

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

## **APPENDIX E: COMPARATIVE SUMMARY ANALYSIS LABORATORIES**

**March 2009**

Health Information Security & Privacy

**COLLABORATION**



## Committee

**Privacy**—Consent for Sharing Laboratory Information

## Issue

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

Currently, consent is not required for sharing some laboratory information among health care providers/payers under HIPAA and California law.

## Assumptions

- Treating physician and a pharmacy can have an electronic data exchange relationship without being a participant in the HIE.
- Sharing laboratory information will be limited to 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.
- Lab information goes to multiple entities. The lab collects and tests, then transmits to the requestor and into the sharable EHR.
- For purposes of this analysis, the following definitions are provided:
  - *No Consent*—this choice will result in the *most* information being available to the physician, thus potentially providing a better quality of care. However, this option may result in (1) less data being available because patients choose not to seek care, or (2) less accurate information being available because patients provide incorrect information.
  - *Opt Out*—this choice will result in *more* information being available because all patient information will be in the system except for those patients who choose 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 who choose 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.

## 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.

**Table E-1A. Patient—Quality of Care**

**Specific Issue:** Patients want effective treatment balanced with protection of their information

<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 the HIE)	– Least quality of care (portion not IN the HIE)	• Some quality of care (portion not IN the HIE)	– Less quality of care (portion not IN the HIE)
+ Most potential increase in efficacy of care	+ More potential increase in efficacy of care	– Least potential increase in efficacy of care	• Some potential increase in efficacy of care	– Less potential increase in efficacy of care
+ Most patient participation	+ More patient participation for patients who do not opt out.	– Least patient participation for: 1. patients who do not opt in, 2. patients who choose to restrict significant information	• Some patient participation for: 1. patients who do not opt out, 2. patients who choose to restrict significant information	– Less patient participation for patients who do not opt in.
– No patient choice	• Some patient choice (OUT or IN)	+ Most patient choice and specificity in choice	+ More patient choice and specificity in choice	• Some patient choice (IN or OUT)

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

**Table E-1B. Provider—Quality of Care**

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

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—all patients IN	+ More quality of care for portion IN	– Least quality of care for portion not IN	• Some quality of care for portion IN	– Less quality of care for 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 high volume of information	– More safeguards required to protect patient information due to lower volume of information	+ Fewest safeguards required to protect patient information due to low volume of information	• Some safeguards required to protect patient information due to low volume of information	+ Fewer safeguards required to protect patient information due to less volume of information
+ Fewest safeguards required to protect patient information due to low complexity	• Some safeguards required to protect patient information due to low complexity	– Most safeguards required to protect patient information due to high complexity	– Most safeguards required to protect patient information due to high complexity	• Some safeguards required to protect patient information due to low complexity

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

**Table E-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.

<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>
+ Least need for education due to low complexity	+ Less need for education due to less complexity	– Most need for education due to most complexity	– Most need for education due to most complexity	• More need for education due to more complexity
+ Least potential errors due to high volume of information	• Some potential errors due to volume of information	– Most potential errors due to least volume of information and most complexity	– Most potential errors due to most volume of information and most complexity	– More potential errors due to less volume of information
– No patient choice, low trust	• Some patient choice/trust	+ Most patient choice/trust	+ Most patient choice/trust	+ More patient choice/trust
– Most need to protect patient information due to high volume	– Less need to protect patient information due to more volume	+ Least need to protect patient information due to least 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 low complexity	• Some need to protect patient information due to complexity	– Most need to protect patient information due to most complexity	– Most need to protect patient information due to most complexity	+ Less need to protect patient information due to less complexity

Note: 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.

**Table E-2B. Provider—Level of Trust: HIE**

**Specific Issue:** Provider wants other provider in HIE to safeguard information and provide accurate and complete information.

<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>
+ Least potential errors due to most volume	+ Less potential errors somewhat due to more volume	– Most potential errors due to low volume and most complexity	– Most potential errors due to most complexity and somewhat due to less volume	– More potential errors due to low volume
– Most need to protect patient information due to high volume	– More need to protect patient information due to volume	+ Least need to protect patient information due to low volume	• Some need to protect patient information due to volume	+ Less need to protect patient information due to low volume
+ Least need to protect patient information due to least complexity	+ Less need to protect patient information due to less complexity	– Most need to protect patient information due to most complexity	– Most need to protect patient information due to most complexity	+ Less need to protect patient information due to less complexity
+ Least need for staff and patient education	• 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 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.

**Table E-3. Savings and Cost Avoidance**

**Specific Issue:** 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 info for claims and eligibility. (Degree of cost avoidance will apply to all ancillary services in health care.)

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 process impacts due to most volume, least complexity and non-duplicative lab tests	+ More savings from business process impact due to most volume, less complexity and non-duplicative lab tests	– Least savings from business process impact due to least volume, most complexity and most potential for duplicate lab tests	– Least savings from business process impact due to less volume, most complexity, with some potential for duplicative lab tests	– Less savings from business process impact due to less volume, less complexity with some non-duplicative lab tests
+ 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 most volume	– More cost to educate due to more volume	+ Least cost to educate due to least volume	+ Least cost to educate due to less volume	• Some cost to educate due to volume
+ Least cost to educate due to least complexity	• Some cost to educate due to complexity	– Most cost to educate due to most complexity	– Most cost to educate due to most complexity	– More cost to educate due to less complexity but need for outreach

**Table E-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

**Table E-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

Note: Markle—Connecting for Health and the NCVHS—National Commission on Vital & 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.

**Table E-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

**Table E-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, (8) accountability—NA

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>+ Consistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>	<b>+ Consistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>	<b>+ Consistent with:</b> <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>	<b>+ Consistent with:</b> <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>	<b>+ Consistent with:</b> <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>
<b>- Inconsistent with:</b> <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>	<b>- Inconsistent with:</b> <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>	<b>- Inconsistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>	<b>- Inconsistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>	<b>- Inconsistent with:</b> <ul style="list-style-type: none"> <li>Health information quality</li> </ul>

**Table E-8. 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)
+ Promotes quality of care	+ Promotes quality of care	- Diminishes quality of care	+ Promotes quality of care	- Diminishes quality of care
+ Least costly/most sustainable	+ Less costly/most sustainable	- Most costly/least sustainable	- Most costly/least sustainable	- More costly/less 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
+ Most likely to reduce duplicate tests	+ More likely to reduce duplicate tests	- Least likely to reduce duplicate tests	- Less likely to reduce duplicate tests	- Less likely to reduce duplicate tests