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ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

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The House of Medicine: On a National Health Reliability Organization

EMPOWERING AMERICA'S HEALTH SECTOR TO PROVIDE QUALITY
HEALTHCARE THAT IS ACCESSIBLE AND AFFORDABLE
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Purpose: This document describes the need for and elements of an organizing structure for the Healthcare and Public Health Sector to improve innovation and reliability (quality, accessibility, affordability) during normal “blue sky” conditions and predictable disaster response conditions.

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I. Executive Summary:

The House of Medicine--our nation's \$3.5 Trillion Healthcare and Public Health Sector—faces disruptive forces that will have impact on our nation’s health security. From novel alignments of industrial and corporate partners, the tsunami of personal and population health data, cyberthreats, and emerging infectious diseases, to rapid biotechnology development, the Sector must gain and maintain vigilant understanding of the potential impacts and address issues that arise on the appropriate timelines. The Sector—this House--must be constantly renovated, remodeled, and updated to meet the challenges posed by that dynamic, chaotic environment.

This proposal defines the shared responsibilities of the public and private components of the Sector and outlines a framework for a “National Health Reliability Organization”, an approach that allows industry to identify and address issues through a “reliability” culture as applied to national healthcare and public health ensuring that healthcare remains affordable, accessible, and of good quality. This formal construct drives effective and efficient development of *codes, standards, best practices* that become *industry standards with implementation, compliance and enforcement, and validation* activities, with limited, appropriate government oversight. Reliability organization principles ensure those activities are deliverable on normal “blue sky” days and during extraordinary but predictable “black sky” disasters, events, or incidents.

The corporate privilege of providing health related goods and services in the marketplace comes with responsibilities: ensuring healthcare reliability—quality, accessibility, and affordability under all predictable circumstances *as part of the baseline business process, planning, and risk management*; ensuring an organizing construct that serves as the forum between the public and private components of the Sector to develop standards done in a neutral, pre-competitive, transparent environment; and ensuring that there are gateways, switchboards, evolving master reference architectures, and operations center capability able to organize the Sector through a system of systems architecture on a national scale, and providing situational awareness for the Sector.

While these concepts are not new, they have not been incorporated culturally into the fabric or framework of the House of Medicine. This proposal borrows from Reliability Organization, systems architecture, operations, and engineering approaches in other critical sectors such as Energy and Commercial Aviation. It recognizes the value of broad data collection and analysis used for predictive modeling as applied across our daily activities, such as is seen in weather forecasting and reporting. The Energy Sector has its Federal Energy Regulatory Commission (FERC)/ North American Electric Reliability Corporation (NERC) construct meeting the Federal Powers Act amendments in the Energy Policy Act (EPA) of 2005. Section 215 of the EPA requires an “Electric Reliability Organization (ERO)” private sector entity. The National Weather System has its distributed networks of weather stations, satellites, and RADAR stations feeding data to supercomputers providing models and current weather system information used across other critical sectors.

This proposal identifies notional constructs for an analogous National Healthcare Regulatory Organization Governance (NHROG), recognizing the regulatory roles and authorities granted to Federal and state government, and a private sector National Healthcare Reliability Organization (NHRO). The goal is to develop a similar culture of reliability across the Sector, driving collaboration and interoperability, compiling and analyzing evidence, learning, forecasting, improving healthcare and public health systems, and integrating with other critical sectors. The notional NHROG is outlined briefly with a background primer with information on regulatory commissions. A notional NHRO design follows.

A note on regulations--they exist generally to identify and modify activities that pose threats to public safety, health, or well-being. Healthcare and public health are the quintessential areas focused on treating and preventing the consequences of faulty or lacking regulations. These “regulations” effectively already exist in the myriad forms of standards, best practices, clinical pathways, and guidelines. It is the way medicine and public health are practiced. In striking the right balance between

more regulations and smaller government with less interference, the NHROG/ NHRO construct seeks to empower the professionals in the healthcare sector to identify and develop healthcare "standards" (vice regulations) requirements and provide self-governance through transparent activities of implementation, compliance and enforcement, and validation. The intent is not to increase the regulatory burden, but to facilitate a more efficient, scientific, evidence-based approach to testing, validating, and updating practices and processes within the sector to improve reliability and mission assurance. Processes that improve health, safety, and well-being can then be captured, implemented more broadly, analyzed more effectively, and adjusted as appropriate in an actively learning, adaptive systems approach. The end result must be a House of Medicine that is ethically grounded, science-based, efficient, economically optimized, reliability-driven, and accountable to the American people.

Straight and Level Flight...

Flying a plane at cruising altitude during good weather conditions with no other air traffic around is easy. Nearly anyone could fly it. In fact, the plane can pretty much fly itself. But we have pilots for good reason--takeoffs, landings, navigation, turbulence and foul weather conditions, air traffic avoidance, weight-balance, unruly passengers, in-flight emergencies. In fact, the entire Aviation Sector is built around safety and reliability. It includes highly trained flight crews and mechanics, maintenance, fuel management, scheduling, ground control, air traffic control, weather monitoring and forecasting, airplane design and manufacturing. All accidents are meticulously investigated. The commercial Aviation Sector is a vast combination of decentralized, competitive industries that work together to deliver highly reliable transportation services moving millions of people around the world every day. In many countries, the sector can go an entire year without a single death due to an accident. It has a culture of safety. Safety is institutionalized across the sector.

How did it get there?

II. Issue Paper on Development of a National Health Reliability Organization

Issue: The Healthcare and Public Health Sector needs a formal, organizing structure to allow efficient and effective engagement of issues impacting the reliability of our nation's healthcare and public health systems for daily operations and when responding to extraordinary but predictable disasters.

Background: The House of Medicine, the Healthcare and Public Health Sector (the Sector, aka, the House), lacks key [organizing principles](#) that allow the Sector to adapt to critical issues effectively and efficiently on a national scale. With the privilege to work in the Sector come shared responsibilities. Our nation's healthcare sector must be able to provide "reliable" healthcare for the nation--healthcare and public health that is available, accessible, and of good quality under both normal, "blue-sky" conditions and under predictable, "black-cloud" conditions. The Sector must also address those complex, cross-sector, interdependent issues that affect reliability and impact the ability to provide the goods and services of the sector. Needed activities include participation in the development of, updating, and compliance with best practices, standards and codes, and optimization of systems across the Sector. An organizing entity for the Sector would need to capture the immense complexity of the market, ensure free and fair competition, prevent formation of monopolistic behavior, and drive collaboration across competitors to assure accountability, transparency, and reliability. Such a structure must leverage the resources and harness the innovation within the private sector. It would allow stakeholders to form the public/ private partnerships that span governance at the Federal, state, local, territorial, and tribal (FSLTT) levels, and within the private sector to address specific issues. It would also provide a touchpoint for the sector to engage across critical sectors to recognize and address interdependencies that impact reliability. NHRO initiatives are intended address national pre-competitive needs. The NHRO will be chartered to ensure collaborative, transparent, and balanced membership processes. The NHRO recommendations are intended to be binding once approved by the federal oversight authority. The shared responsibilities would be enshrined in a private healthcare system that is largely self-governing but that has appropriate regulatory oversight authorities in Federal and state government offices and agencies. Such changes would require acknowledgement in both the public and private sector that such changes are necessary, in the interest of the people, and will continue to foster free and fair competition within the Sector.

Discussion: The Medical and Public Health Sector represents approximately 1/6th of the US GDP (~\$ 3.5 Trillion) in economic activity. The Federal Government contributes healthcare spending through the HHS

Center for Medicare and Medicaid Services (CMS) of ~\$ 1.4 Trillion, and through two Federal Healthcare Systems, the Veterans Health Administration (\$ 71 B) and the DOD Defense Health Agency (\$ 44 B). Current coordination occurs in piecemeal fashion with very limited use of any formal process or use of current technological solutions to facilitate collaboration, coordinate effort, instill a "governance" structure and order, promote situational awareness, capture current and previous efforts, identify and introduce challenges, or promote business process management across the sector.

This project will explore possible models for such a structure. While large healthcare organizations likely provide fractal views of optimized systems, they do not capture the complexity of the nation's system. A more likely solution is a self-building taxonomy (or more likely a folksonomy) that captures enough actual structure and architecture as to represent the sector in reality. The solution must allow for broad participation, transparency, and easy access for the multitude of stakeholders and partners that play a legitimate role in the Sector, while ensuring appropriate engagement and oversight of governance authorities. Ultimately, the intent is to identify the system of systems architecture, in a master architecture of the sector, and conduct systems operations optimization based on shared, enterprise wide situational awareness. The corporate structure would be self-organizing and self-governing, evolving based on recognition of the relevance of stakeholders, critical analysis of results and outcomes, but responsive to National Health Regulatory Oversight Governance. Ideally, codes or standards developed and promulgated by this entity would be linked to regulatory agencies in FSLTT governments for rapid review, validation, and co-adoption and promulgated as statutory, regulatory, or guidance across the sector as appropriate. The structure would be non-profit, self-funded, with voluntary membership, with authorities derived through Federal Legislation and exercised through broad membership across the healthcare sector. Governance would also be in accordance with appropriate law overseeing such an engagement between public/ private partnerships.

The organizational structure should exist outside of the Federal Government for several reasons. Medical practice is a complex matrix of healthcare and public health professionals and support staff, training requirements, academics, buildings and campuses, labs and pharmacies, certifications, supplies, logistics, diagnostics, research and development, waste management, health insurance, patients, and the public, all with interdependencies between them and with other, critical sectors. It's an institution built up over years of evolution, development, and refinement. Healthcare is largely regulated through licensing at the state and territorial government level, and so requires input, oversight, and participation with those authorities. Specialization is controlled by the American Board of Medical Specialties, with each specialty determining certification requirements. The numbers trained in each specialty is controlled by the Center for Medical and Medicaid Services (CMS)¹. Credentialing and privileging is done usually at the corporate, institutional level governed by multiple standards and policies throughout the sector. Nearly all of the practice of medicine is in the private sector and governed by professional societies and professional colleges. Most of public health is practiced and governed at the local, county and state level, and so requires participation with county and state level authorities. The Center for Disease Control and Prevention (CDC) provides most of the Federal public health coordination and expertise.

¹ Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99-272) and implemented in regulations at existing §§413.75 through 413.83, establish a methodology for determining payments to hospitals for the costs of approved graduate medical education (GME) programs.

The charter and rules of governance for the NHRO would drive transparent processes and standards development activities that encourage membership and participation across the broad stakeholder base. Empowered by Federal Statute as the source for standards for the Sector, the key activities would be development, implementation, enforcement and compliance, and validation. Participation for “governance” within the sector would be through the NHRO. Membership would occur through existing associations, professional societies, corporations, and institutions, and participation would be organized through various committees, sub-committees, and working groups for topical issues staffed by association members and corporate employees. Various processes would be linked as appropriate to specific government agency rule-making or review and approval in accordance with Federal Advisory Committee Act (FACA) and other pertinent laws. An analogous example would be the [National Fire Protection Association \(NFPA\)](#) and OSHA, where many codes and standards become accepted industry practices or guidelines and enforceable. Essentially, this organizing structure provides a broad-based forum to address complex issues or develop standards that require integration or have interdependencies across multiple disciplines. The approach would be able to capture the complexity of a system of systems that is the healthcare sector and would be able to address critical issues in a timely manner.

Themes to Consider:

- **The House of Medicine is currently a house divided, perhaps even splintered:** Largely governed as a loose collection of medical specialty tribes led by healthcare professionals who have gone through the crucible of long years of education and training, it is difficult to capture a holistic perspective of such a critical, dynamic, complex, and loosely governed environment. This governance structure is not efficient or effective enough to meet today’s rapid pace of technology cycling and innovation. It also lacks the organizing construct that mandates transparent collaboration, drives broad systems integration and optimization, or that promotes awareness and understanding of critical interdependencies within the sector and between other critical sectors. There are few deliberate drivers for "reliability" beyond baseline daily, just in time operations. That said, the Health Sector workforce represents a servant culture that is caring, engaging, committed, and responsible. But, they are often subject to long, round-the-clock hours, understaffing, competitive corporate environments tending to be isolating, with limited time or processes that allow an attempt to understand the level of complexity within the Sector. Collaboration across the multitude of medical, surgical, and nursing disciplines and fields is limited. Collaboration with supporting disciplines in diagnostics, devices, therapeutics, and information technology is even more challenging. Chasms remain between classic Western medicine versus holistic practitioners, and tribalism is the order of the day. And coordination across critical sectors such as food/ agriculture, public safety, energy, public works must be done, too.
- Participation in the NHRO would be through **voluntary membership, chartered with standard corporate business processes and practices, precompetitive, transparent, and binding** once approved by the national oversight authorities.
- **Process versus issues:** There are a multitude of interdependent issues that need to be addressed within the Sector (e.g., treatment errors, seasonal flu, lack of forecasting ability, lack of surge capacity, critical shortages of critical supplies and medications, dependency on foreign manufacturing for critical supplies, a National Trauma System, the opioid crisis, health data system cybersecurity, the oncoming tsunami of healthcare data, ...). The need is for an organizing entity within the Sector to be empowered to solve problems and to be responsible for identifying and addressing these issues in a deliberate, intentional, formal process to provide solutions that can then be implemented and validated.

- **Health Information and the coming health data tsunami:** Beyond cybersecurity are the various challenges (and opportunities) associated with the internet of things. As the amount of relevant information in healthcare and public health doubles every 5 years (or less), the ability to assimilate this information within healthcare management processes requires advancing knowledge management. Machine Learning (ML) and Artificial Intelligence (AI) are already making their mark in healthcare. Just as basic piloting can already be replaced by autopilots, the role of healthcare provider teams will evolve, with today's basic healthcare able to be assisted by apps algorithms, and robotics, thus freeing up healthcare providers to focus on even more advanced aspects of health. The sector needs a sub-industry of health information data exchanges that allow for the development of markets for data exchange for multiple purposes.
- **National Security:** The issue of when aggregated information becomes intelligence should be considered in this effort with the proper balance between transparency, accountability, and security. Success in implementation looks like a busy, crowded, complex marketplace that allows for "mash-ups" of ideas, innovation, and more rapid advancement and execution of ideas and concepts into the marketplace. The rapidity of discovery, innovation, and experimentation might be beyond the ability of the community to recognize threats that become intelligence concerns. Consideration needs to be given to vetting of users and use of information, international engagement, need to know versus need to share, walls and boundaries between public and private entities, the balance between information and intelligence--when does the consolidation of information become an intelligence or national security risk?
- **Coordination of Strategic Goals:** The NHRO would also be a logical, robust feedback mechanism to assist the Federal Government in coordinating across its bureaucracy for implementing and executing national policies related to science and technology objectives in the public health, healthcare, biodefense and related sectors impacting homeland and national security. It would also tie in to states and their authorities governing healthcare and public health.

Establishment of the NHRO would require appropriate oversight authorities at the Federal and state government level, likely available in current offices and agencies, to review the NHRO reliability standards to ensure they are just, reasonable, nondiscriminatory or preferential, and in the public interest. It would likely include transferring certain operational functions now done in the Federal Government to the private sector. The role of the government agencies would become more oversight, review, and compliance enforcement. Like the NERC, NHRO procedures would have appropriate transparency to the end customers, the American public.

Recommendations:

1. Engage with the National Academy of Medicine for further consideration of a Way Ahead.
2. Engage across White House Executive Office of the President (EOP) councils to collaborate on this proposal. All councils have skin in the game and engage with key stakeholders to work on specific objectives. These objectives overlap and are interdependent, and no one council or office covers the breadth of engagement needed with a NRHO effectively.
3. Engage with relevant Federal departments and agencies through the Executive Office of the President.
4. Study the issue through the relevant and proper Federal Advisory Committee for further recommendations.
5. Identify needed legislative changes. These include the following:
 1. Formal establishment of a Healthcare Reliability Organization (HRO);
 2. Establishment of new federal regulatory review and oversight authorities either in a commission or in Federal departments and agencies;

3. Realignment of interagency manning, roles, responsibilities, and authorities;
4. Establishment of new, appropriate requirements for handling, sharing, and securing of medical and public health data and information to account for novel uses in medical and public health response, systems operations management, research, and other uses in the public interest.
5. Adjustment of Federal Advisory Committee Act authorities for engagement between Federal Departments and Agencies with the NHRO
6. Identify key stakeholders in the Private Sector to engage with the ongoing establishment and evolution of the NHRO.
7. Consider the “Reliability Organization” culture and concept for other critical sectors and discovery paths for interdependencies across critical sectors that impact security, mission assurance, enterprise risk.

NHRO fiddled while Rome burned...

Hurricane Irma was one of the costliest hurricanes in U.S. history at nearly \$50 Billion in damages. It hit the Florida Keys heading north on September 10, 2017, heading up Florida's western coast, leaving Florida as a Tropical Storm and entering Georgia on September 11. In preparation for the storm, the Energy Sector had Linesman technicians pre-staged near the state but outside the projected path of the storm. Governor Rick Scott quickly declared a state of emergency allowing Energy Sector workers from outside of Florida to support response operations, and within 3 days of Irma leaving Florida, over 60,000 Linesman technicians from nearly every continental state and Canada entered Florida to repair the damaged power lines and restore electricity to about 6.5 million customers who had lost power. All were licensed professionals under the management of the private sector coordinating with Florida and FEMA for the hurricane response. Their wages were paid by Florida Power and Lights Company, those costs covered by a hurricane insurance policy paid for by its customers as part of their rates.

III. Why a National Health Reliability Organization (NHRO)? The House of Medicine and the Need for Standards Development Processes

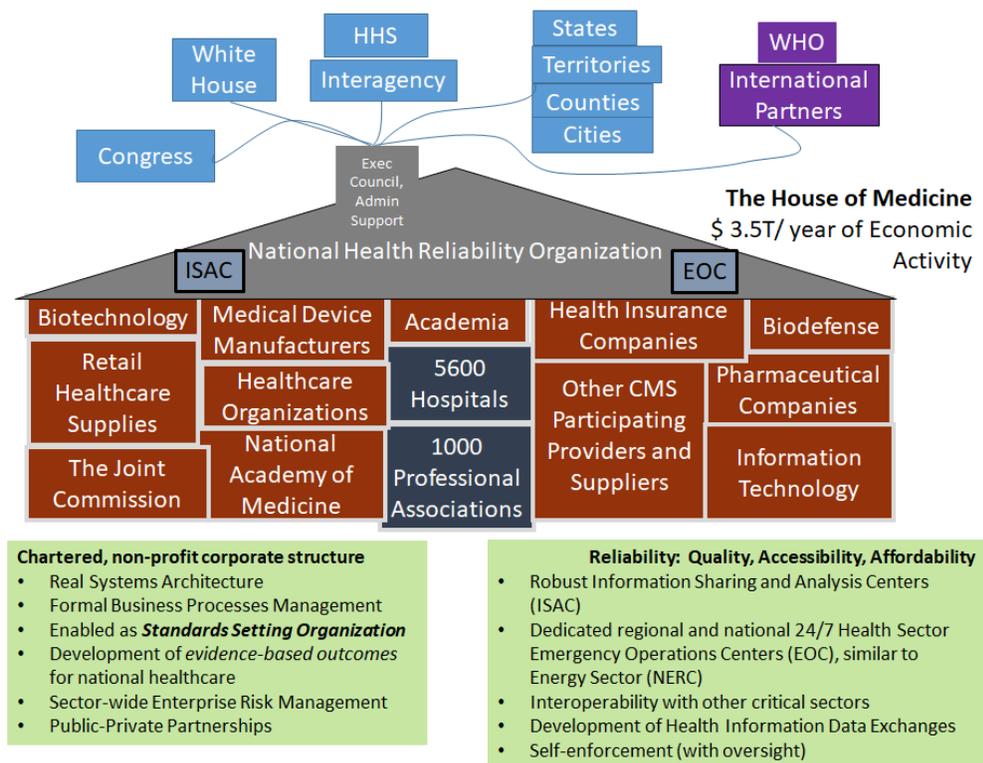
We can look to the Energy Sector for instructive solutions driving reliability that may apply to the Health Sector. The Federal Power Act (FPA) of 2005 derived the authorities for the Federal Energy Reliability Commission (FERC) to have oversight of an Electric Reliability Organization (ERO), ultimately the National Electric Reliability Corporation (NERC), in its responsibilities to develop and enforce mandatory “reliability standards”. These standards impose requirements on users, owners, and operators of the bulk power system to ensure reliability of the power grid. Over \$1 Trillion in infrastructure owned and operated by over 3,500 utility organizations provides electricity to over 334 million customers.

The Energy Sector had its watershed moment with the Great Northeast Blackout of 1965 when a faulty setting of a protective relay on a high voltage transmission line in Ontario, Canada, failed. Over 30 million customers in the Northeast were without power for nearly 13 hours. In response to the blackout, voluntary reliability councils were established to investigate the causes and develop measures to reduce the likelihood of such events recurring. The NERC was established to provide a means for coordinating among interconnected utilities to ensure that the transmission network in the U.S. was reliable, adequate, and secure. In 1981, as the grid expanded to include sections of Canada and Mexico, the NERC changed from the *National* to the *North American* Electric Reliability Corporation with the same NERC acronym. On August 14, 2003, North America experienced its largest power blackout affecting 50 million customers extending across the Northeast into the Midwest. The cause was linked to “the 3 T’s” of power outages—trees, tools, and (lack of) training. As a result, Congress added Section 215 to the Federal Powers Act of 2005 that authorized the development of mandatory Reliability Standards by an independent electric reliability organization. This mandatory approach replaced the industry’s voluntary protocols and guidelines for operating and planning the bulk power system that had been in place since the 1960’s. While the NERC only covers bulk power generation and transmission, the regional councils broadened the membership to include all segments of the electric industry bulk power supply.

While NERC reliability standards do not cover the local, lowered voltage distribution of electricity--the power lines most often affected from storms--the industry as a whole has extended the reliability culture to the end customer through the NERC governance process that includes public stakeholders (i.e., customers) in the review of nearly all standards. Many corporations operate in bulk generation, transmission, *and* distribution, so are incentivized to “keep the lights on”. Within the industry, “coopetition” thrives because of the interdependencies, and the need for mutual aid and assistance that is frequently needed. And, at the end of the day, the industry is required to be reliable—keep the power on, and keep it affordable.

In the Health Sector, the same risks of cascading effects exist in the form of public health emergencies. The Sector is decentralized with limited, traditional, ineffective standards development processes and a splintered organizational structure. Associations, academies, and societies are formed by medical guilds to ensure specialty voices are heard; however, very little signal rises above the noise unless done so through adversity, crisis, or sensationalism. Contagious diseases, poorly established practices, defective devices, or dangerous treatments can impact the end customers, but the Sector lacks the infrastructure or mechanisms to measure and recognize adverse outcomes rapidly and effectively. The private sector is essentially disconnected from government coordination except through limited, tenuous paths, including licensing at the state level, and reimbursement rates by the Center for Medicare and Medicaid Services (CMS) driving standards and pricing. The “House of Medicine”, \$3.5 Trillion of annual economic activity in the U.S., is not merely a house divided, it is a house in splinters. So, what would a “Health Reliability Organization” look like in our health sector?

Figure 1. A National Health Reliability Organization (NRHO) for the House of Medicine, \$ 3.5T of economic activity.



This ICE is Cool...

Amir Patel is a patient recovering from 4 vessel coronary artery bypass graft (CABG) surgery in a small, private hospital in Calcutta, India. Under the watchful eyes of his intensive care unit nurses, he has no less than 12 medical devices monitoring or treating his condition, including a pulsox to monitor his oxygen levels, an end-tidal CO2 monitor, an ECG monitoring his heart rate and tracing, several IV infusion pumps giving him IV fluids and medicines, and a blood pressure cuff cycling every 10 minutes to measure his blood pressure. Each device operates independently from the other with alarms programmed to trigger should that device detect some abnormal level of function. All of the data from these devices is being captured and recorded in an Integrated Clinical Environment (ICE) device—an “ICE Box”. It is a large amount of data that, under normal circumstances will never make it to Amir’s electronic health record. But today, unfortunately, this will not be a normal outcome. One of Amir’s graft sutures to a vessel supplying blood to his heart has failed, and the vessel is leaking. Though several of the devices are registering significant, detectable changes consistent with this blood loss and the loss of blood supply to his heart, none are reaching a threshold level to alarm. By the time one of them alarms, and the nurse responds, and the surgeon is consulted, and they investigate and identify the cause of the alarm, Amir has lost too much blood to his heart and suffers a fatal cardiac arrest. While this is a known complication and risk of these surgeries, his surgeon is not satisfied.

This surgeon, a renowned cardiac surgeon who practiced in the United States for decades before “retiring” and opening this specialty hospital in India, provides these surgeries to patients for a flat fee of \$ 600. The patients would otherwise have no hope of affording it elsewhere. His hospital is extremely efficient, utilizing a systems operations engineered approach to optimize the process. He is also working with a research project from the U.S. to integrate the data from the multiple medical devices into the ICE Box. On analyzing the output from Amir’s case, he is able to identify a pattern of changes captured by several of the medical devices that demonstrated a predictable pattern expected with this type of complication. This pattern begins to emerge nearly 30 minutes before any single device alarms, and it is fairly specific for the injury type. Applying this pattern to all the patients in his care, he now has a more sensitive indicator for an adverse outcome that is also specific to the type of complication that is occurring. It can be applied as an “algorithm” looking across the entire enterprise to identify complications earlier to the benefit of all patients being monitored and improving the quality of care. It is likely additional devices could add sensitivity or specificity to the predictive strength. It’s also likely there are patterns that identify other complications, that they can be further refined for sensitivity and specificity— cool, always improving apps for the ICE Box.

But where do these algorithms or apps get submitted? How are they validated? Who controls the “library” or registry for other such algorithm? Is this intellectual property? Is there a marketplace for these discoveries? Who controls what goes on the shelves in the ICE Box?

IV. National Health Reliability Organization Systems Architecture

The rate of technology advancements across the various sectors of society continues its exponential climb. The balance between regulatory oversight and free, unfettered development and innovation must be managed through a deliberate, intentional, systematic process. Public-private partnerships play a role, as do development of consensus based industry standards. Title XII of Energy Policy Act of 2005 added Section 215 to the Federal Powers Act that authorized the Federal Energy Regulatory Commission (FERC) to certify an independent electric reliability organization to develop and enforce mandatory

Reliability Standards. This empowered the private sector to self-enforce compliance of its industry standards. If and how this could be applied in the Health Sector requires much further, careful consideration. It requires the collection of data to analyze and validate outcomes. It introduces new drivers for the sector that seek to optimize operations, improve efficiency, and incorporate improvements system wide that are evidence-based. It requires new tools and disciplines to find these efficiencies, identify risk, improving quality while reducing costs.

A. Basic Organizing Principles Applied to the National Healthcare Reliability Organization (NHRO)

Guiding Principles (Harvard Leadership Course)

- Unity of Effort
- Generosity of spirit and action
- Stay in one's lane and assist others to succeed in theirs
- No ego, no blame
- A foundation of trusting relationships

Structural Principles

- **Map the Systems Architecture Out:** [Enterprise Architecture with Agile Taxonomy \(Folksonomy\) and Ontology](#) that captures the Engineered, Systems of Systems of [the sector](#)
- **Determine the Business Rules:** Business Process Management with structured Rules of Engagement
- **Use a [Common Enterprise Knowledge Management System](#):** Keep data authoritative and relational, Web 2.0, 3.0 enabled.
- **Measure the Performance:** Outcomes, Cost, Efficiency, Effectiveness, Risk Analysis, Process Improvement, Learning

B. National Health Regulatory Oversight and Governance (NHROG)

- The NHROG authority would be empowered under a National Healthcare Reliability Act
- Would focus primarily on *oversight* of the development, implementation, enforcement, and validation processes of "healthcare reliability standards" developed by the National Health Reliability Organization (NHRO).
 - Ensure the stakeholders in the Health Sector fulfill their responsibilities in providing reliability of the Health Sector—quality, affordability, and accessibility.
 - Health reliability standards impose requirements on stakeholders in the Health Sector that address beyond day to day "blue sky" operations to include preparedness for and response to "black sky days"—risks identified through Health Sector threat and hazard identification risk assessments (THIRA) and individual hazard and vulnerability assessments at the local, state, and regional level.

C. Proposed Federal Executive Oversight Council

Staffs of these offices support process, projects, and proposals. If the commission lacks sufficient regulatory power, the HHS components would need to be considered to be given additional regulatory oversight investigation, and auditing authorities to ensure that industries and organizations do not pose threats to public safety or well-being.

- White House: National Economic Council (1), Domestic Policy Council (1), National Security Council (1)
- HHS (9): ASPR, ASH, FDA, NIH, NIAID, CDC, CMS, SG, ONCHIE
- DOD (2): ASDHA, TMA

- VHA
- DHS: CMO
- USDA
- DOC (NIST)
- DOJ
- State (MED)
- Ad hoc participants: National Center for Medical Intelligence (NCMI), DOJ/ FBI, DOL (OSHA), EPA, ODNI, NCTC, DOD Branch Surgeons General, Regional Combatant Commanders Command Surgeons
- **State/ Tribal/ Territorial Health Regulatory Oversight Authorities**
 - State Public Health organizations and agencies
 - Quarantine
 - Professional licensing and monitoring authorities
 - Emergency waiver process during disasters
 - EMACs
 - Prescription Monitoring
 - Biohazardous Waste Handling and Transport
 - EMS Systems
 - County and City Health Departments

D. National Health Reliability Organization (NHRO):

- Mission: Ensure the reliability of healthcare sector to the American public with the triple aim of quality, affordability, and accessibility. This includes during response to predictable disasters.
- Vision: A national healthcare sector that unleashes the innovation and compassion of the American people working in the free-market economy to provide reliable healthcare to the nation.
- Purpose: Provide the Healthcare sector a structure for self-governance to provide reliability--quality healthcare that is affordable and accessible. The NHRO is answerable to oversight for standards development, implementation, compliance, and validation.
- Goals:
 - Ensure a reliable, resilient Health Sector able to meet the healthcare needs of the nation even under extreme conditions or circumstances
 - Drive innovation in healthcare to reduce costs, gain efficiencies, and improve individual and national health and wellness,
 - Recruit the next generation of researchers and healthcare providers that continue to innovate and provide compassionate, reliable healthcare.
- Includes [Private Sector Organizations, Associations in membership](#)
- **The Regional Disaster Healthcare Response System (RDHRS)** is the preparedness model of the nation's Healthcare System: Hospital or cluster of hospitals covering a defined catchment area that is integrated with community level critical sector partners including public works, public safety, energy, transportation, logistics, and all of the [Medicare and Medicaid Participating Providers and Suppliers](#)
- Example from the Energy Sector: "[North American Electric Reliability Corporation \(NERC\)](#)"

NHRO Lead Council

- Chairman elected by Member Voters
- Executive Committee composed of NHRO Committee.

- Answers to the NHROG
- Reports to the Administration, Congress, Members, Customers
- Coordinates with Health Sector Coordinating Council (SCC)/ Government Coordinating Council (GCC)
- Administrative Support Staff (n=100's)
- Chartered with corporate governance processes, most work and output is done virtually.
- Public and External (inter-sector) Affairs



Admin Support Staff and the Gateway

- Gateway into the NHRO Environment
- Administrative support staff (n=100's) connected via the Portal Enterprise who manage the activities behind the scenes
- Help Desk for issues, topics, projects
- Virtual Emergency Operations Center, Incident management capability
- Information Sharing Analysis Center (ISAC)

Members (Partners?)

- Any organization engaged in meaningful aspects of healthcare or public health in the United States
 - Obligation to keep healthcare reliable—affordable, accessible, of good quality
 - Based on Mission, Purpose, Objectives, Activities
- Associations, Organizations, Professional Societies, Corporations, Hospitals
- All Members are characterized and "tagged" with specific traits for matching to "Alliances": Committees, Sub-committees, issues and projects
 - Functional Mission and Purpose
 - THIRA Risks
 - The 10 Dimensions of National and Homeland Security Framework
 - Financial (e.g., revenues, Profit/ non-profit)

Voters (Members?)

- Voters are members or employees of the Associations, Organizations, Hospitals, Corporations
- Voters retain one vote for each organization that they participate in that is a member of the NHRC.
- For hospitals and CMS Participating Providers and Suppliers, this includes staff members that are credentialed and privileged
- Note that many federal workers are voters through their professional associations
- Excludes unions



Committees and Subcommittees

Committees mirror the oversight within the Federal departments and agencies for ONE Health and the components contributing to healthcare and public health.

- They further define oversight to streamline process, clarify roles, responsibilities, and authorities, and facilitate coordination across the sector and public private partnership (FHRC/ NHRC)

- Chairman of Committees sit on the NHRC Executive Committee
- Sub-committees may be formed to account for greater specificity of effort.
- Alliances, issues, and projects may work across committees and sub-committees
- Committees/ sub-committees may want to include separate but linked issues/ projects that are closely related but look for different outcomes through the Forum.
- Committees are topic based and address issues that are interdependent. They use a matrixed approach to work issues and projects.
 - Healthcare Coalitions and Systems
 - Outcomes, Performance, and Learning
 - Biosafety and Ethics
 - Workforce
 - Education, Training, Certifications
 - Recruitment, Suitability, Career Progression
 - Professional Ethics Compliance
 - Implementation
 - Compliance and Enforcement
 - Global Health Security
 - Food Safety and Security
 - Drug Safety, Security, and Utilization
 - Science and Technology Advancement
 - Artificial Intelligence (AI) and Patient Interface
 - Diagnostics
 - Therapeutics
 - Advanced Vaccine Development
 - Healthcare Economics
 - Biodefense and National Security
 - Preparedness and Response to All Hazards
 - Health Information Technology and Data Exchanges

National Health Reliability Corporation develops standards to address challenges within the Health Sector

- Cost, quality, accessibility of healthcare
- Standards, best practices, clinical pathways guidelines
- Single Points of Failure in manufacturing, supplies, logistics
- Critical shortages of critical medications
- Health information ownership, handling, storing, exchange
- Actuarial registries for injury/ illness treatment outcomes
- Integrated clinical device algorithms
- National Trauma System (Zero Preventable Deaths Campaign)
- Stop the Bleed Campaign
- ...

- Issues are submitted to the NHRO for development of solutions
 - These become standards for the sector
- NHRO workforce includes employees in health sector industry and professional association members
- Issues are addressed by multidisciplinary sub-committees and working groups cross-linked to other, relevant sub-committees and working groups addressing interdependencies.

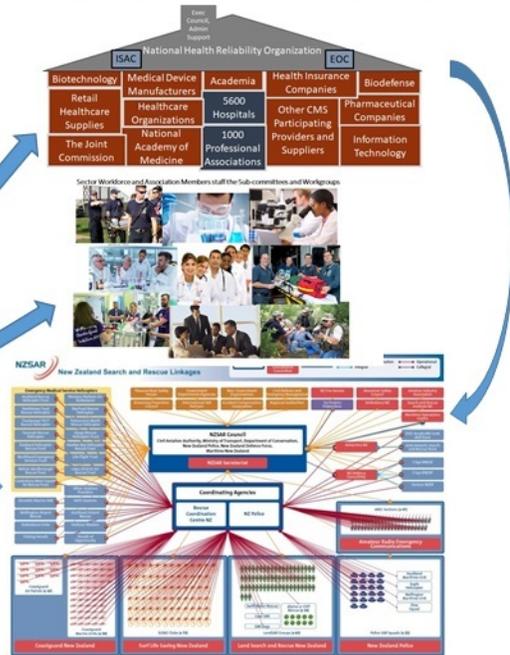


Figure 2. Standards Setting Organization Function for the National Health Reliability Organization (NHRO)

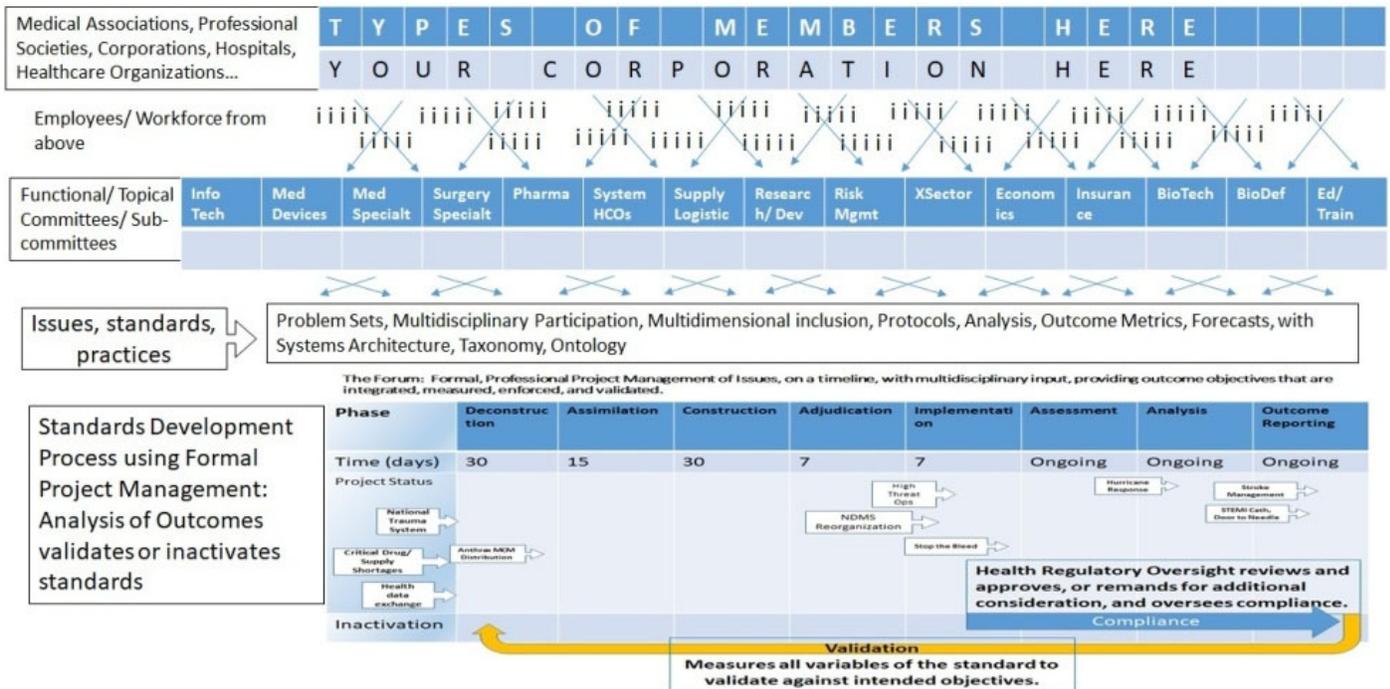
E. Standards Development Process, Alliances, and Working Groups

Alliances are determined by Issues or Projects, using members’ characterizations to identify who should participate.

- Requires a very detailed taxonomy and ontology of the healthcare system
- Relevance determines "mandatory" participants and "ad hoc".
 - Measurements and weighting factors identify significance of elements and their links and attachments to other elements to identify relevance for prioritization of attention and action level
 - Thresholds identify triggers and warning signaling or flags for attention to issues identified
 - Weighting factors employ fuzzy logic to capture various factors impacting relevance
 - Comprehensive PowerPoint Presentation
- Relationships
 - The system uses algorithms and smart humans using search to seek out common functions, objectives, activities, tasks, roles, responsibilities, authorities that indicate synergies that should be matched, aligned, collaborative, or may offer ready-made solutions.
 - "Match.gov"-like capability
 - Seeks to avoid redundant work, leverage good work already done, allow for crowd-sourcing issues for solutions.
 - Breaks through silos.
 - Interoperability, Dependency, Interdependency, Collaboration, Coordination
 - Personal relationships are promoted via gamification and use of avatars highlighting characteristics of users and leveraging the diversity of skill sets, talents, and experience, and characteristics

- Build great teams that express the diversity of personalities in the dramedy of the workplace
- Mandatory participants are those with "skin in the game", primary expertise or operational relevance to the issue (including secondary relevance).
- Operational Filters: Need to find all those with primary, secondary, tertiary interdependencies to consider the solutions
 - The systems are complex, non-linear, and dynamic over time
 - Solutions must be crowd-sourced (not group-think) to find single points of failure
 - The NHRC must measure outcomes across all healthcare coalitions to pick up indicators and warnings of failure points
- Operational mandates: The sector must account for beyond the daily routine missions and be able to conduct operational response that is unified with FSLTT government efforts.
- Solutions may also need to be customized to account for variables specific to or that have greater impact on different parts of the system.
 - For example, power outage requirements for air-conditioning in hospitals or nursing homes in the South during summer or heat in the North during winter.

Figure 3. diagram displays the process for developing topical committees, multi-disciplinary representation, and standards development structure.



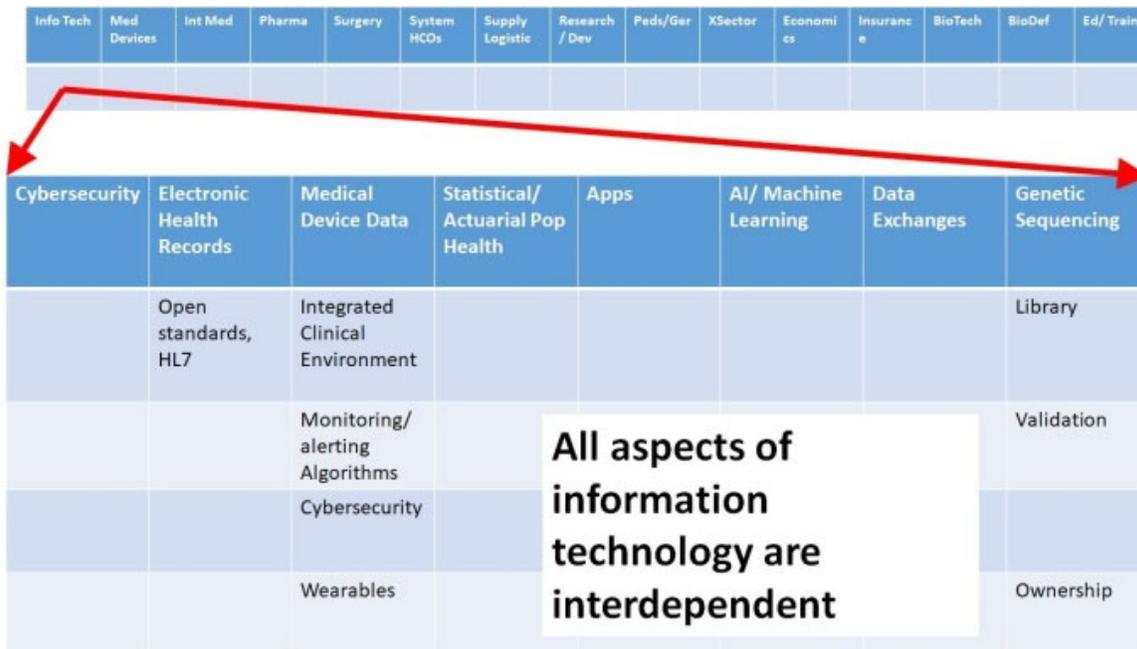


Figure 4 displays the sub-components of main topics, broken down further to critical sub-topics

F. Health Information Data Exchanges

Health Information Data Exchanges (HIDE) represent a new, emergent sub-sector

- A cottage industry allowing for secure, private sharing of data and information to optimize the healthcare provided nationwide
- Data has intrinsic and extrinsic value. Big data has big value. Trash or treasure, who can use the data?
- Data sharing/ brokerages in support of the NHRC.
- Another analogous system is the [National Weather Service](#)--billions of dollars invested in weather stations, satellite systems, and computational science now allows very accurate characterization, forecasting, and prediction of local weather patterns and national impact.
- Internet of Things (IoT) will collect data. The integration of data layers will need to be explored to find meaningful information (improving quality, decreasing cost, increasing access to healthcare).
- Should be a part of the publication of medical journals consolidated into libraries (see "The Academy" below).
- Actuarial versus statistical data outcomes that include additional data layers (demographics, geo-spatial locations, time, geography...)
- Algorithms for search, treatment, research, surveillance,
- Registries (virtual and active) for disease processes, treatments, etc..

G. The Forum

The Forum captures the business process "Rules of the Road" for addressing issues and projects using PNP Project Management Principles

- Wiki collaboration capturing authoritative, relational data in netcentric operations style with smart push, pull
- Provides situational awareness and is transparent to the public

- Has an associated healthcare information/ data exchange for capturing and measuring outcomes
- Issues/ Projects can be specific to national, regional, state, county, community, healthcare coalition
- Captures progression of projects/ issues through 8 phases
 - Deconstruction: Identifying the issue in detail to irreducible complexity including manpower, organizational structure, requirements, equipment, training, exercises, assessments, maintenance (annual costs), sustainment (outyear costs)
It should all use a standard format that forces the details to be determined up front. This makes assessment and outcome metrics determination easier (or possible) later on.
 - Assimilation: identifying relevant members to form the sub-committee (alliance) and bring them together to work the issue/ project
 - Construction:
 - Adjudication
 - Implementation
 - Assessment
 - Analysis
 - Outcomes Reporting and Standards Development
- Output is a "Standard", "Practice", or appropriately titled solution that is presented back to the appropriate subcommittee/ committee for review and approval, then sent to the appropriate regulatory entity for review.
- Compliance: Ensures objectives of the project are being met and are aligned with Healthcare Reliability Standards

The Forum: Formal, Professional Project Management of Issues, on a timeline, with multidisciplinary input, providing outcome objectives that are integrated, measured, enforced, and validated.

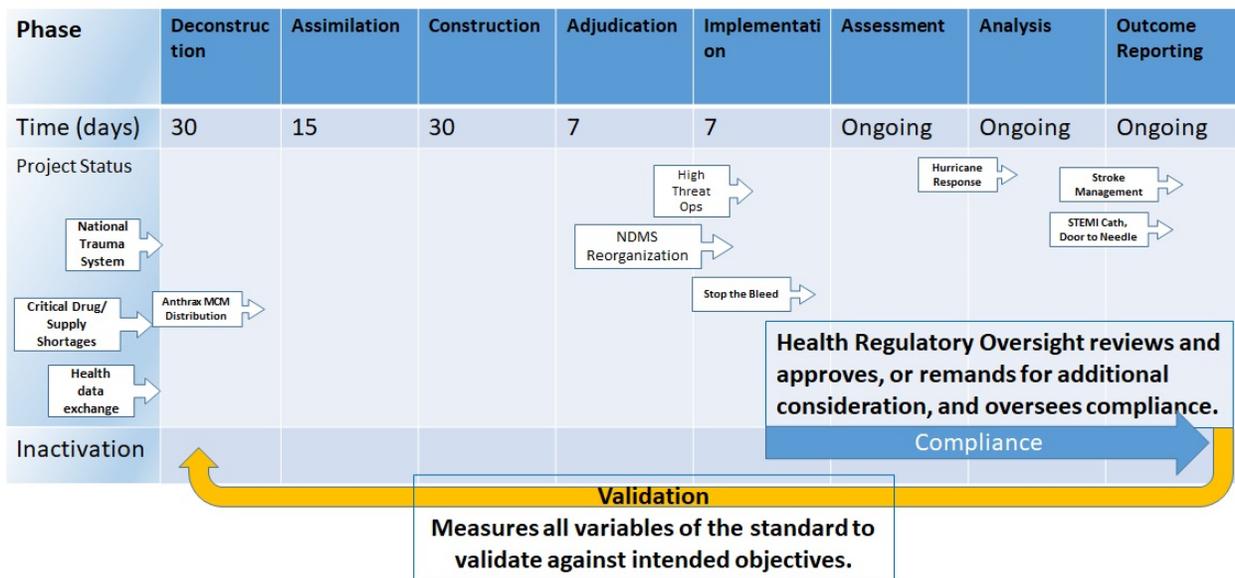


Figure 5 displays the Forum process for Project Management and Workflow for development, implementation, and validation of standards, best practices, guidelines.

H. Projects/ Issues

Projects and Issues address the key questions impacting the reliability of healthcare to keep in affordable, accessible, and of good quality

- Project Management Professional principles
- Voters cast ballots through Balanced Voting process
- Projects include a “[Clinical Scenario Repository](#)” to allow crowd-sourced patient and public input to provide insight on situations with potential or actual patient harm, as well as hypothetical situations where a clinician or layperson sees room for improvement.
- Issues/ projects require higher quorum and voter thresholds as they advance to the next section
- Failure to advance on time sets issue back to previous section
- Failure to meet quorum drops issue to inactive category
- Issues may be grouped to meet the needs of similar (but not the same) alliances
- Deliverable is a "standard", practice, guideline, or recommendation that is submitted to the FHRO for review and either approval or remanding back to the NHRO for further work.
- Sample Issues
 - National Trauma System
 - National Stroke Treatment System
 - National Cardiac Arrest Treatment System
 - National Burn Treatment System
 - National Poison Control System
 - National Biodefense System
 - Until Help Arrives Bystander Care System
 - Stop the Bleed
 - Basic Lifesaving
 - Health Information Data and Information Exchange
 - National Disaster Medical System
 - Preventable Adverse Events in Hospitals System
 - Altered Standards of Care
 - Emergency Preparedness and Response
 - Use of Social Networking, Apps, and Smart Phones in Disaster Response
 - Cybersecurity in Medical Devices and Systems
 - Combating Antimicrobial Resistance System
 - National Healthcare Contingency Response System
 - National Burn Treatment System
 - High Threat Response System (Active Shooter, Bombing)
 - Economies of scale and optimum sizing of healthcare organizations
 - The Healthcare Sector–Are Federal Healthcare Systems Necessary?

I. Outcomes and Investigations

Outcomes and Reports measure performance and test hypotheses of issues/ projects

- Standards
- Guidelines
- Best Practices
- Tiering Thresholds
- Performance and Outcome Metrics
- Implementation and Enforcement Mechanisms
- Expectations
- Performance Improvement Process
- Lessons Learned Information System (LLIS)

- Customized Reports are developed using the elements from the frameworks to provide **official** reports that are unique, informative views that allow for analysis, monitoring, and response actions.
- Data provided is "near real time", valid, and provided by the official authoritative source responsible for its validity.
- Max Collect and Analytics are an example of [Web 3.0](#) capability to do this.
- Advisory reports can provide "un-official" reporting (see below)

Independent National Health Safety Review Board and Process

- Standardized review process for significant events
- Specialized teams to review significant events (akin to National Transportation Safety Board (NTSB))

J. The Academy

Mega/ Meta Research Proposals, Novel use of data, Data Mining, Algorithm Development, Analytics, Modeling, Forecasting, NowCasting, Actuarial Data Analysis, Registries.

Goals: All scientific communication, technical papers involving data, analysis, analytics, modeling, graphing, predictions, forecasting, etc., must be captured in dynamic, technological formats in ways that capture incremental improvements—not on paper, Word, PDF, or Power Point (but exportable).

- [Bazaar versus Cathedral](#) academic research and development approach
- ["Computational Essays"](#)--text + computer input + and computer output.
- Understand motivators and challenges in health IT R&D;
- Accelerate health IT innovation and infrastructure development;
- Facilitate cross-sector collaboration and bridge existing silos;
- Boost innovation and promote U.S. global leadership; and
- Focus on people-centered solutions that support safety and effectiveness and enhance economic competitiveness.

Objectives:

- Improve medical, functional, and societal health outcomes through R&D in the use of data and IT for advanced health IT applications.
- Utilize digital information, data, and technology across the human lifespan in the areas of screening, diagnosis, treatment and surveillance; preventable medical error reduction; disease prevention; self-management of health behavior and wellness; healthcare; and disaster and emergency response that support improved individual and community health outcomes.
- Identify the motivators and challenges, needs, mechanisms of collaboration, and the ongoing research, in order to identify gaps and allow for enhanced coordination and planning of health IT R&D.
- Accelerate fundamental R&D for health IT;
- Facilitate accurate, secure and resilient health IT infrastructure, systems, and services;
- Foster health IT R&D innovation through data and knowledge sharing, best practices, and collaboration; and
- Enable evaluation of progress and long-term growth of health IT

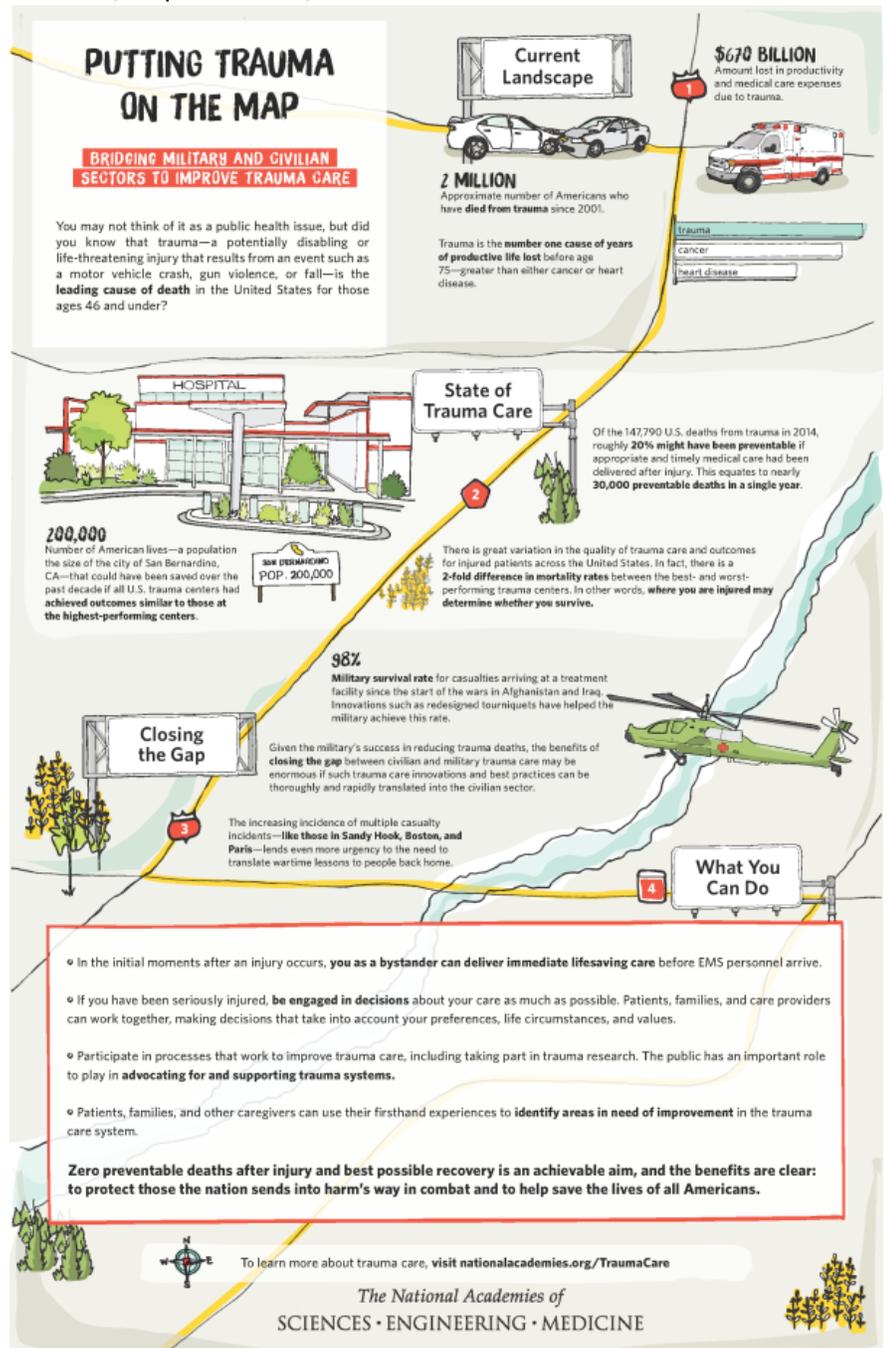
[Energy Sector](#) Academy example.

[Federal Health Information IT Research and Development Strategic Framework \(draft\)](#)

V. Next Steps

1. Engagement with Key Stakeholders for level of interest and validation and refinement of the concept.

- This is a transformational change to the Healthcare and Public Health Sector with the potential to impact the roles and authorities of keys stakeholders; however, there is good precedence rom other critical sectors.
- It is important to understand this impact, to design and refine the structure of the organizations in order to strike the proper balance of roles, responsibilities, and authorities. The intent is to shift the functional organizational responsibilities to an organizational structure empowered to represent the sector to make it more adaptive rapid technological advancement while keeping it focused on reliability drivers.
- The National Academy of Science, Engineering, and Medicine (NASEM) should host a workshop to evaluate the utility of a health reliability organization and the current status of the public-private partnership in the Sector. Building a coalition of the willing using key issues that are currently ripe as examples to demonstrate both the need for the organizing structure and a process to use. The “National Trauma System” represents a worthy example, using the recommendations from the 2016 NASEM study on “A National Trauma System: Zero Preventable Deaths”.
- A key follow-on effort should focus on the National Disaster Medical System and coordination of public (DOD and VHA) and private sector disaster response resources.



2. Further refinement of Roles, Responsibilities, and Authorities of the public and private sector organizations, captured in charters, business processes, policy, and legislation.

- This effort should be led by a specially commissioned group that includes the Executive Office of the President, Federal interagency, and private sector experts charged to look at current and future roles, responsibilities, and authorities between the FHRO and a NHRO. This should include looking at the impact on economics, standards, regulations, innovation, and leadership roles within the FHRO/NHRO and on the global stage.

3. Engagement with Congress for appropriate legislative changes

- Legislation would require the establishment of new regulatory oversight powers either in the Department of Health and Human Services, in a newly established Health Regulatory Organization, or both. These would be partnered with a private sector “Health Reliability Organization” empowered to ensure the reliability of healthcare and public health under normal and predictable disaster conditions.

4. Formal establishment of the organizations with process for establishment and assignments of roles, responsibilities, and authorities.

Annex A. Potential Members of a National Health Reliability Corporation (NHRC)

- International Partners:
 - WHO
 - PEPFAR
 - TB
 - PMI
 - Global Fund
 - Standards
 - [HL7 International](#)
- [ASTHO](#) Association of State and Territorial Health Officials
- [NACCHO](#) National Association of County and City Health Officials
- National Governors Association (NGA)
- Accreditation Entities
 - [The Joint Commission](#)
 - [National Center for Quality Assurance](#)
- Academia
 - Colleges and Universities
 - Research
 - Medical Centers
 - ACGME
 - Trade/ Technical Schools (Radiology, Laboratory, US, EMS,...)
- "Private Sector" (not all are truly private sector)
 - [American Red Cross](#)
 - Health care sector Industry (including [Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers](#).
 - Hospitals—section 1861(e)(9) of the Act and [42 CFR 482.1](#) through 482.66, (n=5564) [page link](#)
 - Fed Gov: 212
 - State or county owned: 1045
 - Private, non-profit: 2903
 - Private, for profit: 1025
 - Nonfed Psych: 401
 - Nonfed LTC Hospitals: 79
 - Hospital units in institutions: 10
 - Religious Nonmedical Health Care Institutions (RNHCIs)—section 1821 of the Act and [42 CFR 403.700](#) through 403.756.
 - Ambulatory Surgical Centers (ASCs)—section 1832(a)(2)(F)(i) of the Act and [42 CFR 416.2](#) and 416.40 through 416.52.
 - Hospices—section 1861(dd)(1) of the Act and [42 CFR 418.52](#) through 418.116.
 - Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Residential Treatment Facilities (PRTFs)—sections 1905(a) and 1905(h) of the Act and [42 CFR 441.150](#) through 441.182 and [42 CFR 483.350](#) through 483.376.
 - Programs of All-Inclusive Care for the Elderly (PACE)—sections 1894, 1905(a), and 1934 of the Act and [42 CFR 460.2](#) through 460.210.
 - Transplant Centers—sections 1861(e)(9) and 1881(b)(1) of the Act and [42 CFR 482.68](#) through 482.104.

- Long Term Care (LTC) Facilities—Skilled Nursing Facilities (SNFs)—under section 1819 of the Act, Nursing Facilities (NFs)—under section 1919 of the Act, and [42 CFR 483.1](#) through 483.180. Start Printed Page 63863
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)—section 1905(d) of the Act and [42 CFR 483.400](#) through 483.480.
- Home Health Agencies (HHAs)—sections 1861(o), 1891 of the Act and [42 CFR 484.1](#) through 484.55.
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)—section 1861(cc)(2) of the Act and [42 CFR 485.50](#) through 485.74.
- Critical Access Hospitals (CAHs)—sections 1820 and 1861(mm) of the Act and [42 CFR 485.601](#) through 485.647.
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services—section 1861(p) of the Act and [42 CFR 485.701](#) through 485.729.
- Community Mental Health Centers (CMHCs)—section 1861(ff)(3)(B)(i)(ii) of the Act, section 1913(c)(1) of the PHS Act, and [42 CFR 410.110](#).
- Organ Procurement Organizations (OPOs)—section 1138 of the Act and section 371 of the PHS Act and [42 CFR 486.301](#) through 486.348.
- Rural Health Clinics (RHCs)—section 1861(aa) of the Act and [42 CFR 491.1](#) through 491.11; Federally Qualified Health Centers (FQHCs)—section 1861(aa) of the Act and [42 CFR 491.1](#) through 491.11, except 491.3.
- End-Stage Renal Disease (ESRD) Facilities—sections 1881(b), 1881(c), 1881(f)(7) of the Act and [42 CFR 494.1](#) through 494.180.
- Healthcare organizations
- Health Insurance
- Pharmaceutical Companies
- Medical Equipment
- Medical Devices
- Medical Supplies
- Information Technology
 - Apps
 - EHR
 - Operation Systems Management
- S&T, R&D
- Biodefense
- Medical Publications
- Professional Societies: e.g., AMA, AHA
- Professional colleges: e.g. ACS, ACEP
- NREMT
- Industry
 - Occupational Safety and Health
- Policy Thinktanks
- Charitable Foundations
- Standards Organizations
 - FCC (wireless equipment, radio (EMS))
 - FAA (air transport)
 - ASTM
 - [IEEE](#)

- ISSO
- Integrated Clinical Environment (ICE) Medical Plug and Play
[Primer on Regulations in the Health Sector](#)

Annex B. Primer on Regulatory Commissions and Agencies

What are "Regulations" in Healthcare and Public Health Sectors?

- Regulations are intended to govern activities that potentially pose threats to public safety, health, well-being
- Healthcare and public health activities and services are based on these principles of public safety and health; access to affordable, quality healthcare; and well-being as the foundation for the sector.
- Need to distinguish between regulations, standards, best practices, guidelines, clinical pathways, recommendations, research, etc. as supported by scientific evidence and analysis.
- Processes (business process management) for efficiencies, effectiveness, cost, quality

Regulatory Commissions: Independent regulatory agencies create and enforce regulations to protect the public at large.

Key Points

- Independent regulatory agencies are situated in the executive branch of the government but are not directly under the control of the President.
- Regulatory agencies conduct investigations and audits to ensure that industries and organizations do not pose threats to public safety or well-being.
- Regulatory agencies are intended to be transparent, such that they are accountable to public oversight and legal review.

Key Questions

- Is a Health Regulatory Commission necessary, or would it simply be redundant to the authorities vested in government agencies at the FSLTT level?
- Would it add value that could not be obtained by placing the activity in the appropriate government agency or office?

Key Terms

- **Regulatory Agency:** A public authority or government agency responsible for exercising autonomous authority over some area of human activity in a regulatory or supervisory capacity.

A regulatory agency is a body in the U.S. Government with the authority to exercise authority over some area of human activity in a supervisory capacity. An independent regulatory agency is separate from the other branches of the federal government. These agencies are within the purview of the executive branch of government, *but are internally regulated rather than subject to the direct control of the President*. Regulatory agencies exist to supervise the administrative functions of organizations for the benefit of the public at large. To carry out this function, regulatory agencies are composed of experts in a specific policy area of administrative law, such as tax or health codes. Agencies may carry out investigations or audits to determine if organizations are adhering to federal regulations. Regulatory agencies are authorized to produce and enforce regulations by Congress, and are subject to Congressional and legal review as they carry out their functions. Congress may determine that regulatory agencies are obsolete, for example, and may therefore discontinue funding them. Similarly, Congress may choose to expand the authority of a regulatory agency in response to a perceived threat to public safety. Additionally, regulatory agencies are designed to be transparent, such that their decisions and activities are able to be evaluated by the public and by legal review boards.

Members of the Council of Independent Regulatory Agencies

MEMBERS

- Consumer Financial Protection Bureau
- Consumer Product Safety Commission

- Commodity Futures Trading Commission
- Equal Employment Opportunity Commission
- Federal Communications Commission
- Federal Deposit Insurance Corporation
- Federal Election Commission
- Federal Energy Regulatory Commission
- Federal Housing Finance Agency
- Federal Maritime Commission
- Federal Mine Safety and Health Review Commission
- Federal Reserve Board
- Federal Trade Commission
- U.S. International Trade Commission
- Merit Systems Protection Board
- National Labor Relations Board
- Nuclear Regulatory Commission
- **Occupational Safety and Health Review Commission**
- Postal Regulatory Commission
- Securities and Exchange Commission
- Surface Transportation Board

*Note no oversight of healthcare quality, cost, and effectiveness.

Major U.S. Federal Regulatory Agencies

- **Consumer Product Safety Commission (CPSC):** enforces federal safety standards
- **Environmental Protection Agency (EPA):** establishes and enforces pollution standards
- **Equal Employment Opportunity Commission (EEOC):** administers and enforces Title VIII or the Civil Rights Act of 1964 (fair employment)
- **Federal Aviation Administration (FAA):** regulates and promotes air transportation safety, including airports and pilot licensing
- **Federal Communications Commission (FCC):** regulates interstate and foreign communication by radio, telephone, telegraph, and television
- **Federal Deposit Insurance Corporation (FDIC):** insures bank deposits, approves mergers, and audits banking practices
- **Federal Energy Regulatory Commission (FERC):** Oversees reliability of the Energy Sector and electricity supply
- **Federal Reserve System (the FED):** regulates banking; manages the money supply
- **Federal Trade Commission (FTC):** ensures free and fair competition and protects consumers from unfair or deceptive practices
- **Food and Drug Administration (FDA):** administers federal food purity laws, drug testing and safety, and cosmetics
- **Interstate Commerce Commission (ICC):** enforces federal laws concerning transportation that crosses state lines
- **National Labor Relations Board (NLRB):** prevents or corrects unfair labor practices by either employers or unions
- **Nuclear Regulatory Commission (NRC):** licenses and regulates non-military nuclear facilities
- **Occupational Safety and Health Administration (OSHA):** develops and enforces federal standards and regulations ensuring working conditions
- **Securities and Exchange Commission (SEC):** administers federal laws concerning the buying and selling of securities *Note no oversight of healthcare quality, cost, effectiveness.

Annex C. Dimensions of National and Homeland Security Framework

Understand the multidimensional framework for homeland and national security, the dimensions that must be included in developing the systems architecture. Understand the implications for “reliability”, mission assurance, interoperability, and interdependencies.

- **PNT:** The conventional dimensions captured by position, navigation, and time (PNT)
- **FSLTT:** Across the governance jurisdictions including international and Federal, (regional), state, local (county, township, city, town, village), tribal, territorial (FSLTT)
- **Geography type:** Geographical regions and locations (Mountainous, Hills, Plains, Coastal, Desert,...)
- **Accessibility/ isolation,** e.g, by distance, terrain (rivers, mountains, gorges) and dependency on critical infrastructure (bridges, seaports, airports,...)
- Associated **regional risks/ hazards** (hurricanes, earthquakes, mudslides, fires, volcanos, tsunamis, tornados,...)
- **Demography:** Demographics, population density (dense urban, urban, suburban, exurban, rural, wilderness) and land/ resources usage
- **Criticality of nearby Infrastructure** and potential interdependencies
- **Critical Sectors and Functions** aligned with economic sectors and encompassed in Federal department leads and emergency support functions.
- **C4:** Level of management/ command from strategic to operational to tactical.
- **Incident Type:** chemical, biological, radiological, nuclear, explosive (CBRNE), cyber, to “all-hazards” including naturally occurring
- **Source of threat:** Nation state, terrorist supported, lone-wolf, accidental, and naturally occurring incidents
- **Phases of an incident** (Prevent, Protect, Mitigate, Respond, Recover)
- **Complexity:** Level of understanding of conditions (Known, Knowable, Complex, Chaotic), Wicked Problems
- **Information Technology:** Degree of information interconnectivity (Web 1.0-4.0)
- **Oversight surety of actions:** regulations, standards, best practices, guidelines, recommendations
- **Quality, Accessibility, Cost**
- **Risk**
- **Security**
- **Safety**
- **Supply lines**
- **Surge Capacity**
- **Resilience**
- **Complexity**