

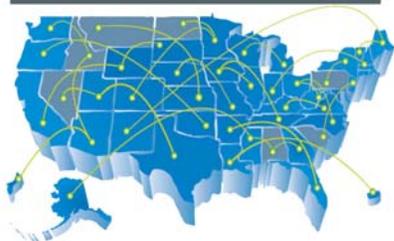
# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **APPENDIX K: GUIDE TO THE DEVELOPMENT AND USE OF INTRASTATE CONSENT POLICY ALTERNATIVES ANALYSIS TEMPLATES**

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Health Information Security & Privacy

**COLLABORATION**



## **Purpose: To Guide State Consent Policy Analysis**

This Guide is intended to assist states in developing and using templates to engage stakeholders in a structured analysis of how much control consumers should have over the access, acquisition, disclosure, or use of their health information in a health information exchange (HIE) system. Throughout this document, this concept is referred to as “consumer consent.” The guide describes how the North Carolina and California teams from the Intrastate and Interstate Consent Policy Options Collaborative developed, adapted and used templates to review and analyze consent alternatives in specific health care scenarios, such as e-prescribing, laboratory tests, emergency departments, mental health, and others. Your state Collaborative can use this guide as a framework within which to conduct your state’s analysis of consumer consent alternatives. Doing so will enable your state to compare its findings with those of other states that use the templates. The templates were designed to be flexible and may be modified to reflect your state’s specific areas of interest, stakeholder composition, time and resources, and desired outcomes.

## **How to Use the Documents and Templates:**

If used effectively, the templates can assist your state in pursuing a deliberative, objective analysis of the complex issues surrounding consumer consent. These documents also are useful in consensus building and in identifying and reconciling points of disagreement. There are three categories of templates: (1) research; (2) analysis; and (3) summary and recommendations. If the templates are used in that order, participants in the analysis will see a logical progression. The templates will assist in documenting your state’s collaborative process while demonstrating the variety and complexity of stakeholder interests surrounding consumer consent.

## **Step One: Research**

Initially, every state collaborative initiating an analysis of consumer consent alternatives must determine the breadth and depth of the study. Each state must decide which consent alternatives to analyze and through research must gain an appreciation of the stakeholder interests affected by the alternatives selected for review. To ensure that these decisions are made deliberately, the participating stakeholders should acknowledge and be well informed of the various perspectives and interests of consumers, providers, vendors, payers, and health information exchange organizations. Additionally, stakeholders must consider the applicable federal and state laws as well as various stakeholder practices regarding the use and disclosure of personal health information. For these reasons a literature review is suggested.

Two templates can assist in succinctly distributing pertinent facts and information summarized from available literature. The primary purpose of these templates is to share available knowledge with stakeholders so that they have a common understanding of the issues surrounding consumer consent.

**1a Summary of Pertinent Facts:** Use this template to create and provide a summary of key information from a single source. This is particularly helpful to stakeholders who are too busy to read all of the research compiled by the Collaborative.

**1b Executive Summary of Pertinent Facts:** Use this template to collect and disseminate a compilation of summaries of pertinent facts on a single topic. For example, this template can compile and compare all the summaries from a single research source on the topic of federal laws governing use and disclosure of personal health information.

Your state Collaborative can create a web portal where these templates may be posted and accessed by stakeholders.

## **Step Two: Analysis**

Once your state Collaborative has gathered and disseminated the summaries of its research findings, consider how to use the following templates and documents. You will need to select and define the stakeholder interest areas that will be evaluated for each consent alternative analyzed. These templates can guide and document stakeholder input on which issues are deemed key to your state's analysis. They are numbered in a logical sequence that can lead you through the decision making. The analysis step represents a major portion of the work involved in addressing consent in your state and there are several templates and documents from which to choose.

**2a Developing Consent Policy Stakeholder Issues for Analysis.** We recommend you use document 2a first to frame the scope of the analysis and identify the specific issues. This will form the left-hand column of the analysis documents you choose to utilize. You need to define the strategy of your approach to consent. Will you discuss consent alternatives in general or specific to identified health care scenarios? To what extent will you utilize the consent analyses of other states? Will you analyze the five alternatives to consent selected by the Intrastate and Interstate Consent Policy Options Collaborative, or identify or develop others? Will you build from the analyses of other states and use their findings to start your state discussion on consent? Or will you complete your own analysis covering the same topics? Answering these questions will form the foundation for how you choose what documents are used and/or adapted.

You want to have a broad spectrum of stakeholders involved in the process of selecting consent alternatives. As consent alternatives are identified, this document may be used to stimulate discussion and identify other potential consent alternatives. During these discussions, identify which consent alternatives are to be considered.

In addition to assisting your state Collaborative in selecting consent alternatives to analyze, the template can help your state determine which stakeholder issues or interest areas to evaluate. In making this determination, your state must weigh the scope of the consent analysis it would like to initiate against the time and resources that are available for the effort. Consumer consent is a very complex issue, and stakeholders have a broad range of legitimate interests that will be affected differently by each consent alternative. If your state has limited resources, you can use the document to narrow the scope of the analysis. For example, you can limit the number of consent alternatives considered, or you can look at consent in a limited number of health care scenarios, such as public health, HIV, or e-prescribing. Similarly, instead of analyzing the impact of each consent alternative on eight or ten stakeholder issues or interests in a given health care scenario, you can select a limited number of stakeholder issues or interests and prioritize them.

**2b Alternative Solution Analysis.** Use this template to guide and document the input from diverse stakeholders involved in the analysis of a single consent alternative. A majority of the stakeholder Collaborative discussion, time, and effort will be captured here. The template captures the pros and cons of the one alternative in a specific health care scenario. Try to avoid the tendency to jump to other consent alternatives in the discussion. Remind stakeholders that the other consent alternatives will be discussed separately. This completed template can be quite lengthy, depending on the size and diversity of your stakeholder Collaborative. You may want to capture all major perspectives shared, then go back and edit to remove redundancy and align comments.

*A few tips for using this template:* The template is intended to capture and document all predictable stakeholder polarities that will arise, such as consumer privacy interests vs.

provider access interests. The facilitator should encourage your state Collaborative participants to strive for objectivity and to complete the form by capturing all identified pros and cons for each consent alternative in relation to the identified stakeholder issues or interests. To avoid long debates over the meaning of terms, ensure that all definitions in the template are clear and understood by all stakeholders before starting the analysis. The information on this form will be used to provide input into the Comparative Summary Analysis template.

Revisit the strategy you identified in 2a when reviewing the following templates related to the comparative summary analysis. Which templates you choose will be based on your strategy. Templates 2c through 2fx, as well as 2h and 2i can be used for a more detailed, resource rich approach where the findings are presented to an oversight board or committee. Template 2g is an adapted version of 2c; it includes fewer stakeholder issues or interests but supports covering more health care scenarios. This can then be combined in summary templates 3a and 3b, and presented to an oversight board or committee. Although each template need not list the agreed-upon privacy and security principles, the principles should be reviewed from time to time to remind everyone of the inherent privacy and security risks of HIE.

**2c Comparative Summary Analysis (CSA)** specific to a health care scenario. Use this template to effectively combine all stakeholder input, including commentary regarding the positive, negative, or neutral impact of each of the consent alternatives on each stakeholder issue or interest for the identified health care scenario. Strive to eliminate redundant or similar statements. Use of this template can assist your state Collaborative in comparing the relative effect of each consent alternative on each stakeholder issue or interest for each health care scenario. As mentioned above, before using this template to document a comparative analysis, it is important to clarify terms and to reach stakeholder consensus about the meaning of the terms and assumptions used in the template. Standardizing the ranking terms is also critical; for example, some Collaborative members prefer to rank items using pros and cons, and others prefer using symbols such as +’s, -’s and •’s (which indicate a neutral position). Use this template in evaluating each consent alternative in a specific health care scenario. The primary purpose of this template is to ensure analytical process consistency. Use a separate template for each health care scenario and each consent alternative selected.

Choose one or more health care scenario most relevant to your state’s experience. At the top of the template is a space to include a description of the health care scenario, such as e-prescribing, and a list of limitations and assumptions pertaining to that scenario (e.g., the purpose of the HIE, etc.) Include in the top row of the template a description or definition of each of the consent alternatives (or you can use the definitions this Collaborative has identified). In the far left column of the template, describe each of the specific issues or interests to be evaluated as defined by your stakeholders.

If you complete document 2b, you can use those findings to populate 2c. If you skip 2b, you can take comments directly from your diverse stakeholder discussions for this template. Another option is to complete 2b for one general health care scenario, such as e-prescribing, and then generalize those comments as appropriate to related health care scenarios, such as laboratories and emergency departments. Your state will complete a Comparative Summary Analysis using either template 2c or 2g for each health care scenario chosen.

**2d Comparative Summary Analysis EXAMPLE.** This document is an example of the CSA. It illustrates where information is required and provides examples of definitions, assumptions, and some detailed pros, cons, and neutral statements of five consent alternatives by specific issue or interest.

**2e Summary CSA specific to a health care scenario.** This template is simply a portion of a CSA, which includes the top part of the form, the summary row, and the definitions. It is useful as a one-page handout to provide an overview to your board or committee.

**2f Health care scenario steps.** This template provides a way to cross check your analysis contained in the CSA. Instead of examining consent alternatives by specific issues, the template leads stakeholders through an analysis by steps in a health care scenario. This was developed to analyze how each consent alternative measures up to the original goal of HIE in the identified health care scenario; for example, how e-prescribing HIE will reduce adverse drug interactions (increased quality of care). Using this template requires identification of each step in the scenario. This template fits well with the Summary of Laws template (2h).

**2fx Emergency Department scenario steps EXAMPLE.** Template 2fx is an example of an Emergency Department scenario to test against “Increased Quality of Care.” Note that health care scenarios are not perfect and certain assumptions need to be made in order to move forward with the analysis.

**2g Comparative Summary Analysis Modified.** This template is a modification of CSA 2c. It has the same format but fewer specific issues or interests were identified based on state preference. Also note the state specific definitions of the alternatives. This format was used to facilitate analysis of multiple health care scenarios when resources of stakeholders and time were limited. Using this approach facilitated the state to further develop the analysis between health care scenarios, as captured in the summary templates 3a and 3b.

**2h Summary of Laws.** This template arranges the state’s applicable laws by steps in the scenario. Once steps in a scenario have been identified, they can be used for both templates 2f and 2h. Federal and state law is identified and summarized by each step in the scenario with the citation provided for reference. The obligations column identifies the legal obligation between the parties involved in the health information being exchanged in each specific step of the scenario. A completed Summary of Laws template is included in Appendix C of the Intrastate and Interstate Consent Policy Options final report.

**2i CSA Public Mental Health.** This template is another version of a CSA, but is specific to the health care scenario of public mental health. When the health care scenario involves sensitive information some aspects of the analysis different. For example, there are subtle word changes, such as from patient to client, and the order of the specific issues is changed. Many health care scenarios, such as e-prescribing, laboratories, and emergency departments, are very similar. But it is the dissimilar health care scenarios, specifically sensitive health care scenarios, that will define the ends of the bell curve which must be addressed before interoperable HIE can be achieved.

### **Step Three: Summary and Recommendations**

Once your state has completed its analysis of the consent alternatives in each health care scenario, use the following templates to compare analyses between health care scenarios and to make a recommendation.

**3a Summary of Pros and Cons.** Use this template to compile and report stakeholder input across all of the health care scenarios. The template can be used to summarize your state’s CSA findings by consent alternative, for each state specified issue. For example, you would combine all “Provider Business Impact” by consent alternative in all health care scenarios analyzed.

**3b Summary of Findings.** Use this template to compile and report stakeholder input across all of the health care scenarios. The template can be used to report an overall summary of your state’s CSA findings regarding the pros and cons identified. For example, you would combine all “Quality of Care” by consent alternative in all health care scenarios analyzed.

**3c Issue Recommendation.** If your state decides to formulate a recommendation to present to an oversight Advisory Board or Steering Committee, use this fairly simple and straightforward template. The template identifies the committee or group which is presenting the recommendation to the oversight body and provides space to describe the issue. The template also provides for inclusion of the recommended consent alternative, support for the finding, recommended implementation strategies and any dissenting opinions (summarized). Although it will be difficult to reach consensus, do strive for compromise. However, it is important to provide a process for stakeholders to put their dissenting opinions on the record, and any dissenting opinions should be submitted in writing.

**FORM 1A**  
**SUMMARY OF PERTINENT FACTS**

**INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS**  
**COLLABORATIVE**  
**SUMMARY OF PERTINENT FACTS**  
**Related to**  
**ONE SOURCE**

*(Limit to one page for each source, if possible)*

<b>Committee:</b>			
<b>Issue:</b>			
<b>Document Title:</b>			
<b>Web Link:</b>			
<b>Key Word(s) Searched</b>			
<b>Document Source:</b> (Organization/ Publisher, etc.)		<b>Author</b>	
		<b>Document Date</b>	
<b>Bullets of Pertinent Facts Relating to Issue:</b>			<b>Page Number</b>

**FORM 1B**  
**EXECUTIVE SUMMARY OF PERTINENT FACTS**



**FORM 2A**  
**DEVELOPING CONSENT POLICY STAKEHOLDER ISSUES FOR**  
**ANALYSIS**

# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **DEVELOPING CONSENT POLICY STAKEHOLDER ISSUES FOR ANALYSIS**

**Purpose** The purpose of this form is to identify criteria within specific areas that relate to the issue of your task group. This criteria will be used help formulate viable alternative solutions to the issue under consideration.

**Instructions** Identify specific laws, business processes, and solutions from other standards below that specifically pertain to a task group issue as it relates to HIE in your state.

This list should contain anything pertinent to the Task Group discussion of viable alternative solutions for the Task Group issue.

The criteria below are *suggested* areas. Add, delete, or modify as necessary.

### **Task Group Issue—Enter Task Group Name Here**

#### **Laws**

- State law changes
- State regulation changes
- Federal law/regulation changes
- Federal policy changes
- IT software solutions
- IT hardware solutions
- Inventory or tracking mechanism
- Publicity campaigns to change social drivers
- Training/education

#### **Business Processes**

- Business practice changes
- Tools and/or templates
- Contract language
- Certification standards increased resources
- Business missions or core values adoptions/recommendations
- Increased resources
- Business missions or core values adoptions/recommendations

## Solutions from Other Standards

- The Markle Foundation Connection to Health standards
- Health Information Portability and Accountability Act (HIPAA)  
<http://www.hhs.gov/ocr/hipaa/>
- The Privacy Act of 1974
- Organization of Economic Cooperation Development Privacy Guidelines  
[http://www.oecd.org/document/18/0,2340,en\\_2649\\_34255\\_1815186\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/18/0,2340,en_2649_34255_1815186_1_1_1_1,00.html)
- United Nation Guidelines Concerning Personalized Computer Files
- European Union Data Protection Directive 95-46/EC
- Canadian Standards Association Model Code
- U.S. FTC Statement of Fair Information Practices Principles
- U.S./EU Safe Harbor Privacy Principles
- Australian Privacy Act—National Privacy Principles
- Japan Personal Information Protection Act
- Asia-Pacific Economic Cooperation Privacy Framework
- American Health Information Community (AHIC)
- American Health Information Management Association (AHIMA) Position Statements  
<http://www.ahima.org/>
- Health Information Technology Security Panel (HITSP)  
[http://www.ansi.org/standards\\_activities/standards\\_boards\\_panels/hisb/hitsp.aspx?menuid=3](http://www.ansi.org/standards_activities/standards_boards_panels/hisb/hitsp.aspx?menuid=3)
- State Alliance for E-Health—Health Information Protection Task Force  
<http://www.nga.org/portal/site/nga/menuitem.1f41d49be2d3d33eacdcbbeb501010a0/?vgnnextoid=5066b5bd2b991110VgnVCM1000001a01010aRCRD>
- Health Information Security and Privacy Collaboration
- Certification Commission for Health Information Technology (CCHIT) Certification Standards  
<http://www.cchit.org/>
- National Institute of Standards and Technology (NIST) standards  
<http://www.nist.gov/>
- Information Security Organization (ISO) standards  
[http://www.iso.com/index.php?option=com\\_frontpage&Itemid=965](http://www.iso.com/index.php?option=com_frontpage&Itemid=965)
- Federal Information Processing Standards (FIPS) <http://www.itl.nist.gov/fipspubs/>
- State Administrative Manual (SAM) <http://sam.dgs.ca.gov/TOC/default.htm>
- State Information Management Manual (SIMM)  
<http://www.dof.ca.gov/OTROS/StatewideIT/SIMM/SIMM.asp>
- Other states standards

**Enforcement Alternatives**

- Penalties
- Sanctions
- Inability to Utilize System

**FORM 2B**  
**ALTERNATIVE SOLUTION ANALYSIS**

**INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS  
COLLABORATIVE**

# **Alternative Solution Analysis**

<b>COMMITTEE</b>				Date:
<b>ISSUE</b>				
<b>ALTERNATIVE</b>				
		<b>PROS</b>	<b>CONS</b>	
	Stakeholder Impact			
	Business Practice Impact			
	Consumer Impact			
	Cost			
	Economic Impact			
	Legal Liability			
	Federal/State Law Conflict			
	Technology Compatibility			
	Public Acceptance/ Confidence			
	Consistent with Other Standards			
	Risks/Threats			

**FORM 2C**  
**COMPARATIVE SUMMARY ANALYSIS (CSA)**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## COMPARATIVE SUMMARY ANALYSIS [HEALTH CARE SCENARIO]

**Date**

### COMMITTEE

[Insert the name of the committee or working body that is completing the analysis.]

### ISSUE

[Put your issue statement here.]

### BACKGROUND

[Put your background statement here.]

### ASSUMPTIONS

[Put your agreed upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- 
- 
- For purpose of this analysis:
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
  - *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available because patient information will be in the system except for those patients choosing to opt out and the information patients choose to exclude.
  - *Opt In*—this choice will result in *less* information being available because patients will need to take an action to be included in the system.

**NOTE**

Consent: A patient's informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system.

**Form 2c—Table 1A. Patient Quality of Care**

**Quality of Care** based upon availability of information—outcome, informed decisions, and coordination of alerts, allergies, drug interactions, tracking medication compliance, and continuity of care (specialist to general practitioner, relocation, or disaster).

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Patient</b> wants effective treatment balanced with protection of their information.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 1B. Provider Quality of Care**

**Quality of Care** based upon availability of information—outcome, informed decisions, and coordination of alerts, allergies, drug interactions, tracking medication compliance, and continuity of care (specialist to general practitioner, relocation, or disaster).

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Provider</b> wants to deliver effective treatment in the most efficient and cost-effective way.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 2A. Patient Level of Trust**

**Level of Trust in HIE**—Influenced by patient choice (whether info is exchanged and if so, what info is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information.

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Patient</b> wants to be informed and know that the provider and HIE will provide accurate information for treatment and will safeguard information.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 2B. Provider Level of Trust**

**Level of Trust in HIE**—Influenced by patient choice (whether info is exchanged and if so, what info is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information.

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Provider</b> wants other provider in HIE to safeguard information and provide accurate and complete information.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 3A. Savings and Cost Avoidance**

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests and harmful drug interactions and drug shopping, increased accuracy and effectiveness, savings in long term, better quality of care, quicker reimbursements, accessing payer info for claims & eligibility.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 3B. Investment**

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<p>Provider business process improvement expenses and time for technical upgrades, tech support, maintenance, oversight, complexity of implementation, education and notices, inputting and managing patient choice (ongoing).</p> <ul style="list-style-type: none"> <li>• Cost of enforcement effort (design and implementation).</li> <li>• Secondary process for those patients not participating in exchange or for sensitive info.</li> <li>• Sustainability and success of HIE system affected by the percentage of participating patients and providers.</li> </ul>	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 4. Technology**

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<p>Compatibility, integration, and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.</p>	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 5. National Efforts**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Markle—Connecting for Health and the NCVHS—National Commission on Vital and Health Statistics address patient consent to access their information, not patient consent to control the input of their information into an HIE or for exchange.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 6. Liability and Laws**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2c—Table 7. Principles**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Consistency or inconsistency with your State Principles.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]
1. Openness					
2. Health Information Quality					
3. Individual Participation					
4. Collection Limitation					
5. Use Limitation					
6. Purpose Limitation					
7. Security Safeguards					
8. Accountability					

**Form 2c—Table 8. Summary**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**FORM 2D**  
**COMPARATIVE SUMMARY ANALYSIS EXAMPLE**

# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **INTRASTATE COMPARATIVE SUMMARY ANALYSIS EXAMPLE [HEALTH CARE SCENARIO]**

### **Date**

#### **COMMITTEE**

[Insert the name of the committee or working body that is completing the analysis.]

#### **ISSUE**

[Put your issue statement here. For example, Patient consent to exchange laboratory information through a Health Information Exchange, for treatment. This issue analysis will examine how the consent options will affect clinician and laboratory business processes, public perception, and legal liabilities of all parties involved.]

#### **BACKGROUND**

[Put your background statement here. It can be whatever length is appropriate to support stakeholder collaborative review and analysis. For example, consent is not currently required for sharing some prescription and laboratory information among healthcare providers/payers under HIPAA and California law.]

#### **ASSUMPTIONS**

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- Treating physician and various providers (labs, pharmacies, other physicians) can have an electronic data exchange relationship without being a participant in the HIE.
- Sharing clinical information will be used for treatment.
- Technology is able to carry out policy and requirements.
- This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases and family planning.
- Patient education/informing are required for all options.
- Consent alternative was chosen by patient at previous annual visit.
- For purpose of this analysis: [You can use these definitions or adapt.]
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less

- data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
- *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
  - *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

## NOTES

- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.
- Consent: A patient’s informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system. [CMS ePrescribing Medicare regulations]

**Please note: A State using this template can choose to adapt Specific Issues to reflect your State landscape. Italic text in the five alternative columns has been left in as an example and place holder for your own State identified text. Likewise, you can identify your own explanations of 1. Quality of Care and 2. Level of Trust in HIE.**

**Form 2d—Table 1A. Patient—Quality of Care**

**Specific Issue:** Patient wants effective treatment balanced with protection of their information.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most quality of care. Patient receives effective, appropriate treatment, avoids unnecessary risk. Expediting referrals increases quality of care. Scarce resources are available when needed.	+ More quality of care (portion IN the HIE)	– Least quality of care (portion not IN the HIE); patient receives unnecessary treatment that over-utilizes scarce resources. Unsafe situation if cath lab is unavailable to someone who really needs that treatment.	• Some quality of care (portion not IN the HIE) + More patient choice specificity	– Less quality of care (portion not IN the HIE) – Less patient choice (IN or OUT)
+ Has the most patient participation	• Has the potential for more patient participation	– Has the potential for the least patient participation.	• Has the potential for some patient participation	• Has the potential for lesser patient participation
NA	• For patients who do not opt out	• For patients who do not opt in	• For patients who do not opt out	• For patients who do not opt in
NA	NA	• For patients who choose to restrict significant information	• For patients who choose to restrict significant information	NA
– No patient choice	• Some patient choice (OUT or IN)	+ Most patient choice and specificity in choice	NA	NA

Note: Quality of care based upon availability of information—outcome, informed decisions, coordination of alerts, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Form 2d—Table 1B. Provider—Quality of Care**

**Specific Issue:** Provider wants to deliver effective treatment in the most efficient and cost-effective way.

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Most quality of care	+ More quality of care (portion IN)	– Least quality of care (portion not IN)	• Some quality of care (portion IN)	– Less quality of care (portion not IN)
+ Most cost-effective	• Somewhat cost-effective	– Least cost-effective	– Least cost-effective	– Less cost-effective
– Most safeguards required to protect patient information due to volume information	• Some safeguards required to protect patient information due to volume information	+ Least safeguards required to protect patient information due to volume information	+ Fewest safeguards required to protect patient information due to volume information	• Less safeguards required to protect patient information due to lesser volume
+ Fewest safeguards required to protect patient information due to lack of complexity	• Some safeguards required to protect patient information due to complexity	– Most safeguards required to protect patient information due to complexity	– Most safeguards required to protect patient information due to complexity	• Some safeguards required to protect patient information due to lack of complexity

Note: Quality of care based upon availability of information—outcome, informed decisions, coordination of alerts, and continuity of care (specialist to general practitioner, relocation, or disaster).

**Form 2d—Table 2A. Patient—Level of Trust: HIE**

**Specific Issue:** Patient wants to be informed and know that the provider and HIE will provide accurate information for treatment and will safeguard information.<sup>1</sup> (Trust the HIE and health care providers regarding protection of their information.)

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least need for education due to complexity	+ Lesser need for education due to complexity	– Most need for education due to complexity	– Most need for education due to complexity	• More need for education due to complexity and availability
– No patient choice, low trust	• Some degree of patient choice/trust	+ Most patient choice/trust	+ Most patient choice/trust	+ More patient choice/trust
+ Least potential errors due to volume of information	• Some potential errors due to volume of information	– Most potential errors due to least volume of information and complexity	– Most potential errors due to less volume of information and complexity	– More potential errors due to volume of information
– Most need to protect patient information due to volume	• Less need to protect patient information due to volume	+ Least need to protect patient information due to volume	• Some need to protect patient information due to volume	• Some need to protect patient information due to volume
+ Least need to protect patient information due to complexity	• Some need to protect patient information due to complexity	– Most need to protect patient information due to complexity	– Most need to protect patient information due to complexity	• Lesser need to protect patient information due to complexity

Note: Level of trust in HIE—influenced by patient choice (whether information is exchanged and if so, what information is exchanged and by whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information. [Errors amplified as carried forward through HIE. Increased professional responsibility.] This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug, and alcohol, minors, sexually transmitted diseases, and family planning.

<sup>1</sup> A considerable level of education will be needed for all alternatives; however, some alternatives will require more extensive education due to their complexity.

**Form 2d—Table 2B. Provider—Level of Trust: HIE**

**Specific Issue:** Provider wants other provider in HIE to safeguard information and provide accurate and complete information.<sup>2</sup> (Trust between providers)

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least potential errors due to volume	+ Less potential errors somewhat due to volume	– Most potential errors due to volume and complexity	– Most potential errors due to complexity and somewhat due to volume	– More potential errors due to volume
– Most need to protect patient information due to volume	– More need to protect patient information due to volume	+ Least need to protect patient information due to volume	• Medium need to protect patient information due to volume	+ Less need to protect patient information due to volume
+ Least need to protect patient information due to complexity	+ Less need to protect patient information due to complexity	– Most need to protect patient information due to complexity	– Most need to protect patient information due to complexity	+ Less need to protect patient information due to complexity
+ Least need for staff and patient education due to complexity	• Some need for staff and patient education	– Most need for staff and patient education	– Most need for staff and patient education	– More need for staff and patient education

Note: Level of trust in HIE—influenced by patient choice (whether information is exchanged and if so, what information is exchanged and to whom), efforts to inform and educate, safeguard patient information, ability to provide extra protections of sensitive information<sup>3</sup> [Errors amplified as carried forward through HIE. Increased professional responsibility.]

<sup>2</sup> A considerable level of education will be needed for all alternatives; however, some alternatives will require more extensive education due to their complexity.

<sup>3</sup> This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases, and family planning.

**Form 2d—Table 3A. Savings and Cost Avoidance**

**Specific Issue:** Savings and cost avoidance—provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests, increased accuracy and effectiveness, long-term savings, better quality of care, quicker reimbursements, accessing payer information for claims and eligibility.

Risk analysis—could affect a small number of cases, but if the adverse outcome is death, etc., it could have a costly outcome.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Most savings from business processes impacts due to volume and complexity. Costs are appropriate and minimal.	+ More savings from business processes impact due to volume and complexity	– Over-utilizes scarce and expensive resources of helicopter and cardiac cath lab	– Least savings from business processes impact due to volume and complexity	• Less savings from business processes impact due to volume and complexity
+ Most savings from access to complete information, payments, increased accuracy and quality of care	+ More savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Least savings from access to complete information, payments, increased accuracy and quality of care	– Less savings from access to complete information, payments, increased accuracy and quality of care
– Most cost to educate due to volume	– More cost to educate due to volume	+ Least cost to educate due to volume	+ Least cost to educate due to volume	• Some cost to educate due to volume
+ Least cost to educate due to complexity	• Some cost to educate due to complexity	– Most cost to educate due to complexity	– Most cost to educate due to complexity	– More cost to educate due to complexity and outreach
NA	NA	– Least savings from business processes impact due to volume and complexity	NA	NA

**Form 2d—Table 3B. Investment**

**Specific Issue:** Provider business process improvement expenses and time for technical upgrades, tech support, maintenance, oversight, complexity of implementation, education and notices, inputting and managing patient consent choices (ongoing): (1) cost of enforcement effort (design and implementation); (2) second process for those patients not participating in exchange or for sensitive information; (3) sustainability and success of HIE system affected by the percentage of participating patients and providers.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least cost of process improvement	• Lesser cost of process improvement	– Most cost of process improvement	– Most cost of process improvement	• More cost of process improvement
– Most cost to address sensitive information—requires secondary process	– Most cost to address sensitive information—requires secondary process	+ Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	+ Least cost to address sensitive information as no secondary process needed since option has the capability to exclude	– Most cost to address sensitive information—requires secondary process
+ Most sustainable	+ More sustainable	– Least sustainable	– Less sustainable	• Somewhat sustainable

**Form 2d—Table 4. Technology**

**Specific Issue:** Technology—compatibility, integration and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT Plus Choice)	Opt Out w/Exceptions (Patient Auto IN Plus Choice)	Opt In (Patient Auto OUT)
+ Least complex	• Somewhat complex	– Most complex	– Most complex	– More complex
+ Least challenge to small practice providers	• Some challenge to small practice providers	– Most challenge to small practice providers	– Most challenge to small practice providers	• More challenge to small practice providers

**Form 2d—Table 5. National Efforts**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
NA	NA	NA	NA	NA
NA	NA	NA	NA	NA

**Form 2d—Table 6. Liability and Laws**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Some legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution	Less legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.	Less legal risk due to patient’s right to privacy under CA Constitution.

**Form 2d—Table 7. CalPSAB Principles**

**Specific Issue:** Consistency or inconsistency with the CalPSAB principles: (1) openness, (2) health information quality, (3) individual participation, (4) collection limitation, (5) use limitation, (6) purpose limitation, (7) security safeguards—NA, and (8) accountability—NA.

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Consistent with health information quality	+ Consistent with health information quality	+ Consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	+ Consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	+ Consistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>
- Inconsistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	- Inconsistent with: <ul style="list-style-type: none"> <li>• openness</li> <li>• individual participation</li> <li>• collection limitation</li> <li>• use limitation</li> <li>• purpose limitation</li> </ul>	- Inconsistent with health information quality	- Inconsistent with health information quality	- Inconsistent with health information quality

**Form 2d—Table 8. Summary**

<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT Plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN Plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
+ Most quality of care	+ More quality of care	- Least quality of care	• Some quality of care	- Less quality of care
+ Least costly/most sustainable	+ Less costly/most sustainable	- Most costly/most sustainable	- Most costly/most sustainable	• More costly/most sustainable
• Some legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk	+ Less legal risk
- Inconsistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles	+ Consistent with CalPSAB principles
- Least patient choice	• Some patient choice	+ Most patient choice	+ Most patient choice	+ More patient choice

**FORM 2E**  
**SUMMARY CSA SPECIFIC TO A HEALTH CARE SCENARIO**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## [HEALTH CARE SCENARIO] SUMMARY

**Date**

### COMMITTEE

[Insert the name of the committee or working body that is completing the analysis.]

### ISSUE

[Put your issue statement here.]

### BACKGROUND

[Put your background statement here.]

### ASSUMPTIONS

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- 
- 
- For purpose of this analysis: [You can use these definitions or adapt.]
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
  - *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
  - *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

### NOTES

- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.

- **Consent:** A patient's informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system.

**Form 2e—Table 1. Summary**

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Put the summary row of the complete Comparative Summary Analysis in this row.	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 2e—Table 2. Definitions of Alternatives**

No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Patients records are automatically placed into the HIE system, regardless of patient preferences. This alternative assumes that all records of participating entities will be available to the system.	Patient’s records are automatically placed into the HIE system and exchange is allowed for sharing medical information without prior permission provided by the patient. The patient’s information remains available for electronic exchange until the patient chooses to opt-out of participation in the HIE and revokes permissions.	Patients’ prescription records are <b>not</b> automatically placed into the HIE system and exchange is <b>not</b> allowed for sharing medical information without prior permission provided by the patient. Restrictions on which health information may be disclosed, the purpose for the disclosure, or specified health information to be disclosed are also allowed under this option.	Patient’s records are automatically placed into the HIE system and exchange is allowed for sharing medical information without prior permission provided by the patient. The patient’s information remains available for electronic exchange until the patient chooses to opt-out of participation in the HIE and revokes permissions. In addition, patients have the right to specify information be removed from the electronic exchange.	Patients records are placed into the HIE system after the patient provides permission. Exchange of medical information is not allowed without prior permission provided by the patient. This alternative assumes fewer records will be available to the system.

**FORM 2F**  
**HEALTH CARE SCENARIO STEPS**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## [HEALTH CARE SCENARIO] SCENARIO STEPS

**Date**

### COMMITTEE

[Insert the name of the committee or working body that is completing the analysis.]

### ISSUE

[Put your issue statement here.]

### BACKGROUND

[Put your background statement here.]

### ASSUMPTIONS

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- 
- 
- For purpose of this analysis: [You can use these definitions or adapt.]
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
  - *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
  - *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

**Form 2f—Table 1. Scenario Steps**

Scenario Step	No Consent (Patient Info IN)	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**FORM 2FX  
EMERGENCY DEPARTMENT SCENARIO STEPS EXAMPLE**

# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **EMERGENCY DEPARTMENT SCENARIO STEPS INCREASED QUALITY OF CARE**

### **Date**

#### **COMMITTEE**

PRIVACY—Consent for Sharing Clinical Information in an Emergency Department Setting

#### **ISSUE**

Patient consent to have their clinical information shared through an electronic Health Information Exchange (HIE) for treatment. This issue analysis will examine how the consent alternatives affect provider business processes, public perception, and legal liabilities of all parties involved. Scenario is to test the consent alternatives relative to quality of care.

#### **BACKGROUND**

Currently consent is not required for sharing clinical information among healthcare providers/payers under HIPAA and California law.

#### **ASSUMPTIONS**

- Treating physician and various providers (labs, pharmacies, other physicians) can have an electronic data exchange relationship without being a participant in the HIE.
- Sharing clinical information will be used for treatment.
- Technology is able to carry out policy and requirements.
- This analysis excludes health information protected by specific laws limiting access to information such as, but not limited to, HIV, mental health, genetic, drug and alcohol, minors, sexually transmitted diseases and family planning.
- Patient education/informing are required for all options.
- Consent alternative was chosen by patient at previous annual visit.
- The quality of care will not be less than that provided in the current systems. However, for those patients that choose to not participate in the HIE, the quality of their care may not improve due to the increased availability of information.
- For purpose of this analysis:
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.

- *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
- *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
- *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
- *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

### **Story or Scenario**

Calvin P. Sab, 65 years of age, was in an auto accident. Ambulance Emergency Medical Technician (EMT) conducts partial medical screening. Patient is extremely short of breath, incoherent, and having chest pains. Available demographics, vitals, etc. taken, low blood pressure is identified. Calvin is transported to the nearest hospital Emergency Department (ED). Calvin’s last annual physical was February 2007. Three weeks ago his physician, Dr. P, referred Calvin to the following specialists:

- + Dr. C, cardiologist for chest pains, EKG ordered, anti-hypertension medication prescribed. Cardiac catheterization last year, stents placed for anterior wall MI.
- + Dr. D, endocrinologist for diabetes, medication prescribed
- + Dr. R, rheumatologist for rheumatoid arthritis, medication prescribed

**ALLERGY ALERT:** Severe anaphylactic reaction to Vancomycin. Alert information accessible through the HIE.

**Form 2fx—Table 1. Emergency Department Scenario Steps—Example**

<b>Scenario Step</b>	<b>No Consent (Patient Info IN)</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Patient presents at scene of accident	Calvin has no choice, Calvin’s health information is accessible through HIE.	Calvin chose to opt out, his health information is NOT accessible through HIE.	Calvin chose to opt in with restrictions, his health information is accessible through HIE, except for rheumatoid arthritis information.	Calvin chose to opt out except for general medical information. Much of his specific health information is NOT accessible through HIE.	Calvin chose to opt in, Calvin’s health information is NOT accessible through HIE.
Transported to emergency department	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.	Emergency Medical Technician (EMT) notifies emergency department of incoming patient and shares available health information from medical screening.
Transported to emergency department	His records are available through HIE.	No additional information is available.	His records are available through HIE minus Rheumatoid Arthritis information	Only his general information is available through HIE.	His records are available through HIE.
Admitted to emergency department	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).	Patient is logged in and a pre-registration exam initiated. Clinical records search performed, no clinical records on Calvin in this hospital’s electronic health record (EHR).
Admitted to emergency department	His records are available through HIE.	His records are not available through HIE.	His records are available through HIE, minus the rheumatoid arthritis information.	His general medical information is available but not specialist information through HIE.	His records are available through HIE.

<b>Scenario Step</b>	<b>No Consent (Patient Info IN)</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Admitted to emergency department	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.	Current episode record initiated in EHR. EMT partial medical screening is available and entered into EHR.
Emergency department physician	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.	Emergency department physician reviews the partial medical screenings of ambulance EMT and emergency department staff and accesses Calvin’s information.
Emergency department physician	All Calvin’s information is available through HIE.	No information on Calvin is available through HIE.	Calvin’s information is available through HIE, minus the rheumatoid arthritis information.	Calvin’s general medical information only is available through HIE.	All Calvin’s information is available through HIE.
Emergency department physician	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.	Begins listing potential causes of shortness of breath and chest pains. Calvin presents with agonal breathing—is intubated on arrival. Immediate chest x-ray reveals proper tube placement and bilateral infiltrates consistent with pneumonia. Shortness of breath could contribute to heart attack.

<b>Scenario Step</b>	<b>No Consent (Patient Info IN)</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Emergency department physician	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.	Potential causes Pneumonia—probable sepsis, angina, new myocardial infarction, new ischemic event, potential stent displacement.  Labs ordered complete blood count, Chem 8, lactate, blood cultures, EKG, and cardiac markers.
Laboratory	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).	Laboratory collects and tests; enters results. Specific blood panel results are entered into the hospital EHR, including: Lactate 4.5 mmol/L; slightly elevated CK MB (disease or damage to heart muscle).
Patient status	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.	Calvin reports decreased chest pain but continuing discomfort and shortness of breath. Questioning yields no usable information.
Lab results	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.	Physician interprets lab results, determines diagnosis, and enters treatment plan orders.

<b>Scenario Step</b>	<b>No Consent (Patient Info IN)</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/ Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/ Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Diagnoses	Negative drug interaction with rheumatoid arthritis medication and angina based on unchanged EKG from previous cardiologist’s study. Heart issue ruled out.	Pneumonia with sepsis confirmed. Heart issue—evidence of prior STEMI (ST segment elevation myocardial infarction). Previous EKG information not available.	Pneumonia with sepsis confirmed—rheumatoid arthritis medication information not available. Heart issue ruled out, previous EKG information available.	Pneumonia with sepsis confirmed. Heart issue—evidence of prior STEMI (ST segment elevation myocardial infarction). Previous EKG information not available.	Negative drug interaction with rheumatoid arthritis medication and angina based on unchanged EKG from previous cardiologist’s study. Heart issue ruled out.
Treatment prescribed	Cease use of rheumatoid arthritis medication and prescribed alternate anti-inflammatory administered through IV to flush patient’s system. Monitor.	—	Antibiotic therapy ordered with alternative therapy given due to Vancomycin allergy. Suggest transfer Calvin to cardiac catheterization laboratory for further workup on heart issue.	Vancomycin antibiotic therapy ordered. Suggest transfer Calvin to cardiac catheterization laboratory for further workup on heart issue.	Antibiotic therapy ordered with alternative therapy given due to Vancomycin allergy.
Patient response to treatment	Patient is stabilized. Blood pressure normal. Responding well IV with alternate anti-inflammatory medication. Calvin is transferred to the ICU for continuing care and monitoring of new anti-inflammatory medication.	—	Calvin’s blood pressure normal, heart attack still possible diagnosis, no hives. Patient transferred to cardiac catheterization lab for further workup.	Calvin develops hives and increasing ventilator settings are required to maintain oxygenation and ventilation. Patient is immediately transferred via helicopter to cardiac catheterization lab for further workup and alternative ventilation therapy.	Benadryl IV is prescribed and given, but there is still difficulty breathing. Increasing ventilator settings are required to maintain oxygenation and ventilation.

Scenario Step	No Consent (Patient Info IN)	Opt Out (Patient Auto IN)	Opt In w/ Restrictions (Patient Auto OUT plus Choice)	Opt Out w/ Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Outcome	Treatment plan is effective and appropriate for Calvin. Quality of care is high. Costs are appropriate and minimal. Chest pain is accurately diagnosed as Angina based on comparison to the cardiologist’s study results in HIE.	—	Rheumatoid arthritis medication drug interaction identified in general health information in HIE, so hives and decreased breathing drug reaction avoided. But, Calvin receives unnecessary treatment that over utilizes scarce cardiac catheterization lab resources. Increased costs to system. Unsafe situation if catheterization lab is unavailable to someone who really needs that treatment.	Treatment plan is not effective and harmful to Calvin. Quality of care is lower without HIE. Dangerous drug reaction to Vancomycin occurs. Helicopter and cardiac catheterization lab utilization increase costs and makes those resources unavailable to patient actually in need.	Treatment plan only partially effective. Although heart attack is ruled out, the drug interaction involving the rheumatoid arthritis medication with another recent medication prescribed was not identified. Calvin remained in the emergency department, more tests ordered to determine the cause of breathing problem. Calvin referred to ICU to be stabilized for the negative drug interaction. Increased costs.

**FORM 2G**  
**COMPARATIVE SUMMARY ANALYSIS MODIFIED**

# **INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE**

## **COMPARATIVE SUMMARY ANALYSIS (MODIFIED VERSION)**

**Date**

### **COMMITTEE**

[Insert the name of the committee or working body that is completing the analysis.]

### **SCENARIO ONE**

[Insert scenario here.]

### **ASSUMPTIONS**

[Insert assumptions here.]

### **BACKGROUND**

List the most significant pros and cons with respect to the impact each of the five (5) consent policy options is likely to have on health care costs and quality of care, the business processes of the health care providers, consumer and provider trust in HIE, and legal liabilities of parties involved.

**Form 2g—Table 1. Definitions**

Specific Issue	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
Definitions	<b>Auto In.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission and regardless of consumer preferences. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization.	<b>Auto In with Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i>	<b>Auto Out with Granular Choice.</b> Consumer’s health information is not automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i> In addition, consumers may specify (i) who may access their EHR; (ii) for what purposes the EHR may or may not be accessed; and/or (iii) what specific information may be placed in their EHR.	<b>Auto In with Granular Choice.</b> Consumer’s health information is automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that all of the consumer’s health information, except as otherwise prohibited by law, will be accessible across more than one health organization <i>unless and until the consumer chooses to opt out.</i> In addition, consumers may specify: (i) who may access their EHR; (ii) for what purposes their EHR may or may not be accessed; and/or (iii) what specific health information may be placed in their EHR.	<b>Auto Out with Choice.</b> Consumer’s health information is not automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization <i>unless and until the consumer opts in.</i>

**Form 2g—Table 2. Quality of Care**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2g—Table 3. Business Practice Impact**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2g—Table 4. Public Confidence—Trust in HIE**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2g—Table 5. Health Care Cost Avoidance**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2g—Table 6. Liability and Laws**

No Choice	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**FORM 2H  
SUMMARY OF LAWS**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## SUMMARY OF LAWS [HEALTH SCENARIO]—APPLICABLE LAWS

**Form 2h—Table 1. Health Scenario**

Step in the Case Scenario	Area of Concern	Applicable Law Citation	Obligations
—	—	—	—
—	—	—	—

**FORM 2I**  
**CSA PUBLIC MENTAL HEALTH**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## COMPARATIVE ANALYSIS PUBLIC MENTAL HEALTH SCENARIO

**Date**

### COMMITTEE

[Insert the name of the committee or working body that is completing the analysis.]

### ISSUE

[Put your issue statement here.]

### BACKGROUND

[Put your background statement here.]

### ASSUMPTIONS

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

- 
- 
- For purpose of this analysis: [You can use these definitions or adapt.]
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus a better quality of care. However, this option may result in less data being available due to patients choosing not to seek care or less accurate information being available due to patients providing incorrect information.
  - *Opt Out*—this choice will result in *more* information being available as all patient information will be in the system except for those patients choosing to opt out.
  - *Opt In with Restrictions*—this choice will result in the *least* information being available to the physician.
  - *Opt Out with Exceptions*—this choice will result in *some* information being available as patient information will be in the system except for those patients choosing to opt out and the information patients choose exceptions.
  - *Opt In*—this choice will result in *less* information being available since patients will need to take an action to be included in the system.

## NOTES

- (1) Preferred Terms—clients/consumers rather than patient. (2) Client Philosophy—client prefers to manage and control his/her mental health information and may not wish to have the information shared.
- **Legend**—+ (plus sign) is equivalent to a pro statement, – (minus sign) is equivalent to a con statement, and a • (bullet) is equivalent to a neutral statement.
- **Consent:** A client’s informed decision to provide permission for their personal health information to be entered and exchanged in an electronic health information exchange system.

[Note—Since this format was used for a public mental health treatment situation the order of the issues is different. Laboratories, e-prescribing, and emergency departments treatment situations were similar, but mental health subject matter experts put the issues into a different priority.]

**Form 2i—Table 1. Client—Public Acceptance/Social Drivers**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Client—public acceptance/ social drivers	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Client—public acceptance/ social drivers	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 2. Principles**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Principles	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Principles	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 3. Quality of Care**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
<b>Provider</b> wants to deliver effective treatment in the most efficient way.	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
<b>Provider</b> wants to deliver effective treatment in the most efficient way.	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]
<b>Client</b> wants effective treatment balanced with protection of their information.	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
<b>Client</b> wants effective treatment balanced with protection of their information.	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 4. Level of Trust in HIE**

Influenced by Client Choice (whether information is exchanged and if so, what information is exchanged and to whom), efforts to inform and educate, safeguard client information, ability to provide extra protections of sensitive information [errors amplified as carried forward through HIE, increased professional responsibility].

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
<b>Provider</b> wants other Provider in HIE to safeguard information and provide accurate and complete information.	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
<b>Provider</b> wants other Provider in HIE to safeguard information and provide accurate and complete information.	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]
<b>Client</b> wants to be informed and know that the Provider and HIE will provide accurate information for treatment and will safeguard information.	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
<b>Client</b> wants to be informed and know that the Provider and HIE will provide accurate information for treatment and will safeguard information.	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 5a. Savings and Cost Avoidance**

Provider business processes improved; ease of integration, less paperwork, improved communication, reduced duplicative tests and harmful drug interactions and drug shopping, increased accuracy and effectiveness, savings in long term, better quality of care, quicker reimbursements, accessing payer information for claims and eligibility.

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Savings and cost avoidance	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Savings and cost avoidance	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 5b. Investment**

Provider business process improvement expenses and time for technical upgrades, tech support, maintenance, oversight, complexity of implementation, education and notices, inputting and managing client choice (ongoing).

- Cost of enforcement effort (design and implementation)
- Secondary process for those clients not participating in exchange or for sensitive information
- Sustainability and success of HIE system affected by the percentage of participating clients and providers.

Specific Issues	No Consent	Opt Out (Patient Auto IN)	Opt In w/Restrictions (Patient Auto OUT plus Choice)	Opt Out w/Exceptions (Patient Auto IN plus Choice)	Opt In (Patient Auto OUT)
Investment	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Investment	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 6. Technology**

Compatibility, integration, and complexity. Size of entity affects the ease of integrating the technology. Technology compatibility equally challenging due to lack of identification of data elements and standard code sets.

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Technology	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Technology	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 7. National Efforts**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
National efforts	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
National efforts	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 8. Political Viability**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Political viability	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Political viability	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**Form 2i—Table 9. Liability and Laws**

<b>Specific Issues</b>	<b>No Consent</b>	<b>Opt Out (Patient Auto IN)</b>	<b>Opt In w/Restrictions (Patient Auto OUT plus Choice)</b>	<b>Opt Out w/Exceptions (Patient Auto IN plus Choice)</b>	<b>Opt In (Patient Auto OUT)</b>
Liability and laws	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]	+ [Insert text here.]
Liability and laws	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]	- [Insert text here.]

**FORM 3A**  
**SUMMARY OF PROS AND CONS**

**Form 3a—Table 1. Quality of Care**

Quality of Care	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p><b>GOAL:</b> High quality of health care resulting from timely access to a high volume of complete and accurate EHRs, and high level of consumers involvement in the management of their own health care</p> <p><b>FACTORS:</b></p> <ul style="list-style-type: none"> <li>• Amount of reliable information available to providers through HIE</li> <li>• Consumer participation in HIE</li> </ul>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>

**Form 3a—Table 2. Provider Business Impact**

Provider Business Impact	No Choice	Opt Out	Opt In with Restrictions	Opt Out with Exceptions	Opt In
<p><b>GOAL:</b> A consent policy that:</p> <ul style="list-style-type: none"> <li>• is easy and cost effective to implement and administer</li> <li>• is inexpensive to train staff and consumers</li> <li>• ensures cost savings from HIE</li> <li>• ensures consumer participation</li> </ul>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>

**Form 3a—Table 3. Confidence in HIE**

<b>Confidence in HIE</b>	<b>No Choice</b>	<b>Opt Out</b>	<b>Opt In with Restrictions</b>	<b>Opt Out with Exceptions</b>	<b>Opt In</b>
<p><b>GOAL:</b> A consent policy that:</p> <ul style="list-style-type: none"> <li>instills consumer confidence and trust in HIE</li> <li>instills provider confidence and willingness to participate in HIE</li> </ul>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>

**Form 3a—Table 4. Liability and Laws**

<b>Liability and Laws</b>	<b>No Choice</b>	<b>Opt Out</b>	<b>Opt In with Restrictions</b>	<b>Opt Out with Exceptions</b>	<b>Opt In</b>
<p>How will current federal and state laws about release of information and consent (and liability for breaches of those laws) likely affect the risk/advisability of each consent option?</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>	<p><b>Summary of Pros</b> [Insert text here.]</p> <p><b>Summary of Cons</b> [Insert text here.]</p>

**FORM 3B  
SUMMARY OF FINDINGS**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## SUMMARY OF FINDINGS

### Date

#### COMMITTEE

[Insert the name of the committee or working body.]

#### FACTORS

[Put your factors here.]

#### ASSUMPTIONS

[Put your agreed-upon assumptions here. These are usually agreed upon in stakeholder collaborative discussions.]

#### CONSENT OPTIONS

**NO CHOICE: Auto In.** Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission and regardless of consumer preferences. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization.

**OPT OUT: Auto In with Choice.** Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization *unless and until the consumer chooses to opt out.*

**OPT OUT WITH EXCEPTIONS: Auto In with Granular Choice.** Consumer's health information is automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that all of the consumer's health information, except as otherwise prohibited by law, will be accessible across more than one health organization *unless and until the consumer chooses to opt out.* In addition, consumers may specify: (i) who may access their EHR; (ii) for what purposes their EHR may or may not be accessed, and/or (iii) what specific health information may be placed in their EHR.

**OPT IN: Auto Out with Choice.** Consumer's health information is **not** automatically placed into an interoperable EHR without the consumer's prior permission. Assumes that none of the consumer's health information will be accessible across more than one health organization *unless and until the consumer opts in.*

**OPT IN WITH RESTRICTIONS: Auto Out with Granular Choice.** Consumer’s health information is **not** automatically placed into an interoperable EHR without the consumer’s prior permission. Assumes that none of the consumer’s health information will be accessible across more than one health organization *unless and until the consumer opts in*. In addition, consumers may specify (i) who may access their EHR; (ii) for what purposes the EHR may or may not be accessed; and/or (iii) what specific information may be placed in their EHR.

**Form 3b—Table 1. Quality of Care**

No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]	[Insert text here.]

**Form 3b—Table 2. Provider Business Impact**

No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Design and implementation: [Insert text here.]				
Provider business process: [Insert text here.]				
Patient and provider education: [Insert text here.]				

**Form 3b—Table 3. Liability and Laws**

Where the law requires advance consumer consent to exchange health information through HIE, consent is not a policy option.

No Choice	Opt Out	Opt In w/Restrictions	Opt Out w/Exceptions	Opt In
Release of info: [Insert text here.]				
Malpractice liability: [Insert text here.]				

**FORM 3C  
ISSUE RECOMMENDATION**

# INTRASTATE AND INTERSTATE CONSENT POLICY OPTIONS COLLABORATIVE

## ISSUE RECOMMENDATION

Date

<b>COMMITTEE:</b>		<b>DATE:</b>	
<b>ISSUE:</b>			
<b>INSTRUCTIONS:</b>	Identify the recommended alternative, supporting information for selecting the alternative and the recommendation for how the alternative would be implemented.		
<b>RECOMMENDATION:</b>	Alternative #:		
<b>SUPPORT FOR FINDING:</b>			
<b>RECOMMENDED IMPLEMENTATION STRATEGIES:</b>			
<b>DISSENTING OPINION:</b>			

Created by CALIFORNIA PRIVACY AND SECURITY ADVISORY BOARD