



Recommended Practices for Exchange of Electronic POLST Information

Charting a Path for Greater Electronic Exchange of POLST

Executive Summary

Building on the work of the California POLST eRegistry Pilot Project, these recommended practices for key areas of electronic POLST registry development provide a framework for the reliable capture, storage, and use of electronic POLST information in California. These recommendations represent one of four "next step" objectives identified by the project's lead organizations as important work in moving California closer to realizing the vision of statewide access to electronic POLST information.

POLST (Physician Orders for Life-Sustaining Treatment) is a medical order signed by both a patient or their decisionmaker and physician, nurse practitioner, or physician assistant that specifies the types of medical treatment a patient wishes to receive toward the end of life. POLST is a tool that encourages conversation between patients, decisionmakers, and providers about their end-of-life treatment options, and helps patients make more informed medical decisions and communicate their wishes clearly.

The recommended practices were developed with the support of the Electronic POLST Registry Workgroup through group discussions and electronic surveys. Issues and potential barriers to electronic exchange of POLST information are also identified and discussed, with a focus on concerns related to POLST quality, provider workflow, interoperability, laws, and regulation.

Many of the recommended practices are based on the Workgroup's assumption that there will be multiple versions of POLST information exchange, rather than one single statewide entity; and there will be a requirement for statewide access to POLST information, independent of where the information is collected.

As discussed in more detail in this report, the stakeholders offer recommendations for:

- Capture of electronic POLST information and quality.
- Electronic completion of POLST
- Use of digital or electronic signature with POLST (guidance needed)
- Storage, access, and use
- Responses to requests for POLST information
- Use of national networks
- Compliance and sustainability

Several of the recommended practices apply equally well to enterprise and regional registries as to a statewide approach.

Workgroup members also developed strong consensus around several key concepts, including:

- Guidance on electronic capture of POLST information in web-based or some other electronic form
- The need for specific guidance on the capture of electronic signatures used in conjunction with electronic POLST information capture
- That POLST registries should continue to support fax-based submission of paper POLST forms
- That a provider should only receive one POLST form in response to a request, even if multiple enterprise or regional registries have POLST information for that patient
- That providers should have access to prior voided or superseded POLST, but only if requested or no current POLST exists
- That California needs to establish and work towards a specific statewide architecture for accessing electronic POLST information
- That architecture is best supported by a single statewide repository of POLST information even if enterprise and regional registries continue to exist

A draft logical architecture and discussion of technical standards is provided as a starting point to meeting the needs of recommended practices identified by the Workgroup.

Finally, based on these concepts and some of the recommended practices identified by the Workgroup, we can begin to envision potential options for a high-level architecture related to statewide submission of and access to electronic POLST information, as well as key next steps that would continue to build upon this important work.

1 Introduction and Background

POLST (Physician Orders for Life-Sustaining Treatment) is designed to provide individuals experiencing a serious illness or medical emergency toward the end of life with an actionable means to communicate their wishes concerning medical care and treatment. POLST became part of California state law in 2009 through Assembly Bill AB-3000 (Wolk). POLST is a medical order designed to travel with a patient across all care settings, and is recognized by California healthcare providers as a valid and legal means to know and honor a patient's treatment wishes whenever the patient cannot speak for themselves.

More recently, providers, vendors, and other stakeholders have begun to explore the use of electronic POLST registries as a means to store POLST information and enable providers to retrieve that information whenever and wherever needed, especially when a paper POLST form is unavailable. In 2015, California passed Senate Bill SB-19 (Wolk) which required the California Emergency Medical Services Authority (EMSA) to establish a pilot project to operate an electronic POLST registry – the POLST eRegistry Pilot – without the use of state funding.

The POLST eRegistry Pilot was conducted from 2016 through 2018 with financial support from the California Health Care Foundation (CHCF) and management support from the Coalition for Compassionate Care of California (CCCC). The stated goal of the pilot was to test the feasibility, functionality, quality, and acceptability of an electronic POLST registry in order to inform and support the development of statewide access to electronic POLST information. Under the pilot, electronic POLST registries were established and used by providers in two communities:

- 1. San Diego, where health information exchange (HIE) was actively used by many of the community's health care providers
- 2. Contra Costa County, in a community without an HIE culture or infrastructure, but with a strong commitment to POLST.

The pilot demonstrated many challenges and considerations for developing a statewide electronic registry of POLST information and sustaining it long term. CHCF published the lessons learned from the pilot experience, documenting these challenges and considerations, in 2019. Lessons were organized into five primary areas:

- 1. Organizational readiness and commitment
- 2. Community engagement / stakeholder and participant education
- 3. Workflow considerations
- 4. POLST document practices
- 5. Technology features and functions

Building on the pilot, CCCC, CHCF, and EMSA identified a next phase for developing and supporting statewide access to electronic POLST information that included four objectives:

- Create and communicate a vision for electronic POLST registry expansion across California²
- 2. Identify motivators and facilitators to successful electronic POLST registry platforms and services in California via interviews with key informants³
- Build on the work of the pilot to establish recommended practices for key areas of electronic POLST registry development

California's POLST Electronic Registry Pilot: Lessons for All States published by the California Health Care Foundation in September 2019 at https://www.chcf.org/wp-content/uploads/2019/09/CaliforniasPOLSTElectronicRegistryPilot.pdf

The results of activity on the first objective are documented in A Vision for Electronic Access to and Exchange of POLST in California

The results of activity on the second objective are documented in *POLST eRegistry in California: Challenges and Opportunities*

4. Develop guidelines for electronic POLST completion and information sharing

This document focuses on objective three, recommended practices.

1.1 Scope

This document summarizes the recommended practices for the capture, storage, and use of electronic POLST information to provide a framework for statewide access, such as through an electronic POLST registry.

Important to this scope are the following:

- The focus is on electronic POLST information. However, some issues, barriers, guidance, or recommendations may apply equally to paper-based and electronic POLST. Where important, the distinction between paper-based and electronic POLST information is indicated.
- The primary focus is on statewide access to POLST information. Some issues, barriers, guidance, or recommendations may apply to local or regional efforts as well. However, the context of the discussion is statewide access.
- The electronic POLST registry pilot required by SB 19 was intended to inform and support the development of a statewide electronic POLST registry. The discussion reflected in this document, however, does not assume a single statewide registry, and instead focuses on statewide <u>access</u> to electronic POLST information, however that might be achieved.

1.2 Approach

The work in this document was developed with the support of the Electronic POLST Registry Workgroup, whose activity was sponsored by CCCC and funded under a grant from CHCF.

The Electronic POLST Registry Workgroup comprised volunteers from across the spectrum of POLST stakeholders, including representatives from healthcare providers, EMS providers, healthcare payers, health information organization (HIOs),⁴ POLST registry vendors/operators, and others. See Acronyms

HIOs are the organizations that govern and/or operate HIE technology within local or regional communities.



AB Assembly bill

UETA Uniform Electronic Transaction

COMPASSIONATE CARE

Act

API application programming

interface

USCDI United States Clinical Data for

Interoperability

CCCC Coalition for Compassionate

Care of California

CDA Clinical Document Architecture

CHCF California Health Care

Foundation

COVID-19 coronavirus pandemic

CPR cardiopulmonary resuscitation

DMS document management

system

EHR electronic health record

EMS emergency medical services

EMSA California Emergency Medical

Services Authority

eRegistry electronic registry

FHIR Fast Healthcare Interoperability

Resources

HIE health information exchange

HIO health information organization

HL7 Health Level 7

IHE Integrating the Healthcare

Enterprise

POLST Physician Orders for Life-

Sustaining Treatment

REST representational state transfer

SB Senate bill





Electronic POLST Registry Workgroup at the end of this document for a list of participants in the Workgroup. The Workgroup was chartered and charged to help reach consensus on recommended practices that will promote the creation and use of electronic POLST information and help enable statewide access to it.

The makeup of the Workgroup was, by design, broader than the key informants engaged to identify motivators and facilitators to successful electronic POLST registries (objective 2). As a result, the consensus opinions of the Workgroup may differ from the challenges and opportunities documented in objective 2.

Stakeholders identified Issues and Barriers through three primary activities:

- Group discussions at the California POLST Registry Vision and Pathways meeting held in Sacramento on August 22, 2019
- 2. One-on-one discussions with more than twenty stakeholders interested in or working on electronic POLST forms, POLST information exchange, and/or POLST registries
- Group discussion of the Electronic POLST Registry Workgroup, adding and adjusting the content summarized from the meeting and interviews to arrive at the list as presented

The Workgroup developed Recommended Practices through two primary activities:

- 1. Group discussions of the Electronic POLST Registry Workgroup via remote web-based meetings, which set the stage at a high level for ways to address issues and barriers
- 2. A series of quantitative surveys distributed to Workgroup members, designed to help select among different potential recommended practices

The initial plan was to engage the Workgroup exclusively through web-based meetings and comments on draft materials as they were developed. However, meetings of the Workgroup were suspended in February 2020 to allow its members to focus on their response to COVID-19. Ultimately, the surveys that replaced the Workgroup meetings provided perhaps a more quantitative view of Workgroup opinions than might have been reached through group meetings and discussions designed to document consensus.

1.3 Issues and Barriers

The following issues and barriers to the capture, storage, and use of electronic POLST information were identified by California stakeholders. For purposes of presentation, issues and barriers have been grouped into five primary categories, namely those associated with:

- POLST information itself
- 2. The workflow for capturing and storing POLST information
- 3. The workflow for accessing and using POLST information
- 4. Interoperability between holders of electronic POLST information
- 5. The practice, legal, or regulatory environment

Not all of the barriers and issues discussed here necessarily represent the consensus of stakeholders or the Workgroup and may not be experienced by all stakeholders. They are all reported here nonetheless, as at least some portion of the stakeholder community considers each one important.

1.3.1 Issues and Barriers Associated with POLST Information

Accessibility

- Most POLST information is captured on paper forms today, not in electronic format, requiring transformation to allow it to be shared electronically.
- It is difficult to extract POLST data elements that might be used in clinical decision support or highlighted based on clinical setting from scanned paper POLST forms.

Quality

- Information captured on paper POLST forms is too often incomplete, incongruent, or unreadable.
- Images of scanned POLST forms may have quality and resolution issues making them difficult to read and interpret.
- There is no accepted and broadly-implemented workflow to ensure that a paper or electronic POLST form is completed properly and therefore valid and actionable.
- Proper identification of patients who are most appropriate for POLST varies depending upon the type of provider, provider education, care setting, etc.
- The onus is on the provider accessing POLST information to verify that it was properly completed and appropriately collected before taking action.

Standardization

- There is often no way for a provider to immediately verify that a particular paper or electronic POLST document is the most recent document if the patient or decision maker is not able to provide confirmation.
- There are no clear requirements or standards for capture of POLST information through electronic forms.
- There exists confusion surrounding a "national" POLST form created in 2019⁵ which is neither an accepted standard nor approved for use in California.

1.3.2 Issues and Barriers Associated with Workflow for Capture and Submission

Capture of POLST Information

 Electronic capture of POLST information does not always integrate well into existing provider workflows.

See https://polst.org/national-form/ for more information on the National POLST Form created and promoted by the National POLST Paradigm

- Electronic capture of POLST information is not always flexible to support different provider workflows.
- Electronic capture of POLST information does not always consider users in different roles within an organization.
- Electronic capture of POLST information often does not account for the variability of workflows in different care settings.
- Electronic capture of POLST information is bundled by electronic solutions (e.g., EHRs) with other advance planning documents, but the workflow for POLST is vastly different.
- Education on how to capture decisions made during discussions with the patient and represent them as POLST information, whether paper-based or electronic, may be inconsistent or lacking.

Submission to a Registry

- Providers feel that electronic capture and/or submission of electronic POLST information to a registry takes significant time away from patient care.
- Existing workflows may delay submission and availability of electronic POLST information.

Both Capture and Submission

- Changes in workflow are slow and difficult to implement, especially in large institutions
- It is not possible to establish or enforce workflow through legislation.

1.3.3 Issues and Barriers Associated with Workflow for Access and Use

Access to POLST Information

- Electronic access to POLST information does not always integrate into existing provider workflows.
- Electronic access to POLST information is not always flexible to support different provider workflows.
- Electronic access to POLST information does not always consider all users across different roles within an organization.
- Electronic POLST forms within EHR systems may not be readily accessible by EMS or in other emergency situations.
- The technical steps necessary to reliably retrieve electronic POLST information are not always clear to a provider, especially for EMS providers.
- The organizational policy requirements to check for electronic POLST information are not always clear to a provider, especially for EMS providers.
- Providers may not check an external source of POLST information for more recent information if a paper POLST form or an electronic document is available within the organization.

Use of POLST Information

 Electronic POLST information is not always presented when and where the provider expects it.

- POLST information is not well-positioned to help drive decision support in EHRs, even if POLST data elements are successfully extracted from scanned paper forms or POLST information was captured electronically.
- Some existing EHR capabilities do not support the needs of POLST workflow, such as being able to void an existing POLST form.
- Education on electronic POLST information retrieval and use may be inconsistent or lacking.

General Workflow

- An electronic registry must contain a critical mass of POLST information in order to provide value to providers and therefore be used regularly.
- It is unclear when/if it is better to access POLST information as a pull (searching for information when needed) or push (alerting that information exists based on triggers).
- Changes in workflow are slow and difficult to implement, especially in large institutions.
- It is not possible to establish or enforce workflow through legislation.

1.3.4 Issues and Barriers Associated with Interoperability

Transformation from Paper

 Patient information requested on POLST forms is insufficient to reliably match a search to the right POLST information or match POLST information submitted electronically to other previous submissions for the same individual.

Technical Standards

- There are no defined and/or widely adopted technical standards for representing POLST information as digital content.
- There are no defined and/or widely adopted technical standards for exchanging POLST information.
- Technical standards, if/when developed, need to be flexible and consider existing proprietary standards.
- There are no consensus triggers for alerts to the existence of electronic POLST information.

Exchange Framework

- There is no system or framework for reliably managing patient identities statewide.
- There is no unified, statewide approach, mechanism, or framework for exchanging, synchronizing, or replicating POLST information across various systems.
- There is no plan to transition to a unified, statewide approach, mechanism, or framework when/if one is created.
- Connectivity is not always reliable for EMS users in the field.

Existing Infrastructure

• The document management systems that hospitals and other healthcare providers use today are not well-suited to interoperability.

- EHRs may not support important interoperability standards, such as ability to retrieve POLST information from an electronic registry without logging on separately (e.g., single sign-on) or without searching for the patient already displayed in the EHR (e.g., with patient context).
- Some technologies, especially those supporting EMS, may save and present old information, including outdated POLST information, if connectivity fails.
- Images of scanned forms are large payloads, making them difficult to provide to EMS users with limited connectivity.

1.3.5 Issues and Barriers Associated with the Practice, Legal, and Regulatory Environment

Institutional Policy

- Providers still confuse POLST with other advance planning documents and activities
- The source of truth is unclear when multiple potential sources of paper and electronic POLST information are available.

State Policy and Regulatory Environment

- The legal status of a paper POLST form is unclear once scanned.
- It is unclear when it is important/acceptable to present individual pieces of POLST information versus a complete image of the POLST form.
- There are no regulations, incentives, or penalties prompting the capture, sharing, and use of electronic POLST information.
- There are no regulations, incentives, or penalties to ensure that all POLST forms/information is made broadly accessible electronically to avoid accidental use of outdated information.
- There is no body designated to govern access to electronic POLST information statewide.
- There is little funding to develop infrastructure, standards, or solutions for sharing electronic POLST information, and return-on-investment is unclear.
- Authorization to retrieve electronic POLST information is unclear, especially across a statewide network.
- There remain questions about whether providers can act upon POLST information shared across state lines.

Other Environmental Issues

- Provider organizations, especially large health systems, may not prioritize widespread sharing of POLST information.
- Provider organizations do not prioritize investment in or integration with external sources of electronic POLST information.
- Costs for participating in electronic POLST access may be too high for small or rural institutions.
- It is difficult to establish an electronic registry as the source of truth until all, or at least some substantial portion of, POLST information is submitted to and retrievable from the registry.

2 Recommended Practices

The following recommended practices for the capture, storage, and use of electronic POLST information are meant to provide a quality, patient-centered framework for statewide access to electronic POLST information, such as through an electronic registry. They are intended to create opportunities and incentives for standardization, facilitate future scale, and ensure appropriate quality and value.

The transition of the Workgroup from web-based meetings to quantitative surveys allowed for a semi-quantitative analysis of Workgroup consensus on individual items of guidance and recommendations, for example differentiating between less-critical and strongly-held recommendations, or between strong consensus and fragmented opinions on items. When possible, a semi-qualitative assessment of consensus accompanies guidance or recommendations.

In total, there were an average of more than eleven separate stakeholder responses to each of five surveys, together comprising a total of 44 total questions, most of them relative rankings, sliding-scale choices, or multiple-choice questions. In general, responses were approximately evenly distributed among healthcare providers, EMS providers, healthcare payers, HIOs, registry vendors/operators, and others (e.g., associations, foundations, consultants), with healthcare providers slightly more heavily represented in responses.

Workgroup discussion of recommended practices and responses to surveys were roughly grouped into three primary categories:

- 1. <u>Capture</u> of electronic POLST information
- Storage of electronic POLST information
- 3. Access to electronic POLST information

For the purposes of presentation, this section has been grouped into those topics as well.

This section also includes a potential <u>architecture</u> for statewide capture of and access to electronic POLST information that would support the recommended practices and includes a potential starting point for technical standards that could support that architecture.

2.1 Assumptions

The discussion at the California POLST Registry Vision and Pathways meeting was designed to reach consensus on a common vision for POLST information access in California. The discussion included a number of commonly-held tenets and assumptions that are documented in *A Vision for Electronic Access to and Exchange of POLST in California*. Key among them for this report was that "multiple versions of electronic POLST information exchange will continue to operate in California, and new versions may be developed".

For the Workgroup, this assumption translated into a need to allow for the continuing existence of multiple electronic POLST registries within California, each of which might have its own mechanism for collecting, storing, and accessing POLST information by/for its customers, and

each offering its own value-added services and unique business models. All four of the electronic POLST registry vendors/operators known to have active operations in California at the time of the Workgroup activities participated in the Workgroup and were invited to contribute to these recommended practices.

The Vision and Pathways meeting also identified a number of technology design requirements for electronic exchange of POLST information. Key among them for this activity was the need for "reliable access to the most recent POLST information independent of where it resides, the care setting in which it was created, or the care setting in which it is retrieved".

For the Workgroup, this assumption translated into a requirement for statewide access to POLST information, independent of where it was collected. ⁶ It was not assumed that access would necessarily be provided by a single statewide repository (i.e., a physical statewide registry) of POLST information, but might instead be accomplished through coordinated interoperability among multiple registries.

2.2 Capture of Electronic POLST Information

POLST Form Completion

Most Workgroup members agreed that there is a need for specific, uniform guidance on best practices and procedures for POLST form completion to ensure an accurate and actionable set of POLST medical orders is captured, whether electronically or on paper. Since CCCC already provides such guidance, this desire probably reflects a need for improved communication with and/or education for those completing POLST forms. Workgroup members suggested that guidance on POLST conversations and completion might in some way be incorporated into electronic POLST information capture.

The Workgroup felt that guidance on POLST form completion should be established by industry stakeholders, such as CCCC which establishes and publishes such guidance today, rather than by regulation. Some Workgroup members believe that providers should be allowed to establish their own internal guidance aligned with the clinical workflow established within their institution, but that was a minority opinion.

Recommended Practices

 CCCC should continue to establish and publish best practice guidance on POLST conversations and POLST form completion.

Workgroup members were unsure that statewide access, versus regional access, to POLST information was an important and necessary assumption – neither strongly agreeing with nor disagreeing with it. However, the Workgroup felt comfortable moving forward with it as a working assumption and the recommended practices provide for statewide access.

- Stakeholders should develop and execute programs to educate providers on POLST conversations and POLST form completion consistent with best practice guidance, striving for uniformity in guidance while aligning with individual clinical workflow.
- Developers and implementers of electronic POLST information capture solutions should consider ways to incorporate guidance on POLST conversations and proper completion, consistent with statewide guidance, as part of the product.

Capture of Electronic POLST Information

There was strong consensus among Workgroup members on the need for specific, uniform guidance on electronic capture of POLST information in web-based or some other electronic form. Most believe that guidance should be established in regulation by a state agency, while some supported establishing guidance instead through industry stakeholder consensus, such as through an organization like CCCC.

Draft guidance on electronic capture of POLST information follows this section in Recommended Practices for Electronic Completion of a POLST Form.

Many Workgroup members felt that there was a need for specific guidance on the capture of electronic signatures used in conjunction with electronic POLST information capture. While the proper use of digital signatures⁷ is outlined in California law and regulation, use of digital signatures for POLST completion is not clearly articulated. Workgroup members felt it would be helpful to summarize the requirements for implementers of electronic POLST information capture. A summary of the current legal requirements for digital signatures, and the barriers for use of digital signatures, follows this section in Use of Digital Signatures with Advance Health Care Directives.

Recommended Practices

- Until regulatory guidance is established, stakeholders developing or implementing electronic capture of POLST information should consider the recommended guidance offered in Recommended Practices for Electronic Completion of a POLST Form.
- Stakeholders should consider advocating for state regulatory guidance on electronic capture of POLST information, using the above-referenced draft guidance as a model.
- Stakeholders developing or implementing electronic POLST information capture should follow the legal requirements for digital signatures summarized in Use of Digital Signatures with Advance Health Care Directives.

Quality of POLST Information

The Workgroup agreed that the responsibility for accurate completion of POLST forms, whether paper or electronic, lies:

Digital signatures and electronic signatures have different legal definitions and requirements, and cannot be used interchangeably.

- 1. First with the provider signing the form, to ensure that the form is an accurate reflection of the patient's wishes, that the responses to each section are congruent, and that the form contains all elements required to make it actionable
- Second with Health Information Management (if it exists) or other administrative function within the provider organization that is scanning and/or submitting the form, again to ensure the form is complete and valid prior to submitting it to an electronic registry
- 3. Finally, with the electronic registry receiving the POLST information, as a final check on quality, completeness, and validity prior to placing the information in the registry where it might be retrieved and used by others.

Placing the responsibility with the provider or their organization was strongly favored over the electronic POLST registry, as incomplete or erroneous forms can best be corrected by providers prior to submission.

The Workgroup noted that electronic capture of POLST information can be designed to enforce required elements for completion and congruence, as recommended in Recommended Practices for Electronic Completion of a POLST Form. Therefore, the above responsibilities should be required only for POLST information captured on paper forms.

Several Workgroup members supported the conversion of scanned paper forms into discrete responses for reasons other than POLST information quality. Potential reasons to capture discrete information might be to enable clinical decision support or to provide alerts containing only the most valuable information for the setting (e.g., not including information captured in Section C to EMS providers, who are not in a position to act upon it). However, many on the Workgroup felt that the effort required to create discrete information and concern over accuracy far exceeded any benefit discrete information might provide.

Recommended Practices

- Provider organizations should develop, implement, and enforce standard practices, integrated into clinical workflow, to ensure that paper POLST forms are complete and responses to each section are congruent.
- Electronic registry operators should develop and implement standard practices to ensure that scanned POLST forms submitted to them are complete and responses to each section are congruent, and develop and implement mechanisms to alert submitting providers of errors when rejecting forms so that errors can be corrected and processes can be improved.
- Electronic registry vendors/operators should consider developing electronic POLST information capture solutions to help ensure complete and congruent POLST information.
- Electronic registry vendors/operators might explore developing technologies that convert scanned paper POLST forms into discrete responses as a value-add to providers or communities interested in using POLST information for decision support or alerts.

Alternative Methods for Submission

There was strong support among Workgroup members that POLST registries should continue to support fax-based submission of paper POLST forms. Fax-based submission was thought to be important primarily to skilled nursing facilities and ambulatory providers that have less established infrastructure and personnel to support electronic submission. However, fax submission to regional POLST registries was favored over establishing a single statewide fax number.

The Workgroup recommended against establishing guidance on provider workflow for completing POLST forms, whether on paper or electronic. Instead, guidance should focus on POLST information completeness, accuracy, readability, etc.

Recommended Practice

 Electronic registry vendors/operators should develop methods for and continue to support submission of paper POLST forms by fax consistent with clinical workflow, especially for skilled nursing facilities and ambulatory providers.

2.2.1 Recommended Practices for Electronic Completion of a POLST Form

As stated above, there was strong consensus among Workgroup members that California needs specific, uniform guidance on electronic capture of POLST information, and that such guidance is best established by a California state agency. The following provides draft guidance until such time that regulatory guidance is available.

The California (paper) POLST form is a standardized form approved by EMSA and must meet specific regulatory requirements in order to be considered valid as defined in Probate Code §4780-4788. The POLST form is periodically updated by CCCC based on changes in law, review of best practices, and extensive stakeholder engagement. All POLST form changes require approval of EMSA.

In order to comply with California regulations for creation of a valid POLST form, it is recommended that any system designed to facilitate electronic completion of the California POLST form must:

- Replicate the language used in the paper POLST form verbatim, including any changes approved by EMSA, with an on-screen format substantially similar to the paper POLST form
- Prevent finalizing a POLST form with "Attempt Resuscitation/CPR" selected in Section A and "Selective Treatment" or "Comfort-Focused Treatment" selected in Section B (i.e., incongruent orders)
- Prevent finalizing a POLST form which does not include, at a minimum, the following information required by legislation for a valid POLST form:
 - The date the form was completed and signed
 - The patient's first and last name

- A selection in Section A (Cardiopulmonary Resuscitation (CPR)) or Section B (Medical Interventions)
- The name of the physician, nurse practitioner, or physician assistant who is signing
- The signature of the physician, nurse practitioner or physician assistant
- The signature of the patient or patient's legally-recognized decisionmaker
- Prevent finalizing a POLST form which does not include the patient's date of birth, which
 is not required by legislation but is important for matching the form to the correct patient
- Provide for optional completion of all other portions of the POLST form
- Provide for capture of digital signatures in accordance with applicable regulations for electronic health records and California law (Use of Digital Signatures with Advance Health Care Directives contains a summary of the legal requirements for implementing digital signatures)
- Provide a means for a completed POLST form to be printed on paper for the patient or decisionmaker to retain, including both the front and back sides with content and format identical to the current EMSA-approved paper POLST form
- Provide ability to add a clearly visible watermark to indicate POLST forms that are "Voided," "Invalid," or "Incomplete"

2.2.2 Use of Digital Signatures with Advance Health Care Directives

As stated above, many Workgroup members felt that California needs specific, uniform guidance on the use of electronic and/or digital signatures for POLST. The use of digital signatures for advance health care directives is addressed in statute but use of electronic or digital signatures for POLST is not. The following provides a summary of California regulatory requirements for the use of digital signatures for an advance health care directive.

California Probate Code § 4673(b)(1-7) requires the use of <u>digital signatures</u> on electronic advance health care directives that meet the following standards:

- (1) The digital signature either meets the requirements of Section 16.5 of the Government Code and Chapter 10 (commencing with Section 22000) of Division 7 of Title 2 of the California Code of Regulations or the digital signature uses an algorithm approved by the National Institute of Standards and Technology.
- (2) The digital signature is unique to the person using it.
- (3) The digital signature is capable of verification.
- (4) The digital signature is under the sole control of the person using it.
- (5) The digital signature is linked to data in such a manner that if the data are changed, the digital signature is invalidated.
- (6) The digital signature persists with the document and not by association in separate files.
- (7) The digital signature is bound to a digital certificate.

A similar requirement to use digital signatures would be a significant barrier to electronic capture of POLST information, as many individuals would not be able to comply with digital signature requirements of § 4673 (b) (1-7) when completing an electronic POLST form in person. Many, perhaps most, patients and decisionmakers will not have established a digital signature that meets these requirements. If they have, they may not have access to it while with their physician and completing POLST.

It may be more convenient when completing POLST electronically to permit the completing physician/nurse practitioner/physician assistant or especially the patient/decisionmaker to "sign" using an <u>electronic signature</u>. An electronic signature is defined under California law as "an electronic sound, symbol, or process attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the electronic record". The use of electronic signatures is authorized by the Uniform Electronic Transaction Act (UETA) for transactions and contracts among parties in California as long as both parties agree to its use. Electronic signatures are commonly implemented as a graphical facsimile of an individual's signature, perhaps captured on a touchpad.

Unfortunately, the use of electronic signatures for POLST is not currently addressed under California law.

2.3 Storage of Electronic POLST Information

Data Retention

Some Workgroup members felt that it might be helpful to provide guidance on storage and retention of electronic POLST information, but opinions were strongly polarized with half believing guidance was critical and half believing it unnecessary. If such guidance is established, most Workgroup members believed that it should be established by industry stakeholders (such as CCCC), with some members supporting a state agency instead.

It might be noted that industry has not set consensus standards for the retention of other health information within HIEs or other business associates, instead allowing such organizations to set their own retention policies for health information and audit and activity logs.

Recommended Practice

 Stakeholders should continue to set their own policies concerning retention of electronic POLST information consistent with policies for the retention of other health-related information within their organization.

2.4 Access and Use of Electronic POLST Information

Authority and Order of Access

Several Workgroup members felt it was critical to establish that a POLST registry was the sole authority for the most current POLST, and that the POLST registry should always be consulted first (or perhaps exclusively) when seeking current POLST information. These members cited two primary reasons that such guidance was important:

- Other systems such as a provider's electronic health record (EHR), document management system (DMS), or community health information exchange (HIE) that might be used to hold POLST information usually do not implement the necessary workflow for POLST, such as voiding superseded or withdrawn forms.
- The POLST registry, as a centralized or regional aggregation point for POLST information, is most likely to contain the most recent form for a patient. EHRs, DMSs, or even paper records might contain the most recent form completed at a specific facility, but a form completed at a later date elsewhere might have superseded it.

There was, however, no real consensus and Workgroup members were polarized on this point – with half believing it critical to establish authority of POLST registries and guidance on EHR use in retrieving POLST information, and half believing it unnecessary. Workgroup members were also divided on who should establish such guidance; understandable given the division on the need for guidance.

Ultimately, consistent with Workgroup recommendations against establishing guidance on provider workflow for completing POLST forms, there was no consensus on establishing guidance on accessing and using POLST forms.

Recommended Practice

- Communities should work together to establish local authority and workflow for accessing POLST information, consistent with the local environment and systems available to the community.
- Communities should identity the most appropriate focus to advocate for electronic POLST within the community, strongly leveraging HIE if it exists.

Statewide Architecture

There was strong consensus among Workgroup members on the need to establish and work towards a specific description of a logical statewide architecture for accessing electronic POLST information.⁸

There were mixed thoughts on how a statewide POLST architecture should be governed.⁹ The majority of Workgroup members believed that governance should rest with a state agency or be established through regulation. Alternatively, participants might establish self-governance that includes representation by important stakeholders such as patient advocates.

Architecture describes the structure for sharing electronic POLST information statewide: the components involved, the externally-visible properties of each component, and the interactions among components.

Governance defines how rules and policies for sharing electronic POLST information statewide should be established and enforced.

There was strong support among Workgroup members to strive to create and maintain a single, statewide repository that aggregates all POLST forms across California to a single location, even if multiple enterprise or regional registries continue to exist. Opinion was somewhat polarized – with many members believing it was critical to establish a statewide repository and while others feeling it unnecessary.

Workgroup members felt that a statewide repository, if established, should probably be operated by a public-benefit non-profit organization, with a state agency as a potential alternative choice. However, opinions were divided and many Workgroup members were uncertain of the best choice. Despite opinions that a single statewide repository might be preferable, most Workgroup members believed it was unlikely to be realized in California. Members therefore recommended exploration of options for an architectural approach that might not require a statewide repository but took advantage if one should it exist.

Recommended Practices

- California should establish a consensus architecture for sharing electronic POLST information statewide
- The consensus architecture should include and leverage a single centralized statewide repository that aggregates all POLST information to one location, but its' viability should not depend upon it should one not exist.

A potential draft statewide architecture for submission and access of electronic POLST information follows this section in Logical Statewide Architecture for POLST. It includes versions that do and do not incorporate a single centralized statewide repository.

Responses to Requests for POLST

Even if a single, statewide aggregated repository of POLST information is not created, there was strong consensus among Workgroup members that a provider should only receive one POLST form in response to a request, even if multiple enterprise or regional registries have POLST information for that patient. This approach is preferable to presenting the provider (or the requesting EHR or HIE) with multiple potential responses from which to choose the single, most recent, and valid form.

This requirement places constraints on potential statewide architectures. The draft architecture in Logical Statewide Architecture for POLST is intended to address this constraint.

There was strong consensus among Workgroup members that providers should have access to prior voided or superseded POLST information as well. The Workgroup was divided on whether such invalid forms should be provided for historical reference only if a current valid POLST form does not exist, or only when a provider requests prior POLST forms. However, they agreed that prior forms should not be provided by default if a valid form is available.

There was strong support among Workgroup members for replicating forms among the multiple enterprise and regional POLST registries across California, in addition to submitting them to a single, statewide repository. Replication would ensure that every registry has a complete set of

all forms completed and submitted, independent of where they were completed and which registry received the submission.

This requirement is one mechanism by which providers might receive a single form, even in the absence of a single, statewide aggregated repository. It also places constraints on potential statewide architectures, adding robustness at the cost of complexity. The draft architecture in Logical Statewide Architecture for POLST is intended to address this constraint. While form replication among multiple registries is technically complex, it might be the best mechanism to deliver a single form to a provider in the absence of a single statewide repository.

Recommended Practices

- Enterprise and regional registries should share POLST information so that all registries have a complete set of all POLST forms completed in California.
- POLST registries should normally respond to requests for POLST information with the single most recent and valid POLST form, if one exists.
- POLST registries should provide a means to retrieve historical voided or invalid POLST information if no valid POLST form exists or if providers request historical POLST information.

Use of National Networks for POLST

There was some thought among Workgroup members that national networks, such as eHealth Exchange, Carequality, and perhaps the emerging Trusted Exchange Framework might be suitable as a statewide framework for POLST information exchange in California. However, many felt that an independent, California-specific framework was preferable to ensure it met the policies and priorities specific to POLST in California. Opinions were somewhat fragmented, with most members simply unsure of the suitability of a national network.

Unfortunately, the existing capabilities of national networks do not easily support replication across multiple enterprise and regional registries, as most are based on query models.

Recommended Practice

 California should establish a consensus architecture for sharing electronic POLST information statewide that considers and perhaps leverages the technical standards and experience of national networks, but is specific to meeting California priorities and needs

Compliance and Sustainability

There was some support among Workgroup members for mandating adherence to consensus standards, guidance, and recommendations for sharing electronic POLST information through regulation. There was also some support for the state mandating participation in a consensus statewide architecture for accessing POLST information once one is established. However, opinions were polarized, with some members strongly favoring voluntary compliance and participation while others strongly favoring regulatory mandates.

Workgroup members did support the government mandating provider participation in a POLST registry.

Workgroup members strongly preferred state support and funding to establish and operate a statewide approach to sharing POLST information. However, members felt it unlikely that California would provide such funding. Therefore, Workgroup members favored an approach that prioritized low cost over one that focused on (potentially complex and costly) robustness. The need for low cost might favor replication over a single statewide registry since costs are distributed.

Recommended Practice

- California should establish a consensus architecture for sharing electronic POLST information statewide that focuses on low cost.
- Communities should actively encourage providers to participate in POLST registries.
- Communities should actively encourage enterprise or regional POLST registries operating in the community to participate in statewide POLST information exchange.
- If state funding is not available, community initiatives should take responsibility for establishing the consensus architecture.

Alternative Methods for Access

Workgroup members were fragmented on the need for a call center as an alternate means for accessing POLST information. However, a statewide call center was not considered necessary.

3 Logical Statewide Architecture for POLST

The recommended practices identified by the Workgroup establish a set of high-level requirements that can be used to construct a potential high-level architecture for statewide submission and access of electronic POLST information.

3.1 Submission of POLST Information Statewide

Figure 1 and Figure 2 illustrate a potential logical statewide architecture for submission of electronic POLST information.

Both architectures assume that multiple enterprise¹⁰ and regional POLST registries exist, and that providers submitting POLST information participate in the registry of their choice. The enterprise or regional registries may provide value-added services and custom user experiences through proprietary interfaces and/or tight integration with the EHRs, DMSs, or HIEs their provider customers use. Once a registry receives submitted POLST information from a provider and validates it, that information is replicated using common, consensus statewide technical standards for content and transport to all other POLST registries.

In this context, "enterprise" registries are those that are established for a health system or other stakeholder that don't necessarily have a "regional" geographic footprint. Enterprise registries may often overlap with other enterprise registries and regional registries.

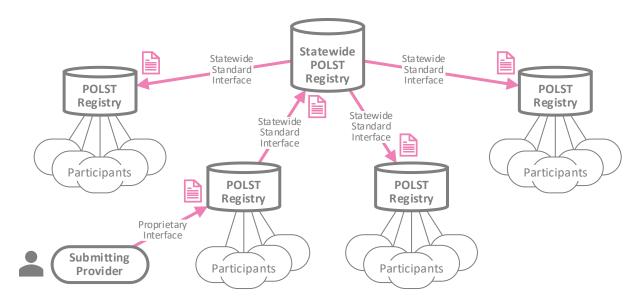


Figure 1 Potential architecture for the submission of POLST information and replication statewide through a statewide POLST repository

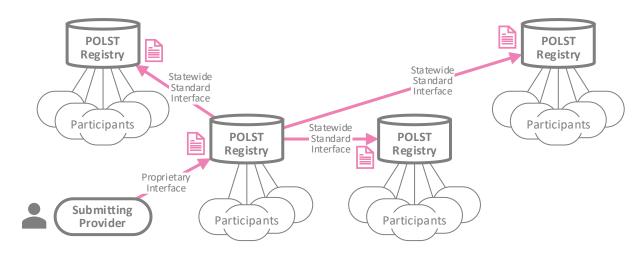


Figure 2 Potential architecture for the submission of POLST information and replication statewide without a statewide POLST repository

In Figure 1, the receiving registry sends POLST information to a central statewide repository that in turn replicates the information with all other participating registries. This option establishes a single statewide authority as ground truth for POLST information that all enterprise and regional registries can reference. Additionally, only the central repository must retain technical information about the other participating registries that must received updates. It is, however, a higher cost approach.

In Figure 2, the receiving registry sends POLST information directly to all other participating registries. This option has the advantage of simplicity, in that a centralized repository of POLST information is not required. However, it distributes the costs of replication among all participating registries and requires that each registry retain technical information about all other registries in order to replicate POLST information. More coordination among registries is required in order to be robust to failures to update all registries upon a new submission or revocation as no single source of ground truth exists.

Figure 1 and Figure 2 both represent enterprise or regional POLST registries as stand-alone entities. HIE may play an important role in the exchange of POLST information as the home for community health records, aggregator of person-centric health information, and facilitator of health information sharing.

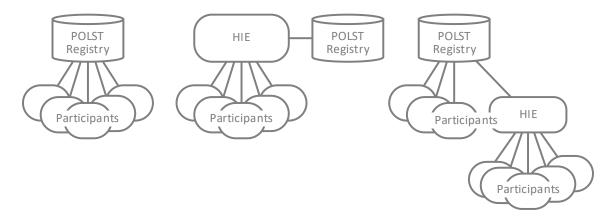


Figure 3 Illustration of potential roles for HIE in a statewide architecture for POLST information exchange

As illustrated in Figure 3, enterprise or regional POLST registries may be stand-alone entities, may be housed within an HIE as part of HIE value-added services, or may have an HIE among its participants, allowing the HIE to aggregate and provide value-added services and consolidate POLST information as part of a patient's community health record.

3.2 Access to POLST Information Statewide

Figure 4 and Figure 5 illustrate a potential logical statewide architecture for access to electronic POLST information.

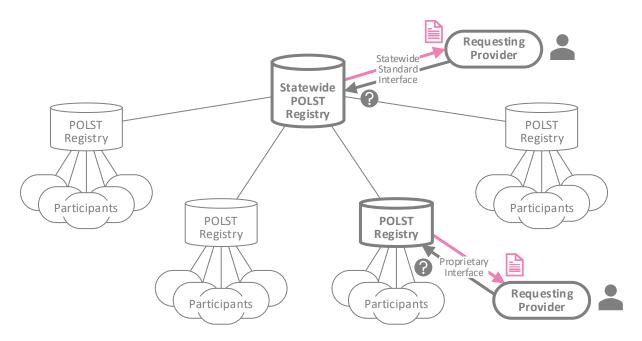


Figure 4 Potential architecture for retrieval of POLST information illustrating options when a statewide POLST repository exists

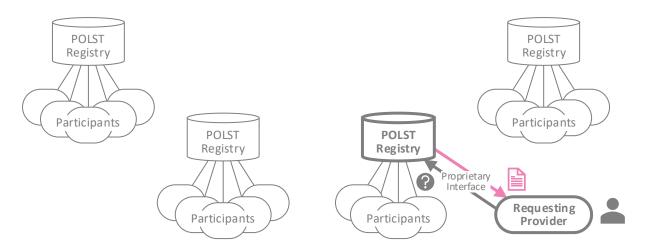


Figure 5 Potential architecture for the retrieval of POLST information without a statewide POLST repository

As above, both architectures assume that multiple enterprise and regional POLST registries exist. Providers accessing POLST information may participate in the registry of their choice, with registries providing value-added services and custom user experiences through proprietary interfaces and/or tight integration with the EHRs, DMSs, or HIEs their provider customers use.

Since all registries contain a full compliment of all completed POLST information, the interaction to retrieve POLST information is simply a query to a single POLST registry.

In Figure 4, a provider that does not submit but only retrieves POLST information (such as EMS) might make use of the statewide POLST repository directly. While this option comes as a higher cost approach to the state, it might provide low cost (or no cost) access to POLST information for providers that don't submit POLST forms or require the value-added services of an enterprise or regional registry. In Figure 5, the provider must have a relationship with an enterprise or regional POLST registry and query it directly for information.

As before, Figure 4 and Figure 5 both represent enterprise or regional POLST registries as stand-alone entities, but the options illustrated in illustrated in Figure 3 that include HIE apply equally here.

3.3 Potential Technical Standards

The Workgroup did not identify or establish recommendations on technical standards as part of a statewide architecture. However, discussions at the 2019 National POLST Paradigm meeting suggested an approach leveraging, at least in part, the technical standards used by national networks.

The discussion focused initially on the ability to access and view POLST information and did not cover submission or replication that would be required for a California architecture. The suggested approach might include the following:

- Update the HL7 (Health Level 7) Personal Advance Care Plan template for the Clinical Document Architecture (CDA) to include an embedded image and all POLST data elements mapped to CDA data elements. This would provide a national standard for POLST content that could be used to share POLST information between providers and POLST registries and among registries statewide.
- Add POLST information to the US Clinical Data for Interoperability (USCDI) standard that is now required content for exchange for all providers, HIEs, and health information networks. This would establish a requirement that health IT systems support the exchange of electronic POLST information.
- Use existing Integrating the Healthcare Enterprise (IHE) profiles for query-based document exchange currently supported by most EHRs, HIEs, and national networks to query for and retrieve the CDA documents. This would establish an initial technical standard for accessing electronic POLST information in a registry using the CDA content standard.

Replication might be accomplished using the CDA content standard and IHE profiles for document submission. Some national networks also have experience supporting the IHE document submission profile, although it is not widely implemented in EHR and HIE systems today.

As adoption of HL7 Fast Healthcare Interoperability Resource (FHIR) standard advances, it might also be considered for content and transport, supporting both submission and retrieval as REST (REpresentational State Transfer) APIs.

4 Conclusions and Next Steps

The effort reported here builds upon the work of the POLST eRegistry Pilot to establish recommended practices for key areas of electronic POLST registry development. It represents the thinking of a diverse set of stakeholders from across the POLST ecosystem.

While the charge of the Electronic POLST Registry Workgroup was to make recommendations to establish a means for statewide access to electronic POLST information, the results of discussions and surveys reported in this document apply to enterprise and regional POLST initiatives as well. In many ways, the Workgroup discussions and recommended practices make progress towards establishing uniform practice across California as much as enabling statewide access to POLST information.

The following are potential next steps that would continue to build upon this work and advance capture, storage, and access to POLST information statewide:

- Many of the recommended practices apply to enterprise or community POLST initiatives.
 Communities should review the recommended practices, establish priorities to implement them within their communities, and advocate that stakeholders providers, plans, HIEs, and registry operators adopt them, aligned with those priorities.
- Many of the recommended practices apply to vendors and operators of POLST registries, whether stand-alone registries or registries associated with HIE. Those stakeholders should review the recommended practices, discuss them with their customers and participants, and prioritize implementation to improve interoperability and uniformity of practice in California.
- Many of the recommended practices provide draft guidance on a number of topics
 considered important by Workgroup members. Stakeholders should partner with local
 and state government in California to adopt industry guidance where available, establish
 guidance through regulation where appropriate, and create guidance where absent.
- Some of the recommended practices speak to a structure for sharing electronic POLST information statewide. Stakeholders, including state government, should collaborate to create a plan to fund, implement, and sustain such a structure, using the recommended practices and draft architecture in this document as a starting point for continued discussion.
- Many of the recommended practices call for collaboration, adoption, and coordination, sometimes without regulatory mandate. Communities and stakeholders should commit to continuing participation in statewide discussion and coordination, advocate that

providers participate in electronic POLST registries, and advocate that electronic POLST registries collaborate and share information statewide.

5 Acronyms

AB	Assembly bill	eRegistry	electronic registry
API	application programming interface	FHIR	Fast Healthcare Interoperability Resources
CCCC	Coalition for Compassionate Care of California	HIE	health information exchange
		HIO	health information organization
CDA	Clinical Document Architecture	HL7	Health Level 7
CHCF	California Health Care Foundation	IHE	Integrating the Healthcare Enterprise
COVID-19	coronavirus pandemic	POLST	Physician Orders for Life- Sustaining Treatment
CPR	cardiopulmonary resuscitation		
DMS	document management system	REST	representational state transfer
		SB	Senate bill
EHR	electronic health record	UETA	Uniform Electronic Transaction
EMS	emergency medical services		Act
EMSA	California Emergency Medical Services Authority	USCDI	United States Clinical Data for Interoperability

6 Electronic POLST Registry Workgroup

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