healthcare system must leverage innovations in communications technologies. However, outdated regulations that have restricted the use of telehealth have long been a hindrance to progress in this space. As a notable example, Section 1834(m) of the Social Security Act has resulted in arduous restrictions on telehealth services (*see* 42 CFR § 410.78). The ICT manufacturer, vendor, and supplier community urges for Congress to work towards realization of a connected healthcare system by removing barriers to the utilization of

advanced technologies. For example, a broad cross-section of stakeholders in the healthcare space have joined TIA in urging for newly-confirmed HHS Secretary Burwell to waive 1834(m) restrictions on Accountable Care Organizations in the Medicare Shared Savings Program.[1]

Remote patient monitoring of patient-generated health data (PGHD) must be utilized for any health care system to realize its full potential. The known benefits of remote patient monitoring services include improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, particularly for the chronically ill.[2] In addition, use of virtual chronic care management by the Department of Veterans Affairs resulted in a substantial decrease in hospital and emergency room use.[3] Involving this data will engage patients in their own care, can lead to improved lifestyle choices and improve overall health.[4] There are also significant potential for cost savings, with a recent study predicting that remote monitoring will result in savings of $36 billion globally by 2018, with North America accounting for 75% of those savings.[5]

We urge Congress to allow for the full range of available technologies to improve quality, safety, efficiency, and reduce health disparities by engaging patients and families while improving care coordination, population and public healthcare. Policies must be in place that enable greater use of these dynamic solutions and promote greater development and opportunities for health care delivery. While national and global efforts to develop, integrate, and utilize innovative technologies that enable eHealth and telemedicine have allowed this industry to mature, we must continue looking for ways to maximize the potential of health ICT.

Another important aspect to consider PGHD is with relation to the Centers for Medicare and Medicaid Services, EHR Incentive Payment Program that oversees the "Meaningful Use" (MU)

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1 *See* http://bit.ly/1na1UrA.

2 *See, e.g.*, U.S. Agency for Healthcare Research and Quality ("AHRQ") Service Delivery Innovation Profile, *Care Coordinators Remotely Monitor Chronically Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs* (last updated Feb. 6, 2013), *available at* http://www.innovations.ahrq.gov/content.aspx?id=3006.

3 *See* Darkins, et al., Telemed J E Health. 2008 Dec. 14 (10) 1118-26. doi: 10.1089/tmj.2008.0021.

4 *See, e.g.*, Sanjena Sathian, "The New 21st Century House Call," Boston Globe (July 29, 2013), *available at* http://www.bostonglobe.com/lifestyle/health-wellness/2013/07/28/century-house-call/tdupWvOQI6b3dKdKcEgdGM/story.html.

5 *See* Juniper Research, *Mobile Health & Fitness: Monitoring, App-enabled Devices & Cost Savings 2013-2018* (rel. Jul. 17, 2013), available at http://www.juniperresearch.com/reports/mobile_health_fitness.

requirements. One of the primary goals for the program is to engage patients and their families in healthcare. However, the ability to upload PGHD that is captured by a patient's home use or mobile medical device is not currently a part of MU, nor has this topic been adequately addressed in Stage 1 or Stage 2 of the program. TIA has long urged CMS that MU criteria should adequately account for all aspects of health IT and the full range of innovative health and medical products, such as health IT medical remote monitoring technologies that could further CMS' goals under Meaningful Use. These technologies can provide timely and crucial information and should be part of the EHR and follow a patient along the continuum of care.

And while there remains a final opportunity to improve health outcomes through Meaningful Use Stage 3 in 2014, there is a true need for federal priorities to address the full potential of the health information technology ecosystem which is comprised of many technologies, including medical remote monitoring products that are enabled with wired, wireless and mobile ICT. Based on the potential benefits that remote monitoring and PGHD can provide to countless Americans, we encourage Congress to approach efforts to advance healthcare past interoperability of EHRs, and to fully support a connected health ICT ecosystem. Embracing the diversity of solutions will allow for innovative improvements at each stage along the continuum of care. Consciously taking a broader focus as we describe above would be a noteworthy step towards encouraging innovation and investment into new technologies that will improve care, reduce hospital visits, and save lives.

In addition, TIA believes there is an excellent opportunity for CMS to remove arduous restrictions on healthcare service providers through its forthcoming revision of the 2015 Physician Fee Schedule. Specifically, chronic care management codes (CCM) should be widely updated to contemplate telehealth and remote monitoring as an eligible service. In a filing to CMS in late 2013,[6] TIA explained that it strongly believes that including remote monitoring solutions as a mandatory supplemental benefit will serve as a significant step towards modernizing the delivery of care by extending beyond the walls of the hospital room, and we urge you to consider these priorities elaborated on in that filing. We also do not believe that CCM codes should be available only to those eligible providers (EP) who currently have met requirements under the MU program, as that would alienate other EPs who stand to benefit from these important reimbursements.

[6] *See* http://bit.ly/1qbHvaw.

III. Regulatory Framework that is flexible and provides clarity/Coordination Among Key Federal Agencies

TIA also urges Congress to work to ensure coordination across all governmental entities in providing certainty to those in the healthcare space, from the healthcare provider to the vendors that enable care. Several examples:

- We encourage CMS, the Department of Veterans Affairs (VA), and other agencies to work with the FCC on how best to position the latter's rural health connectivity programs under the Connect America Fund to holistically address the lack of availability of Internet access and communications barriers, the benefits of telehealth and remote patient monitoring, and reimbursement issues. The FCC's mHealth Task Force has already recommended in September 2012 that FCC, ONC, and CMS should seek a closer collaboration related to ongoing health IT and information exchange efforts.[7] In a coordinated way, CMS and VA (among others) should promote mobile broadband connectivity in rural areas and specifically address barriers to healthcare by providing HIT mobile infrastructure. Investment in multi-purpose commercial mobile broadband networks should be leveraged to support health related mobile broadband products, applications and services. Patients, doctors, and hospitals all need access to ubiquitous mobile broadband coverage if wireless health is to deliver on its potential.
- The FCC and Food and Drug Administration (FDA) should continue to build upon their 2010 Memorandum of Understanding,[8] working towards innovation in broadband and wireless-enabled medical devices, and reduction of uncertainty to improve healthcare. For example, as TIA explained in its comments to the FDA on "home use" devices, the FDA should rely on the FCC for the management of harmful interference.[9]
- The National Institute of Standards and Technology (NIST) has released guidance procedures for design evaluation and human user performance testing of EHR systems for Meaningful Use under the HITECH Act.[10] NIST's *Technical Evaluation, Testing and*

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7 *See* http://www.fcc.gov/document/fact-sheet-mhealth-task-force-recommendations

8 *See* https://apps.fcc.gov/edocs_public/attachmatch/DOC-300200A1.pdf.

9 *See* http://bit.ly/1kTlwCe.

10 *See* NIST, *Technical Evaluation, Testing and Validation of the Usability of Electronic Health Records (NIST Interagency Report 7804)* (Mar. 20, 2012), available at http://www.nist.gov/healthcare/usability/upload/EUP_WERB_Version_2_23_12-Final-2.pdf.

Validation of the Usability of Electronic Health Records (NIST Interagency Report 7804) includes general steps and guidance for evaluating an EHR user interface from clinical and human factors perspectives and for conducting usability tests of an EHR user interface with representative user groups, and provides a three-step testing protocol. Separately, the Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) has issued its proposed next edition of EHR technology certification criteria for eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) may voluntarily meet in order to qualify for Medicare and/or Medicaid EHR incentive payments.[11] We believe that efforts such as this should benefit from close coordination to ensure that the guidance provided to vendors is as accurate as possible.

IV. Ensuring that CMS' Physician Fee Schedule Enables the Use of Advanced Digital Health Solutions

Recently, CMS released its proposed revisions to payment policies under the Physician Fee Schedule (PFS) for calendar year 2015.[12] Notably, this proposal contains a new code for non-face-to-face chronic care management (CCM).

TIA believes that this proposal is consistent with the widely-held view that enhanced telemedicine and other related applications, including the remote monitoring of patient-generated health data (patient bio-metric data,) which have demonstrated better quality health care for patients, better access to medical specialists, and lower health care costs.[13] We strongly urge Congress to confirm with CMS, for the benefit of stakeholders across the healthcare space, that its new proposed CCM code may be billed by providers to cover clinician time spent reviewing patient generated health data, i.e. patient physiological or biometric data generated from monitoring devices (a.k.a remote patient monitoring,) and not only asynchronous non-face-to-face consultation methods.

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[11] *Voluntary 2015 Edition Electronic Health Record Certification Criteria; Interoperability Updates and Regulatory Improvements; Proposed Rule*, Department of Health and Human Services, 45 CFR Part 170 (Feb. 26, 2014).

[12] *See* CMS, *Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015*, 79 F.R. 40318 (Jul. 11, 2014).

[13] For example, the American Telemedicine Association offers numerous case studies that demonstrate the value of telemedicine. *See* http://www.americantelemed.org/learn/telemedicine-case-studies.

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V. Conclusion

Telehealth continues to change the way that health care is delivered and consumed. As we continue looking forward, it is imperative that we have policies and practices in place that enable the development of this important industry and encouraging innovation and investment into new technologies that will improve care, reduce hospital visits, and save lives.

July 22, 2014

The Honorable Fred Upton and the Honorable Diana DeGette
21st Century Cures
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Re: Leveraging Technology to Advance the Discovery, Development, and Delivery of Better Treatments and Cures

Chairman Upton and Representative DeGette:

The Advisory Board Company (ABC) applauds the Committee's efforts to scale health care innovation and eliminate barriers to effective care through the 21st Century Cures initiative. The tremendous amount of activity around innovative therapies, care delivery models, and technologies leads us to be optimistic about the potential future of our nation's health care system and the potential improvement of the health of individuals and communities. We appreciate the opportunity to share our perspective on the information technology-related questions posed in your comment solicitation and would welcome additional discussion of these topics.

ABC is a global research, technology, and consulting firm, with expertise in developing and implementing highly-effective health IT tools and data analytic solutions. Our technologies support health care providers in analyzing administrative, financial, clinical and claims data to improve quality and efficiency at the individual provider, health system, and population level. Currently, our technologies analyze data covering over half of U.S. inpatient admissions. Our Crimson platform includes tools that, among other things, help providers assess physician quality; identify potential gaps in patient care; stratify patients according to clinical risk; engage care team members in care management; and improve physician practice management. Based on our extensive experience developing health IT solutions that help providers elevate the value of care they provide, our comments focus on the importance of interoperability of IT systems to improving quality and efficiency of care.

I. Interoperability Is Key to Enabling Innovations in Care Delivery

Even with the substantial increase in the adoption of electronic health records (EHRs) and other recent advancements in health IT, we are still struggling to realize the full potential of these technologies within the American health care system. In our experience, one of the most significant barriers to scaling innovation is the lack of interoperability between information resources—the lack of universal and seamless data sharing across health systems, providers, and patients—that limits the potential of IT-enabled health care delivery. The increasing emphasis on new payment and care delivery models that drive improvements in quality and in cost offers a renewed opportunity to advance interoperability because it places a premium on actionable information. However, additional work must be completed before we can optimize the use of the data across patients and providers.

Seamless interoperability of information systems is critically important to foster innovation in care delivery and improve patient outcomes and population health. As you note in your call for comments, "[t]o fully realize the potential of big data and the benefits of innovative new technologies, [IT tools] and the information they contain must be able to communicate and work together." Indeed, access to real-time information in a user-friendly and actionable format is a key factor in successfully developing and implementing population health models. Providers depend on a robust health IT infrastructure to enable them to deliver better care to patients in the lowest-cost setting in a timely manner. Patients also benefit from this care redesign – the services they receive are more coordinated and convenient, often focusing on prevention of disease or acute episodes. To achieve these beneficiary-centric goals, successful population health managers need the necessary data and health IT tools to perform three core functions: stratifying patients according to risk; appropriately managing delivery of care; and engaging patients as partners in their care.

Stratify Patients According to Risk

In working with health care providers, we find that the most successful providers categorize the patients that they are managing based on the patients' level of clinical risk. Thinking about patients as multiple cohorts (high-risk, rising-risk, and low-risk cohorts) rather than a single population allows providers to focus on different goals, resources, and care models for each cohort and drive greater gains in care quality. It is, however, incredibly difficult to assess a patient's needs or risk level without the timely and comprehensive information that is available electronically. For example, Crimson offers population risk management tools that can analyze claims data to stratify patients by actuarial risk and other factors but must utilize multiple information sources to do so. The effectiveness of risk stratification grows as providers gain access to data that is closer to real-time as opposed to the retrospective data that has historically been available, and information must be able to move quickly and efficiently to optimize the management of these patients' care. Importantly, the ability to stratify patients and manage their care according to areas of risk is a necessity for providers as they move from volume-based care to value-based care while simultaneously improving quality.

Coordinate and Manage Patient Care

Successful population health management also necessitates migrating away from siloed care management activities and toward cross-enterprise, cross-continuum platforms. To that end, population health managers need tools that enable them to track patients' health and utilization across multiple sites of care, both within and beyond their network of affiliates, likely with multiple EHR platforms. In addition, successful care management must extend to non-traditional sites of care, for example, social service agencies, "Meals on Wheels" programs, and patients' homes. With these interoperable IT tools, providers can support patients' adherence to care plans; help patients avoid acute episodes; and collaborate with other providers on interventions. For instance, IT applications can help care team members identify individual patient needs and tailor workflows to ensure appropriate interventions from the optimal resources. As more systems and stakeholders are connected through interoperable platforms, patient care will be better coordinated and more customized to individual needs.

Engage Patients

Finally, as providers in accountable care models seek to shift health care delivery to lower acuity settings, they will need to establish mechanisms for interacting with patients in the outpatient setting and in patients' homes to ensure successful outcomes and management of utilization risk. Health IT and data analytic tools can enhance and bypass the traditional patient engagement strategies of postcard and email campaigns. IT-enabled patient engagement includes services and platforms that combine real-time, multi-modal, bi-directional communication between providers and consumers; tools to support patient self-management and engagement; and incentives for patients to adhere to care plans. For example, the Crimson platform allows patients and caregivers to view the care plan, supporting self-management and care plan compliance. Advanced patient engagement depends upon accessible information as well as patient confidence in the privacy of that information. Patients often feel empowered as active parties in sharing and utilizing that information when the right safeguards are built into the IT environment.

II. Widespread Interoperability Would Spur Dramatic Innovation

The pioneering providers with whom we work to deploy technology that enables population management are able to overcome some of the challenges of the current IT environment through a combination of smart and aggressive investment, determination and focus. But as we contemplate the widespread adoption of population health models and the performance expectations of managing cost and quality for an older and sicker population, we have concerns about the health care system's ability to scale innovation quickly enough to deliver the quality of care that patients deserve. Providers and solution vendors alike encounter too many challenges to be wholly optimistic about fully realizing the goals of care transformation in the near future. The three challenges outlined below highlight the need for additional action to ensure the reasonable interoperability of IT tools and systems:

1. *Difficulty acquiring and using data from EHRs:* Providers and vendors today face both technical and contractual barriers that restrict access to important data found in EHRs. Some EHR vendors offer the technical capacity to extract EHR data at an extremely high price point. In other cases, providers and vendors can develop their own workarounds to the technical barriers, but the costs to do so are significant, thereby limiting the types of organizations that can afford such solutions and the number of areas where they can develop workarounds. Furthermore, the emergence of cloud-based solutions could further complicate technical workarounds as providers and third-party vendors may be more reliant on vendors to provide an application programming interface (API) or implement messaging standards for use in exchanging data. Additional progress is needed on the reasonable availability of shared standards to facilitate the increased exchange of information from provider to provider as well as provider to third party applications (data analytic tools, mobile applications, etc.) and could reduce significantly the cost of such exchange. Furthermore, vendors should be strongly encouraged to demonstrate a commitment to active and responsible sharing of information in order to facilitate more innovative uses of data on a faster timeline.

2. *Difficulty acquiring data from systems that are not commonly messaged for typical inpatient activities:* For a given health system or hospital, only a portion of patient data is available via the organization's integration engine in real-time. The rest of the data is only available in nightly batches or not at all. For example, physician and nursing progress notes, which often contain very useful data to determine patient risks for

adverse outcomes, such as risk of readmission, are difficult to acquire without the proper interfaces (which may require a significant additional investment from the health system). Ensuring that health IT products are able to share information in a timely and accurate fashion is critically important to optimizing the value of technology and more should be done to facilitate common standards and exchange tools that will provide product interoperability.

3. *Difficulty pushing data and derived insights back into EHR workflow:* After acquiring and analyzing data, organizations almost always encounter additional challenges informing the user of insights within the workflow of the EHR. Necessary additional data or workflow "real estate" is frequently not available to translate raw information into actionable insights. Even the most well-resourced and sophisticated organizations face nearly insurmountable barriers when they try to push information back to a patient or provider, and the vast majority of organizations have no secure or predictable method to achieve this goal, which severely limits the impact of health IT on patient care.

Each of these barriers could be overcome by making greater strides toward a fully interoperable health IT infrastructure that allows data to flow freely out of and back into EHRs as well as out of other key clinical and administrative systems. Lowering the investment required to access data by one or two orders of magnitude would make it possible for a wider range of innovators to enter the health care data and analytics market. The resulting flood of innovation could lead to powerful solutions for engaging consumers in maintaining and improving health and for enabling providers to deliver higher-quality, lower-cost care.

The importance of interoperability extends far beyond EHRs being able to access data in other EHRs. EHR systems hold clinical data that providers need to manage care for patient populations, but EHR systems alone do not offer sufficient tools for care management or patient engagement. Thus, to achieve population health goals, providers need to extract data from EHRs for use by platforms and systems such as mobile devices, disease registries, patient portals, analytics tools, and clinical decision support algorithms. Because most major health systems and ACOs face the challenge of extracting and integrating data from multiple EHRs, achieving an industry-wide standard of interoperability is critical to enabling providers to scale adoption of other key health IT care management tools.

To that end, we generally support concepts that ensure that providers are investing in products that are capable of optimizing information, such as testing the interoperability of select health IT products as explored in the recent FDASIA report. For instance, interoperability testing for EHRs could include a determination as to whether the EHR meets a functional, low-cost standard of interoperability with other EHRs and third-party applications. Moreover, future stages of the EHR Incentive Program and Meaningful Use seem like a natural opportunity to facilitate the interoperability of IT tools, whether it be through testing of interoperability or other means. This approach would ensure that the definition of meaningful use extends beyond capturing data in EHRs to effective use of the data for care management purposes and could maximize the country's health benefit and financial return from its investment in EHRs.

We appreciate the opportunity to comment on the role of interoperability in moving the nation's health care system forward. The health care sector's ability to invest in and embrace these improvements depends upon the appropriate availability of health data at a reasonable acquisition cost. The 21st Century Cures initiative's focus on health IT has the potential to

contribute significantly to the well-being of individuals and populations as well as stimulate additional innovation and economic growth. We strongly support your efforts to explore new approaches that could foster public and private sector collaboration to scale innovation more quickly and look forward to working with you in the future.

Sincerely,

Piper Nieters Su
Vice President, Health Policy