

# **PULSE Getting Started Guide**

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### **Overview**

The Patient Unified Lookup System for Emergencies, or PULSE, orchestrates health information exchange during declared disasters to provide care to displaced patients, whereby improving patient outcomes. Specifically, PULSE is a web portal that allows credentialed providers to view electronic patient data during disaster response. Following disasters such as hurricanes, tornadoes, or public health emergencies, patients often seek medical treatment outside of their typical care network. As a result, providers have access to incomplete clinical data which may compromise the quality of patient care.

With a simple search on PULSE, credentialed providers can view documents which may include medications, allergies, diagnoses, and lab results for patients who are displaced outside of their normal health care environment. Once PULSE is deployed in a state, it can be quickly activated to respond to widespread disasters that can occur at a moment's notice.



## Step 1. Is PULSE the Right Tool for You?

This section helps users assess whether PULSE aligns with their implementation goals and whether they have the infrastructure in place to implement this technology. We suggest that all stakeholders from state and local government who may be involved in PULSE (e.g., Emergency Management, Medicaid, Public Health, etc.) be consulted during these deliberations.

- 1. Do your disaster response personnel and disaster health care volunteers lack access to patient health records?
  - Would you like to ensure that health care providers in medical shelters or other alternate care sites have access to patient records when treating individuals who have been displaced by disaster?
  - Is there value in having real-time electronic access to this information at these facilities?
- 2. Is your population likely to be affected by an incident or event that would require medical care to be provided in alternate care sites?
  - Does your state/locality regularly experience natural disasters?
  - Does your state/locality host mass gatherings that may be a target for terrorist attacks?
  - Are you located in an area where there is a need for advance planning due to seasonal events?
- 3. Have you identified administrative leadership for PULSE implementation, maintenance, and deployment?
  - Have you identified leaders who will serve as champions and advocates for the successful implementation of the PULSE system?
  - Is there clear agreement on which agency/office should have accountability for the PULSE program?
  - Do leaders in emergency response support the use of PULSE?
- 4. What is the state's health information exchange infrastructure capacity?
  - What current health information exchange infrastructure and capabilities (e.g., notifications, query portal, Direct secure message, connections to eHealth Exchange, hospital networks, public health reporting) is available in your state or jurisdiction?
  - Does your state already use other vendor-supported technologies to exchange health records for more coordinated patient care?
  - To what extent does leadership in your state, jurisdiction or locality embrace the value of health information exchange?
  - How extensively are document---based queries implemented in the jurisdiction or state? For instance, is there a sufficient portion of the population covered so that patient information is likely accessible in the event of a disaster?



### 5. Is there a potential overlap or conflict with existing programs and processes?

- Are there existing emergency preparedness programs or applications used in your state, locality or jurisdiction that will require modification if PULSE is deployed?
- Will PULSE need to be customized to align with or complement other existing programs or applications that are used during a disaster response?
- 6. Do you have adequate resources (human and financial) to support the PULSE Program?
  - Have you identified funds to support the initial and maintenance costs of the PULSE Program?
  - Have you identified your <u>funding mechanisms</u> (e.g., state general funds, matching funds, federal emergency funds, matching funds) for PULSE?
  - If you plan to acquire funding through State Medicaid or Public Health agencies, is there an
    advocate responsible for ensuring all Implementation Advanced Planning Document (IAPD)
    documents are created and submitted appropriately for funding requests? <u>(See the
    funding and contracting documentation for further information)</u>
  - Are qualified information technology and emergency preparedness personnel available to support the implementation and deployment of PULSE?

### 7. Are there relevant state or local laws that must be considered?

- If the PULSE system will connect with the Prescription Drug Monitoring Program (PDMP), has the state aligned data access policies for providers, dispensers, and delegates with the volunteer health professional provider types?
- Has the state aligned privacy policies with federal privacy policies?



### Step 2. What are Your Funding Requirements for PULSE?

### **Financial Considerations and Contracting**

### Funding:

• Determine how PULSE will be funded, including funding limitations or other considerations.

### Contracting:

- Determine who is best suited to handle contracting for PULSE.
- Are joint sponsors needed?
- Would there be different contracts for implementation and ongoing support?

### **Operating Costs:**

Lessons learned from early experiences implementing PULSE, suggest allocating a significant portion of the funding (e.g. 50%) to on-the-ground preparations to use PULSE, including:

- Infrastructure assuring there are laptops and Internet connectivity in the alternate care sites (ACS)
  - Communications and Outreach to raise awareness of PULSE and encourage volunteer health professionals to register in the state Emergency System for Advance Registration of Volunteer Health Professionals (ESAR VHP) system (if it is used to authenticate PULSE users)
- User education and training to assure users understand what PULSE is and how it is used prior to disasters, with refreshers available in disasters.

### **Technical Costs:**

- The cost to cover the technical implementation and operation PULSE will vary depending upon jurisdictional operational decision points on management and administration of the system.
- Determine the extent to which the jurisdiction can contract with a third party to implement and operate PULSE and which functions, if any, must be managed by the jurisdiction.



## Step 3. What are Your Funding Options for PULSE?

This section provides information on various potential funding pathways for the implementation and maintenance of PULSE. This section should be considered and discussed in the early planning stage of PULSE Program development.

The Federal Government offers several potential funding options for states to offset the cost of implementing the PULSE program. It is important to keep in mind that there is almost always a "match" that must be in place in order to utilize these federal funds. PULSE is available for use by all states, localities and jurisdictions, however funding at this time is secured through the state process. PULSE funding options included in this document can come from different federal sources noted below 1) Medicaid Enterprise Federal Funding Participation (FFP) and 2) Emergency Management Funding. Once it has been decided that PULSE is going to be pursued within a state, the first step is to become more familiar with the funding options. These are currently as follows:

### Medicaid Enterprise 90-10 Funds

Centers for Medicare & Medicaid Services (CMS) can provide federal funding at 90 percent matching rate for state expenditures on activities to promote health information exchange (HIE).<sup>1</sup> Federal Funding Participation (FFP) funding requests submitted from State Medicaid Agencies to the CMS and other federal agencies through the Implementation Advance Planning Document (IAPD) process. States must secure 10 percent of the funding amount to receive the 90 percent matching rate (90-10). State Medicaid Agencies can pursue different IAPD processes.

*HITECH IAPD* - The HITECH Act provides funds that are available for the design, development and implementation of systems and tools that support health information exchange. This funding stream expires in September 2021. Below are some items to consider when pursuing HITECH funding:

- HITECH funds are only available until September 2021 for design, development, and implementation (DDI) uses
- HITECH funds are available for standing up a new system, tool or program but are not to be used for ongoing maintenance of the tool
- Requests for funds through the IAPD process must identify the Medicare and Medicaid Promoting Interoperability program objective clearly. For instance, if PULSE is going to be part of the health information exchange in your state, you will want to clearly identify and describe this. Here are some examples of projects that are typically approved for the use of HITECH funds:
  - o Building infrastructure

<sup>&</sup>lt;sup>1</sup> <u>https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/SMD16003.pdf</u>

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- o Building specialized registries
- o Projects that encourage the use of the health information exchange
- o Projects that support emergency medical services and response in a disaster event
- o Projects that encourage interoperability among providers and/or payers
- As mentioned, HITECH funding is requested through the IAPD process by the Medicaid Agency in your state. It is not unusual that PULSE might be implemented by another state agency, such as the Public Health Department or Emergency Management Office, however funding is requested on behalf the implementing entity by the State Medicaid Agency
- As with any Federal funding option, there are stringent reporting processes that should be put in place for managing and reporting the use of HITECH funding
- Consider the following criteria (at a minimum) when writing an IAPD:
  - o Activities must support Medicare and Medicaid Promoting Interoperability program measures (formerly known as the Meaningful Use)
  - o Activities must support onboarding of providers and interoperability between such
  - o Investment support activities exchanging exchange of electronic health information
  - o Focus on design, development and implementation (not maintenance)
  - o Reuse previous technical investments to promote sharing, leverage, and reuse of Medicaid technologies and systems
- The 10 percent match can be a challenge in terms of applying for CMS funding. Matching funding options can vary, and the following list identifies examples for matching funds:
  - o State general funds to support emergency preparedness, public health, and/or Medicaid
  - o State dollars appropriated for health information technology infrastructure
  - o State tax on health care services
  - o State tax on commercial health insurance products
  - o Payor taxes/surcharges
  - o Vaccine trust account
  - o In-kind contributions, however state-supported staff time is not allowed

### Additional Resources:

- <u>SMDL #18-007</u> 21st Century Cures Act Section 5006 Compliance Provider Directories
- <u>SMDL #18-006</u> Leveraging Medicaid Technology to Address the Opioid Crisis
- <u>SMDL #18-005</u> Mechanized Claims Processing and Information Retrieval Systems Reuse
- <u>SMDL #16-010</u> Mechanized Claims Processing and Information Retrieval Systems Modularity
- <u>SMDL #16-009</u>Mechanized Claims Processing and Information Retrieval Systems APD Requirements
- <u>SMDL #16-004</u>Mechanized Claims Processing and Information Retrieval Systems-Enhanced Funding
- <u>SMDL #16-003</u> Availability of HITECH Administrative Matching Funds to Help Professionals and Hospitals Eligible for Medicaid EHR Incentive Payments Connect to Other Medicaid Providers



- <u>CMS Answers to Frequently Asked Questions (FAQs)</u>Eligibility for 90 percent Federal matching funds for health information exchange activities through the Medicaid Electronic Health Record Incentive Program
- <u>SMDL #11-004</u>Use of administrative funds to support health information exchange as part of the Medicaid EHR Incentive Program

### Medicaid Enterprise System Funding

Medicaid Enterprise System (MES) funding is available to enhance the Medicaid Enterprise system that each state Medicaid office is required to put in place. The MES is typically more than just a collection of modular software/applications and technology hardware. It often includes business processes that might enhance the very complex process of administering Medicaid (as a payer) in states. Federal law provides the following options in terms of MES funding:

- 90-10 FFP funding is available for design, development, and implementation (DDI) funding for modular systems, such as disaster response platforms for patient triage and care in a declared disaster. This include web-based portals, network interfaces, and analytics capabilities.
- 75-25 FFP funding for the maintenance and operations of a MES system or program. This includes the following:
  - o Manage case information
  - o Care management registries
  - o Manage treatment plans and outcomes
  - In order to utilize 90-10 funding properly for DDI, the state agency must account for several key factors such as cost allocation, modular certification and outcome measures. If these are not met, then CMS may approve at a 50-50 match
  - If you are considering PULSE implementation through MMIS funding, consider using the current HIE cost allocation approach for your state, as PULSE will be connecting to existing networks
  - o Consider using HIE outcome measures as PULSE would support these measures during a declared emergency. Be clear in your request for funding that PULSE would only be activated during a declared emergency
  - Consider using existing outcomes measures for the HIE if those are available as CMS requires 6 months of information on these measures. Ensure that you have your simple and easily measured outcomes ready to go as you implement PULSE so that you can start recording these outcomes early
  - o As with the HITECH 90-10 funding approach, MES 75-25 funding is requested through the IAPD process. Additionally, an Operations Advance Planning Document (OAPD) is required
    - MES 75-25 funding can be used for maintenance and operations.

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# Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act Funding

The SUPPORT Act provides 100% funding for programs and tools that address the nation's opioid overdose epidemic. This funding is available to support PULSE implementation if the state can include information from its qualified Prescription Drug Monitoring Program (PDMP), through an interoperability interface. States must consider alignment with PDMP access policies for appropriate providers and delegate access, as volunteer health professionals may not fall within the allowable PDMP access policies. Below are some items to consider when applying for SUPPORT ACT funding:

- Funding can be used for planning, implementation, interface upgrades, performance reporting and outcomes reporting
- A SUPPORT Act Advance Planning Document is required for this 100% funding option. The funding is available through September 2020

### Additional Resources:

 FAQ SUPPORT for Patients and Communities Act, Section 5042 – Medicaid PARTNERSHIP Act <u>https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/faq051519.pdf</u>

# Public Health Emergency Preparedness (PHEP) and Hospital Preparedness Program (HPP) Funding

The Hospital Preparedness Program (HPP) and Public Health Emergency Preparedness Program (PHEP) are administered out of the Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Centers for Disease Control and Prevention (CDC), respectively. The HPP and PHEP programs each fund 62 cooperative agreement recipients: all 50 states, four localities, and eight territories and freely associated states. Both programs require recipients to develop and implement capability-based work plans and use their funding to build and sustain their readiness and response capacity. These programs include capabilities related to information sharing, surge management, and mass care, all of which PULSE aims to support. Both cooperative agreement programs also allow funding to be used for technology that supports these capabilities and the provision of public health and medical care to populations affected by disaster.

### Additional Resources:

- https://www.grants.gov/web/grants/view-opportunity.html?oppId=313435
- https://www.cdc.gov/cpr/readiness/00\_docs/PHEPNOFOFastFactsDocumentFINAL\_3419.pdf.pdf



### Homeland Security Grant Program (HSGP)

Homeland Security Grant Program funding is administered by the Department of Homeland Security/Federal Emergency Management Agency (DHS/FEMA) and is intended to "enhance the ability of state, territory, local, and tribal governments to prevent, protect against, respond to, and recover from terrorist attacks and other disasters." HSGP supports the goal of Readying the Nation for Catastrophic Disasters. The HSGP is a combination of three grant programs: State Homeland Security Program (SHSP), Urban Area Security Initiative (UASI), and Operation Stonegarden (OPSG) and each has its own requirements. However, DHS/FEMA has recently shifted to organizing its national priority areas according to "Lifelines," one of which is Health and Medical. The State Homeland Security Program (SHSP) allows up to 10 investments, one of which is emergency communications that is interoperable with other systems, but more generally any investment supports closing capability gaps or sustaining capabilities identified in the THIRA/SPR process will be considered. If applying for an investment related to emergency communications Interoperability Plan.

### Additional Resources:

https://www.fema.gov/homeland-security-grant-program



### Step 4. What Contracting Options are Available?

This section can be used to understand the different contracting options which may be used to implement and maintain PULSE. The Patient Unified Lookup System for Emergencies is available to all states, territories and localities to support access to medical records during a declared emergency. In most instances where PULSE is either in production or in the process of being implemented, a state agency typically takes the lead on securing funding either at a state or most likely at a federal level and determining the process for creating a contract to procure PULSE. Below are several options to consider in terms of contracting for PULSE.

### **Types of Contracts**

### **Request for Procurement**

A Request for Procurement (RFP) is defined as a document that defines the goods and services that need to be received by the state, etc. The procurement request package typically includes a detailed statement of work, business requirements and specifications. This forms the basis for an invitation to submit a bid for the work. Sometimes RFPs are written in a broad manner so that those responding to the RFP may present their ideas and strategies for delivering within confines around those strategies.

State governments typically have different laws around how RFPs are issued. If it is determined that a request for procurement is required for PULSE, this will typically add in time in terms of allowing vendors the appropriate amount of time to reply, reviewing the proposals, responding to bidders' questions, bidder conferences, etc.

### **Questions to Consider:**

- 1. Does the state have a designated health technology funding policy and structure (e.g., designated entity)?
- 2. If the state must utilize the Request for Proposal process, are there adequate resources to support this process? This includes staffing and time.
- 3. Does the funding that has been allotted for this procurement support a sole source procurement or must the procurement be competitive only?
- 4. Does the state allow requests for information vs. requests for procurement?

### **Request for Information**

The Request for Information (RFI) is primarily used to gather information to help make a decision on what steps to take next in terms of a procurement. RFIs are seldom the final stage of the procurement and are often instead used in combination with the RFP process. For instance, if the state is not certain that a service or product is a sole source, the entity may opt to issue a RFP with a quick turnaround time to gauge the market in terms of product or service availability. If only one response is received, the state could

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determine that this procurement is indeed a sole source and convert the RFI to a contract document with the responsive vendor. This may result in a quicker turnaround time and less strain on state resources. States should confirm before proceeding down this path whether or not converting a RFI to a contract is allowed in the respective state.

### Sole Source

A sole source procurement can be defined as any contract entered without a competitive process, based on a justification that only one known SOURCE exists or that one single supplier can fulfill the requirements.

Sole source procurements can be tricky depending on the requirements for a particular state government. Typically, most sole source procurements require specific documentation on why this service or product is deemed the sole option. Sole source procurements may also require extensive review and approval from a variety of levels of state government, up to and including the state attorney general's office. State agencies may also have additional requirements and documentation pertaining to sole source procurements on top of or outside of the state government requirements. Documented due diligence in terms of extensive research on the availability of a product or service is also typically necessary.

### **Questions to Consider:**

- 1. Does the state allow sole source procurements?
- 2. If so, are sole source procurements available with for profit vendors or only with sole source vendors?
- 3. What is the specific documentation needed in order to allow a sole source procurement?
- 4. Who needs to approve/review the sole source procurement?
- 5. Will PULSE be implemented by a state government or entity directly or will a nonprofit or state supported resource be responsible for implementation? For example, is there a HIE in the state that will implement PULSE? Is there integration with other HIE services needed?

## Step 5. What Features and Technical Specifications Should You Include?

### Purpose

This section provides information on features and base technical requirements for PULSE. The information included is intended to give implementers an overview of PULSE, the main components of the system (PULSE User Interface (UI), PULSE Authentication & Authorization, and National Network Connectivity), and certain technical considerations that should be planned for when pursuing a PULSE vendor. Additionally, this information serves as a framework for procurement requirements such as contracts and requests for proposal (RFPs).

This section does not include specific system architecture nor other design elements of PULSE. This section also does not include specific implementation guidance, business requirements, or best practices for PULSE. Further information at this level of detail will also be available in the final version of this document due to be released later in 2020.

**Note:** As of the release date of this version, the PULSE platform is undergoing certain enhancements to improve its functionality and ease of use. As these enhancements are further developed and tested, some of the features and technical specifications include in this section may change. The final version of this document, which will be available later in 2020, will include all features and technical specifications related to these enhancements.

### **Target Use Cases**

The PULSE system is designed to allow volunteer health care providers access to electronic health information during disasters. This information could include patient health history, care information, and medications for the following populations:

- Displaced patients evacuated from health care facilities in the disaster area
- Injured victims of the disaster transported by first responders
- Injured victims of the disaster transported by themselves, family, or neighbors
- Evacuees presenting to alternate care facilities (ACFs) with minor injuries or medical needs requiring treatment
- Evacuees whose primary care for chronic conditions or health issues has been interrupted due to the disaster's effects

The main user activities within PULSE are as follows:

- Administrators can activate PULSE during or in preparation of an emergency
- Authenticated volunteer health care providers can login to PULSE
- Users can search and view clinical information that is pulled from national networks
- Users can recall and view previous patient search history
- Audit users can generate reports for audit information

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### **User Roles**

Access to different features in the PULSE system is granted depending on assigned user role. The three user roles included in PULSE are:

- 1. *Administrator*: Able to access all features and functions of PULSE. Can access administrative or configuration functions via authenticated access to underlying server systems and configuration files.
- 2. **Basic User:** Can access the system through a web browser to query for patient matches, query for existing documents related to the matched patient, and retrieve documents relevant to the care and treatment of the patient.
- 3. *Auditor*: Can access only the reporting functions of the system, which can be used alone or used in combination with other roles.

Notes:

- No roles will have access to other roles' functions. However, a user may be assigned multiple roles thereby gaining access to multiple functions.
- Over time, other roles may be created and added to the PULSE platform.

### System Components

The PULSE web application consists of three main functional components:

- PULSE User Interface (PULSE UI) This emergency health information lookup system enables appropriately verified disaster health care volunteers to access electronic health information during disasters. This information may be drawn from disparate systems within and outside of the affected region. Users will access health information through a web-based portal and can search for and retrieve information from within connected electronic health record systems or health information exchange systems. PULSE is not intended to be a replacement for an electronic health record, electronic patient care reporting system, or any other means for documenting care, but a supplement to other such systems.
- 2) PULSE Authentication & Authorization This is the integration point with ESAR-VHP databases or other provider verification systems specific to each state's deployment. Users can login to PULSE via the main PULSE UI and are authenticated using Single Sign On (SSO) via Security Assertion Markup Language (SAML). States can manage credentialed and verified health professionals at a local, regional, or state level. Integrating with the existing provider verification systems improves validation of volunteer health professional at ACFs. Additional integration points may be needed based on the state's technology ecosystem and investments. States that do not have a robust provider verification system are able to manually populate appropriately authorized providers into the PULSE system.



3) National Network Connectivity – The final functional component of PULSE is the interoperability network endpoint that connects the disaster area with regional and national networks to access the health information that will be presented in the UI. National networks include eHealth Exchange and are soon expected to include CareQuality and Commonwell. These networks may also include regional health information organizations and networks that will provide the clinical summary information.<sup>2</sup> PULSE can connect to custom organizations if they are implemented using the Integrating the Healthcare Enterprise (IHE) standard transactions, which follow the technical connectivity specifications from eHealth Exchange.<sup>3</sup> Of these, the transaction to dynamically ingest a directory of participating organizations, query for a patient based on demographics, query for available documents and retrieval of one or more documents are strictly required.<sup>4</sup>

### <u>PULSE UI</u>

The PULSE UI includes a Basic User Interface and an Administrator Interface that together encompass the following functions to meet patient care requirements, administrative uses, and integration needs.

### **Overall System Requirements**

**Basic User Interface Features** 

- SSO via SAML to state ESAR-VHP or other designated provider verification system to provide authenticated users access to the system and patient health records
- ACF assignment selection
- A search function for patient matches based on an individual's demographic information
- Functionality to list and display available documents for a given patient match returned by one or more external health systems
- Document metadata regarding the origin of the documents returned
- Option to select at least one patient document from among the search results for document retrieval
- A patient document viewer to a Consolidated Clinical Document Architecture (CCDA), which is generally a consolidated view of the patient's medications, allergies, problems, etc.

#### Required Technical Architecture for the Basic User Interface

 PULSE is designed leverage Amazon Web Services (AWS) infrastructure. This allows PULSE to be deployed in a scalable cloud hosted infrastructure leveraging multiple technologies<sup>5</sup> including:
 Docker containers<sup>6</sup>

<sup>&</sup>lt;sup>2</sup> https://www.healthit.gov/topic/health-it-initiatives/what-connect

<sup>&</sup>lt;sup>3</sup> https://ehealthexchange.org/testing-program/exchange-specifications

 <sup>&</sup>lt;sup>4</sup> https://www.ihe.net/uploadedFiles/Documents/ITI/IHE\_ITI\_TF\_Vol2b.pdf

<sup>&</sup>lt;sup>5</sup> https://aws.amazon.com/products/

<sup>&</sup>lt;sup>6</sup> https://docs.aws.amazon.com/AmazonECS/latest/userguide/docker-basics.html

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- Various AWS databases and data stores including S3, Aurora, RDS
- AWS Compute services including Lambda, EC2, and EKS
- o AWS Network & Content Delivery including VPC, Route 53, and Cloud Map
- PULSE is composed of several components. The underlying programming languages are:
  - o The UI and web application are based on JavaScript
  - o The SSO and SAML portions are based on Java
  - o The open source CONNECT is based on Java
  - o The business logic of PULSE is based on .NET Core
- PULSE:
  - o Supports the English language
  - o Is available through a web browser and will scale to the size of the device screen
  - o Is not a mobile application
  - o Is not available in the Apple or Android application stores
  - o Must run on a web browser that has been released in the past two years from a common vendor and supports Javascript and HTTPS
  - o Requires HTTPS and TLS security infrastructure using X.509 certificates

### Administrator Interface Features

The PULSE administrator requires an overarching view of the usage, logins, and metrics when the platform is deployed. The following features should be included in the administrator interface (at minimum):

- The capability to for authenticated Administrators to activate and deactivate PULSE
- The ability to activate PULSE at the jurisdictional level by state, county, town, zip code and others as determined necessary
- An administrator dashboard that includes basic user and administrator usage statistics, active ACF locations, number of active users, number of patient searches, and number of successful document retrievals
- Audit log capabilities to record information including emergency health information look up queries received, queries and requests placed to external systems, responses to those requests, and other activities
- An Audit Log feature that includes several tables in a relational database management system and is extensible for future identified audit needs

Required Technical Architecture for the Administrator Interface

• Same as for Basic User Interface

### **PULSE Authentication & Authorization**

When PULSE is activated, the web portal is opened and easily accessible through a URL. PULSE must also be able to integrate with the identified state IT systems to authenticate and authorize appropriate users. There are two key aspects to credentialing users: (1) providing usernames/passwords to authorized Version 1.0 (Draft), 01.27.2020 18



users; and (2) determining who should have access, particularly across states, since state laws differ on access to patient health information. The authentication and authorization component of PULSE must meet the following minimum requirements:

### **Overall System Requirements**

### **Authentication & Authorization Features**

To use PULSE in tandem with an existing user management infrastructure such as ESAR-VHP, the following are required:

- Integration and secured network connectivity with ESAR-VHP portal through SSO
- Ability to facilitate interactions with other components using SSO and appropriate industry standards to identify and authenticate appropriate end users, such as:
  - o SAML 2.0, OAuth, or OpenID

### Required Technical Architecture

- PULSE:
  - o Allows SSO users to login to the PULSE application
  - o Can integrate with any ESAR-VHP application that supports SSO with SAML 2.0 from a support browser
  - o Relies on specific browser requirements (see above)

### National Network Connectivity

National network connectivity enables PULSE users to query regional and national networks for health information that will be presented in the UI. The national network currently included in PULSE is eHealth Exchange, but CareQuality and Commonwell are expected to be added soon. PULSE may also include regional health information organizations. However, PULSE can only connect to organizations using IHE standard transactions supported by eHealth Exchange, including (at minimum) the ability to dynamically ingest a directory of participating organizations, query for a patient based on demographics, query for available documents and retrieval of one or more documents are strictly required.<sup>7</sup>

### **Overall System Requirements**

### National Network Connectivity Features

- A query function that links to external health systems using interfaces to identified national and regional systems
- Queries external health systems for documents containing health information for any matched patient identified through Patient Discovery

<sup>&</sup>lt;sup>7</sup> https://www.ihe.net/uploadedFiles/Documents/ITI/IHE\_ITI\_TF\_Vol2b.pdf

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- Retrieves documents containing health information for the matched patient from external health systems using a standards-based web service that allows PULSE to retrieve specific documents identified through Query for Documents
- Provides the ability for the PULSE Directory Service to connect to the eHealth Exchange nationwide network
- Connects to eHealth Exchange

Notes:

- Other networks including CareQuality, Commonwell, and custom or regional networks may be available in the future
- This functionality requires an appropriate directory of external health care systems using the Universal Description, Discovery and Integration (UDDI) specification

### **Transport Standards**

Using IHE standards, the PULSE system connects a national network such as eHealth Exchange, health systems, or health information organizations as an interoperability broker to query for patients, return lists of documents for a given patient, and then retrieve and display a CCDA document. The specific IHE transactions used are: Cross-Community Patient Discovery (XCPD), Cross Gateway Query, and Cross-Community Gateway Retrieve, respectively.

- **Patient Discovery:** PULSE can search for a patient via at least one node or organization on the eHealth Exchange or similar network. The specific IHE profile used is ITI-55: Cross-Community Patient Discovery (XCPD)
- Query for Documents: PULSE can return a list of documents for a single patient from at least one node or organization on the eHealth Exchange or similar network. The specific IHE profile used is ITI-38: Cross Gateway Query, which is modeled after the Registry Stored Query ITI-18 transaction
- **Retrieve Documents:** PULSE can return a full document for a single patient from at least one node or organization on the eHealth Exchange or similar network. The specific IHE profile used is ITI-39: Cross Gateway Retrieve, which is modeled after the Retrieve Document Set ITI-43 transaction
- Viewable Documents: PULSE can display CCDA documents. Since PULSE will be used during
  emergencies to provide immediate treatment to patients it's believed that a summary of care in
  the CCDA format would be helpful as hospitals and providers produce these documents for their
  transitions of care and encounters. CCDAs commonly contain demographics, problems,
  medications, and allergies.

### **Required Technical Architecture**

• IHE Technical Framework integration profiles<sup>8</sup>

<sup>&</sup>lt;sup>8</sup> https://www.ihe.net/resources/technical\_frameworks/#IT

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# PULSE

- Health Exchange network standards and requirements
- HL7 clinical data architecture standards
- Carequality Connected Agreement (CAA), approved 5 November 2015
- Carequality Query-Based Document Exchange Implementation Guide Version 1.0, adopted 5 November 2015
- HL7 CDA Release 2, CCD.
- HITSP Summary Documents Using HL7 CCD Component HITSP/C32
- HL7 FHIR® Standard for Trial Use 3 (STU3), when released1
- IHE IT Infrastructure Technical Framework Volume 2a (ITI TF-2a) Transactions Part A Revision 13.0, released 9 September 2016
- Nationwide Health Information Network Messaging Platform Specification Version 3.0, released 27 July 2011
- Nationwide Health Information Network (NHIN) Authorization Framework Specification Version 3.0, released 27 July 2011
- Nationwide Health Information Network (NHIN) Patient Discovery Web Service Interface Specification Version 2.0, released 27 July 2011
- Standards-based SOAP web service that allows PULSE to retrieve specific documents identified through Query for Documents containing health information specific patients identified

### **Other Requirements**

### Testing and certification

PULSE will undergo the formal eHealth Exchange testing program that validates the compliance of the PULSE technology with the eHealth Exchange Performance and Service Specifications and allow for standardized interfacing into other common networks.

### Security

PULSE implementers should use a minimum of two forms of security to ensure confidentiality, authenticity, and integrity of sensitive information managed by the system. With that, any infrastructure as code (IaC)/keys/secrets/configuration will not be included in the source repository (similar to the SITE and CHPL systems), and PULSE vendors should demonstrate how they can manage that information privately in an existing system or use external systems for security functions (e.g., AWS OpWorks).

Questions to ask a PULSE implementor can include, but are not limited to:

- 1. Has the PULSE implementer's engineering process has been accredited by HITRUST?
- 2. How does the PULSE implementor isolate networks to reduce our risk surface (e.g., separation of DMZ, application, and durable data store subnets)?
- 3. How does the PULSE implementor utilize end-to-end encryption in transit?
- 4. How does the PULSE implementor ensure all durable data stores are encrypted at rest?
- 5. How does the PULSE implementor practice least privilege access (e.g., deny all, allow explicit)?



- 6. How does the PULSE implementor perform quarterly penetration tests with an independent third party?
- 7. How does the PULSE implementor offer security guidance and recommendations to the state resources securing state-specific implementations and integration points?
- 8. How does the PULSE implementor follow the local, regional, and national network Health Insurance Portability and Accountability Act of 1996 (HIPAA) and consent requirements?

While these are a subset of proper questions to ask, much of the security infrastructure will be dependent upon a PULSE implementer's operational services and capabilities. The security requirements should also be in line with the state's security requirements, as well as the security requirements of any system integrated with PULSE, including the state's ESAR-VHP database or existing health information exchange networks.

#### System Redundancy

A major technical consideration is the location where PULSE components, specifically the interoperability broker and the user web interface, are hosted. Both items should implement a disaster recovery server or location that is in a separate geography from the main infrastructure. This ensures that in the event of a disaster in the location where the interoperability broker and web interface are hosted, PULSE will have a fail over server and continue to be available. Similarly, hospitals and HIOs have their own disaster recovery plans, which typically include a second fail over environment and servers. For PULSE to have access to their data during a disaster, hospitals and HIOs may need to build two connections to the interoperability broker, one for their primary servers and one for their disaster recovery servers.

### **PULSE Source Code**

#### **Open Source**

The source code of PULSE will be available for free to state and local governments in 2020. Download location and licensing terms will be added to a future release of this document.



### Step 6. What are the Steps to Implementation?

### **Identify Key Roles and Responsibilities**

There are number of key roles and responsibilities to support a successful implementation, use and ongoing support for PULSE:

### **Executive Sponsor**

Determine the leader(s) who will direct the successful implementation of the PULSE system.

### PULSE Owner / Administrator

- Determine who has primary responsibility over the PULSE program within the jurisdiction, including which agency(ies) have authority during local and state emergencies.
- Identify key leaders who need to be engaged and supportive of PULSE.
- Identify expectations for governance of the PULSE program, including the stakeholders who must be engaged, including the respective roles and responsibilities of the jurisdictional leadership and the PULSE operator.

### PULSE Activation, Deployment, Deactivation Authority

- Identify decision makers and establish processes for PULSE activation, deployment and deactivation:
  - Who makes these decisions within your jurisdiction's incident command structure?
  - What are the processes for making decisions and the actions that need to be taken to deploy PULSE? What are the processes for deactivation?
  - Is there shared decision making between public health and emergency management? If so, how is this decision facilitated?
- Identify a decision tree or metrics that will lead you to activate and deactivate PULSE unless activation will be executed on a case-by-case basis.
- Identify the types of information that incident command will need in order to recognize a potential utility for PULSE activation and request its deployment.
- Identify who is responsible for communications throughout the incident and ensure clear lines of communication on matters related to PULSE.
- Establish clear communication protocols for activating and deactivating PULSE.

### Identify Exchange Connectivity

• Determine a health information network approach – will you connect via national networks and/or augment existing state and regional networks?

### **Establish Governance, Coordination, and Implementation Policies**

### Jurisdictional Governance

- Governance will vary depending upon several factors, such as whether PULSE is implemented statewide or if implemented to address city, county or local needs.
- At a minimum, the jurisdiction will:
  - o Govern policies and oversee the operation of PULSE for jurisdiction events
  - o Assert authorization for volunteer workers and PULSE users
  - o Define and decide when to activate, deploy and deactivate PULSE
  - o Integrate PULSE into existing disaster response plans and processes
  - o Coordinate with authorities and responders within the jurisdiction and with the PULSE administrator before, during, and after events

### Coordination

- Identify necessary liaisons between those responsible for operating the PULSE system, Incident Command and other responders. These liaisons should have clear lines of communication with the PULSE administrator real-time before, during and after an event.
- Define how PULSE deployment will be coordinated with EMS, hospitals, behavioral health resources, law enforcement, and temporary housing resources.

### Technical Implementation

- Determine the role that the jurisdiction will have in the technical implementation of PULSE.
- Determine if a phased implementation or statewide implementation is appropriate.

### **Plan for Support Services**

### End User and Field Operations

- Identify how disaster health care volunteers will be provided with computers and Internet access to access PULSE. Will they bring their own laptops, or will these be part of the disaster response equipment at the alternate care facility?
- Develop a field operations plan with input from applicable agencies / offices involved in emergency response.
- Develop a user guide that addresses operational issues occurring with PULSE in the field for time- critical problem resolution.

### **Ongoing Support and Maintenance**

- Determine who has responsibility for the ongoing program support and maintenance for PULSE.
- Define a change management process, in consultation with the governance and PULSE administrator.
- Determine how change requests should be submitted, to whom and how they are prioritized

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and addressed.

• Clarify roles and responsibilities of the jurisdiction and the PULSE administrator.

### Plan for Key Operational Requirements

Jurisdictions need to develop PULSE policies and procedures to support operational decisions. Suggested planning elements are included here:

### 1. Identify the response scenario(s) for which PULSE is intended to be used

- Determine which scenarios PULSE is intended to be used for and define appropriate terms regarding the activation, deployment and deactivation of PULSE.
  - o What emergency or disasters will PULSE be activated and available for use?
  - o How will you communicate to providers that PULSE is available?
  - o When is PULSE deployed and in use by disaster health care volunteers?
  - o When is PULSE deactivated?
  - o How will you communicate that PULSE will be deactivated?
- Factors to consider include:
  - o <u>Type of event</u>: Is this event likely to result in large numbers of ill or injured that would require activation of alternate care facilities or result in large numbers of people being evacuated from their homes and current medical support network
  - o <u>Expected duration of the event</u>: The longer an event lasts, the greater the impact on normal health care services and the ability of patients to access those services
  - o <u>Number of people affected and how they are affected</u>: What is the projected impact of the event? Do you expect many people effected, but not severely; or a smaller number of people affected dramatically?
  - o <u>Location (major metropolitan area vs. isolated area)</u>: If the event impacts a major metropolitan area then the number of people affected may be higher but there may be more available health care infrastructure. Isolated areas may have fewer health care resources so even a small number of casualties can require support.
  - <u>Magnitude of event</u>: Assess whether the event is serious enough to require activation of alternate care locations. PULSE enables health care providers who are not part of the local health care delivery system to access information about patients and more effectively triage and treat them. Not every event, even largescale events, will create a demand for this service.

### 2. Determine whether PULSE is intended to be used solely for treatment purposes

 Assess whether PULSE is intended to only be used for treatment purposes for individuals affected by disaster. If it is contemplated for other uses (e.g. public health, non-health related emergency response), then changes to the PULSE system may be needed. To date, PULSE has not been tested for use cases outside of direct patient treatment during disasters.

# 3. Clarify that PULSE only provides the ability to find health records in the routine health care delivery system

- PULSE was designed to request an electronic copy of health records from care providers in order to make timely decisions when treating individuals affected by events.
- PULSE is a historical medical health record lookup system and cannot be used for recording a patient encounter or treatment.

### 4. Identify system administrators for PULSE

• Who will activate PULSE, verify users, and serve as the administrative lead for PULSE operations?

### 5. Identify sites for PULSE deployment

- Will PULSE be available in all alternate care sites or specific locations?
- Do the sites have the required technical capabilities (e.g., Internet, computers)?

### 6. Determine which types of disaster health care volunteers are authorized to access PULSE

- Define which disaster health care volunteers are authorized users of PULSE. For instance:
  - Licensed volunteers will there be an initial starter set of licensed professionals, with plans to expand? Or, are all licensed volunteers authorized to access PULSE?
  - Unlicensed volunteers will unlicensed volunteers be provided access to use PULSE (e.g. to serve as registrars at the ACS locations)?
- 7. Define how user identities will be verified (authenticated) to assure that only authorized users can access to PULSE
  - Define how disaster health care volunteers will be authenticated to PULSE
  - Identify the most appropriate data source for authenticating disaster health care volunteers (e.g., ESAR-VHP system)
  - Determine whether single sign on to PULSE (e.g., using the ESAR-VHP process) is required
  - As an example: in California, the ESAR-VHP system passed the assertion to PULSE, which identified the individual, role (i.e., authorized occupation) and purpose for the request.

### 8. Plan for initial, maintenance, and just-in-time training on PULSE for volunteer health

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#### professionals

- 9. Determine how many patients are likely to have records available in the affected area
  - The jurisdiction should assess how many patients and records are accessible in a disaster area. This is an important metric to assess the value of PULSE during an event.
  - Determine how patient record coverage information can be obtained (e.g., if there is a statewide HIE, the HIE may be able to provide this information. If there is not an HIE, are there other mechanisms to assess the availability of patient records for the affected population, such as working with a national network?)
  - Determine who will maintain or provide access to the patient record coverage information over time, as this will likely be used to assess whether PULSE would be beneficial to the response scenario.
  - Determine the scope of the query will you look for records across the county, the state, or the entire network?

### 10. Determine how long the search history and retrieved documents should be stored in PULSE

### 11. Determine role-based access control options

•\_\_\_\_For details regarding the user and group management functions and the roles defined for PULSE users, see <a href="https://github.com/Jasig/NotificationPortlet">https://github.com/Jasig/NotificationPortlet</a>



### Step 7. How Do I Maintain PULSE?

### **Ongoing Support, Maintenance and Performance Improvement**

### Periodic Testing and Drills

Given the nature of PULSE, the system is expected to be idle for periods of time, until the system is activated and deployed for an event or disaster. It may be very challenging to find licensed professionals who are available during the disaster to test PULSE. If unlicensed professionals are not authorized users of PULSE, it further limits the ability to test PULSE during a disaster. It will be imperative to do advance testing and drills to assure system readiness. It is critical that PULSE be tested periodically to have assurance of system readiness and availability. This can be accomplished through ongoing technical testing and table-top drills.

### Test System Readiness and Availability

 Define process and frequency for ongoing testing to assure system readiness. This could include quarterly or biannual end-to-end testing or periodic technical testing to verify system uptime and availability.

### Table-Top Exercises

- Develop and facilitate tabletop exercises, with end user engagement, to address:
  - o Hypothetical scenarios
  - o Scenarios in an environment with real patients
  - o Assess whether the exercises (which typically use fictitious data) will use a test PULSE environment or a live PULSE environment
    - o If a test environment is used for the exercise, it will be important to assess substantive differences from how PULSE would work in a live environment

### Performance Improvement

- Determine who should be involved in periodic evaluations of PULSE to assess its performance and value in supporting disaster response efforts.
- Incorporate PULSE to existing performance evaluation processes and after action reports to critique and improve disaster preparedness and response.

### **Communications and Information Management**

- **Response Communications:** Determine who is accountable for a communications plan that incorporates PULSE into disaster response plans and communications.
  - o Consider communications channels, protocols and approvals in coordination with other agencies, command center and Disaster Health Care Volunteer Coordinators

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- o Establish clearly understood communications during an event that links to Incident Command
- o Provide disaster health care volunteers with necessary communication gear to support stable and secure communication. Plan for cell service to be unreliable.
- o Implement HIPAA-compliant physical, administrative and technical safeguards to protect the privacy and security of patient information, including authorized access to PULSE.

### • Awareness, Education and Outreach:

- o Develop a communications package for PULSE.
- o Build awareness of PULSE and its role in disaster response efforts, among leadership, disaster response stakeholders and the user community.

### Training

### • Prepare PULSE Training Materials

- o Develop a PULSE Users Guide and rollout plan
- o Develop a PULSE training toolkit for disaster health care volunteers and administrators
- Train End Users, Volunteer Coordinators and Administrators
  - o Deliver advanced and onsite training for local Disaster Health Care Volunteer Coordinators and volunteers on how to use PULSE
  - Define processes for PULSE technical support in coordination with the PULSE administrator



## Document Revision History

Version	Date	Description
1.0	27 January 2020	Initial release
2.0	Anticipated March 2020	Interim release 1