

**RESPONSIVENESS SUMMARY REGARDING PUBLIC COMMENTS
RECEIVED ON THE SCHIEX GOVERNANCE DOCUMENTS**

DEFINITIONS

Commenter	Section	Comment	Response
Greenville Hospital System (“GHS”)	1.14	The term “Governance Authority” should be better defined to make clear who is on the Authority.	The term “Governing Authority” is defined in the Definitions document as the SCHIEx Interim Governance Committee or entity established by statute. The current Governing Authority is the SCHIEx Interim Governance Committee (“IGC”) established by Executive Order 2009-15. The members of the IGC are specified in that Executive Order. When legislation is enacted regarding SCHIEx, the South Carolina General Assembly will determine by statute the members of the Governing Authority. A reference to the Executive Order has been added, however, to clarify the definition.

BUSINESS ASSOCIATE AGREEMENT

Commenter	Section	Comment	Response
Palmetto Health	1.10	Security Rule is not included in the definitions and document.	No change. The Security Rule is incorporated in the definition of “Privacy Rule.”
Palmetto Health	2.8	Business Associate should notify Covered Entity immediately of any actual or suspected breach, etc., instead of within five (5) business days.	No change. Five (5) business days is a reasonable amount of time and ample time to allow the Covered Entity to meet federal notice requirements.

Business Associate Agreement, continued

Commenter	Section	Comment	Response
Palmetto Health	2.9	Business Associate should provide written notice within 48 hours of unauthorized use or disclosure of Protected Health Information (“PHI”), instead of within five (5) business days. If security breach, must give notice immediately.	No change. See response above.
Palmetto Health	2.10	Business Associate must provide notice of Breach of Unsecured Protected Health Information within forty-eight (48) hours rather than five (5) business days. If a security breach, then must notify immediately.	No change. See response above.
Palmetto Health	2.11	Business Associate must notify Covered Entity immediately of any breaches by a subcontractor.	No change. See response above.
Regional Medical Center of Orangeburg and Calhoun Counties (“RMC”)	4.0	Concerned that this section is an indemnity provision.	No change. This section is not an indemnity provision. Rather, it is intended to clarify that each party to the Agreement is responsible for its own acts or failures to act.
GHS	5.3	Reference to Section 5.4 should be 6.4.	Corrected.
Palmetto Health	5.6 (6.6)	Include contact information for immediate notification.	No change. Not requiring immediate notification in the Business Associate Agreement.
Palmetto Health	New 5.10 (6.10)	Include new provision requiring Business Associate to maintain malpractice insurance in an amount approved by Covered Entity.	No change. State will not provide malpractice insurance.
Palmetto Health	New 5.11 (6.11)	Include new provision requiring the State to defend and indemnify Covered Entity because of Business Associate’s performance or lack of performance. Covered Entity would have sole control of defense and/or settlement.	No change. State will not indemnify.

Business Associate Agreement, continued

Commenter	Section	Comment	Response
GHS	6.4	Last sentence add the word “associate” between “business” and “agreement.”	Corrected.

POLICIES AND PROCEDURES

Commenter	Section	Comment	Response
Palmetto Health	Title of Document	Where is Section I?	Section I is an Introductory section and will be included in the final SCHIEEx Policy Manual.
Palmetto Health	Overall Comment	Document is micro-managing policies and staffing.	No change. SCHIEEx does not intend to micro-manage Participants’ operations, but it is responsible for establishing conditions of trust and interoperability to the protect patient information that will be exchanged electronically via SCHIEEx. This legal, policy, and technical framework is key to establishing trust with patients so that they will allow their health information to be exchanged via SCHIEEx.
Palmetto Health	Section II, Third Paragraph	In the first sentence after the word “periodically,” insert the words “in accordance with the Agreement.”	Change accepted. However, the proposed language was revised to say “in accordance with the Participation Agreement and the SCHIEEx Policy Manual.”
GHS	1.c	Delete the word “exchange.”	Section and document as a whole has been revised to clarify that the Governing Authority will be adopting a legal and policy framework for SCHIEEx and providing for the financial stability of SCHIEEx, not all HIEs.

Policies and Procedures, continued

Commenter	Section	Comment	Response
Palmetto Health	1.j	Revise the way specific regulations are referenced so document does not have to updated every time.	No change. This section requires policies and procedures to be consistent with state and federal law including but not limited to the listed statutes. This language would not have to be updated to include new requirements.
GHS	2.d and 8.b	Concerned about the requirement for a Privacy Officer and a Site Administrator.	No change. This document does require that a Participant have a Privacy Officer as well as a Site Administrator. Most Participants presumably already have a privacy officer because of HIPAA requirements. This document does not mandate that these positions be filled by different individuals although it states a preference that there be two individuals unless the Participant is a very small entity. If there are issues with administration of SCHIEEx at the Participant's location, it is preferable that the Privacy Officer who will investigate these issues not also be the Site Administrator.
Palmetto Health	3	Changing the Notice of Privacy Practices is an onerous task for a large organization.	Change accepted. Because exchange of patient information will be a new type of disclosure, patients will need to be informed of this disclosure and their rights regarding having their information exchanged via SCHIEEx, including the right to opt out. SCHIEEx hopes to mitigate any burden placed on Participants by providing sample language that can be included in Notices of Privacy Practices (NPPs). Additionally, the policy has been revised to allow Participant to notify patients regarding participation in SCHIEEx in a document other than a NPP so long as the notification document contains the elements required by the policy.

Policies and Procedures, continued

Commenter	Section	Comment	Response
Palmetto Health	5.f	SCHIEEx should provide the audit log of who has accessed an individual’s information through SCHIEEx, rather than the Participant.	<p>Because SCHIEEx utilizes a federated model architecture, SCHIEEx staff will not have access to the PHI contained in documents transported via SCHIEEx or any ability to decrypt these documents in transport. Nor will SCHIEEx know the identity of the Participant’s individual system user(s) who access the PHI.</p> <p>SCHIEEx will audit log information regarding each patient document level (no PHI) query and retrieval performed between SCHIEEx Participants. For example, SCHIEEx will know that a Continuity of Care Document regarding patient A was sent from provider B to provider C, but will not know the contents of the document or the individual system user(s) who accessed PHI.</p> <p>Participants must maintain their own audit logs as required by federal law. Moreover, any certified EHR must be able to comply with IHE standards which include specific audit log requirements within its repositories. Therefore, if a Participant is using a certified EHR, then the Participant’s EHR will have the capacity to generate an audit log in-house that will identify to whom information regarding a patient was sent via SCHIEEx.</p>

Policies and Procedures, continued

Commenter	Section	Comment	Response
GHS	6	Language of section, which addresses information subject to special protection, is too broad and vague.	No change. Section 6 requires the Participant to determine what information is subject to special protection (such as HIV, substance abuse and mental health) prior to disclosure through SCHIEEx. Participants already have to provide special protection for such information regardless of SCHIEEx. This section clarifies that the special status of such information must be taken into account when releasing information to SCHIEEx and authorizes the Participant to withhold such information from SCHIEEx if necessary.
Palmetto Health	7.a	Utilize a defined term encompassing “employers, agents and contractors.”	Change accepted. Documents revised to utilize the term “Participant User” which is already a defined term.
GHS	8.b	This section imposes a new demand to do SCHIEEx specific training which could be a significant unfunded resource commitment.	No change. SCHIEEx will provide for the electronic exchange of substantial amounts of patient information among providers in a manner that has not been done widely before now. It is essential to the trust framework of SCHIEEx that Participants ensure that their Participant Users are trained and understand all requirements. There are resources that will be made available to Participants to assist with their training programs.

Policies and Procedures, continued

Commenter	Section	Comment	Response
Palmetto Health	8.b	This section micromanages the Participant and its employees	No change. SCHIEEx does not intend to micro-manage Participants' operations, but it is responsible for establishing conditions of trust and interoperability to the protect patient information that will be exchanged electronically via SCHIEEx. This legal, policy, and technical framework is key to establishing trust with patients so that they will allow their health information to be exchanged via SCHIEEx. Establishing trust among Participants requires each have a Site Administrator that ensures only appropriate personnel have access to SCHIEEx, that they can be appropriately identified by their system identification, and that personnel are no allowed access to SCHIEEx via their system identification from Participants upon leaving the employ of the Participant.
Palmetto Health	8.c	This section, which requires that a Participant's internal policies allow for termination of an employee's access to SCHIEEx for a violation, may cause HR issues.	No change. It is essential to the trust framework of SCHIEEx that a Participant at least allow in its policies for termination of access by an employee who has improperly used information obtained from SCHIEEx or caused a breach.
Palmetto Health	8.d	Participant will use a generic training program for first part of section. SCHIEEx should provide training materials, including the document that a Participant User must sign.	No change. The training program, while it may be generic in some aspects, must include a comprehensive review of SCHIEEx requirements. SCHIEEx will assist with training requirements and will provide a sample Participant User Agreement for Participants.

Policies and Procedures, continued

Commenter	Section	Comment	Response
GHS	11	This section does not provide adequate due process and may result in subjective decision making. Penalties are not stayed during appeals.	<p>Change accepted. Section has been revised to allow the Fair Hearing Committee to grant a stay of the penalties during an appeal. It is critical to the trust framework of SCHIEEx that the Governing Authority be able to take appropriate enforcement action if a Participant violates SCHIEEx requirements. This section provides comparable due process procedures to those provided for other enforcement decisions by state agencies.</p> <p>Pursuant to the revised language, the filing of a petition for review does not stay a decision by the Executive Director to terminate a Participant’s participation in SCHIEEx. However, the Fair Hearing Committee assigned to the matter may grant a stay of the decision by the Executive Director upon appropriate terms. If a Participant requests in writing a stay of the decision by the Executive Director, the Fair Hearing Committee must rule on the request for a stay within ten calendar days of receipt of the request or other period of time as agreed to by the parties.</p>
Palmetto Health	11	This section allows for SCHIEEx to get too involved in a Participant’s policies and procedures. This should only apply to security breaches.	No change. The Governing Authority is only concerned with breaches that are connected to or involve SCHIEEx, such as misuse of patient information obtained through SCHIEEx. Breaches that do not involve SCHIEEx need not be reported to SCHIEEx.

Policies and Procedures, continued

Commenter	Section	Comment	Response
South Carolina Medical Association	11.f	This section should be amended to allow for an automatic stay if the Executive Director terminates or suspends a Participant’s use of SCHIEx and for an automatic stay if the Fair Hearing Committee agrees with the Executive Director’s decision. The Administrative Law Court (“ALC”) could decide whether the stay should remain intact during an appeal of the Fair Hearing Committee decision.	Change partially accepted. Section 11.f has been revised to allow the Fair Hearing Committee to stay any penalties imposed by the Executive Director pending a final resolution, by the Committee. Pursuant to the revised language, the filing of a petition for review does not stay a decision by the Executive Director to terminate a Participant’s participation in SCHIEx. However, the Fair Hearing Committee assigned to the matter may grant a stay of the decision by the Executive Director upon appropriate terms. If a Participant requests in writing a stay of the decision by the Executive Director, the Fair Hearing Committee must rule on the request for a stay within ten calendar days of receipt of the request or other period of time as agreed to by the parties. It is anticipated that a Participant’s participation would not be terminated except in the case of serious violations. With regard to the appeal of a decision of the Fair Hearing Committee, the ALC may issue an order regarding the effect of the appeal on the agency decision upon application by any party.

PARTICIPATION AGREEMENT

Commenter	Section	Comment	Response
Palmetto Health	Second “Whereas” clause	Where is the definition of “Permitted Purposes?”	The definition of “Permitted Purposes” is in a separate Definitions document which was posted for public comment along with the SCHIEx guidance documents.

Commenter	Section	Comment	Response
Palmetto Health	Fourth “Whereas” clause.	What are the core services? What is the technology platform?	SCHIEx offers the Core Network services required to engage in health information exchange. These include the following: Record Locator Service (RLS), Master Patient Index (MPI), Terminology Services and Standards, Trusted Uniform Transport: Public Key Infrastructure (PKI) Certificate-based Encryption Scheme and Authentication of Exchange Participants, Audit Log of Document Transport between Exchange Participants, Quality Reporting for Federal EHR Meaningful Use Incentives, Public Health Reporting/ Immunization Registry, RX (Prescription) HUB, Provider Directory, Direct Messaging, and the NHIN Connect Gateway. Definitions for “Core Services” and “Optional Services” have been added to the Policy Manual.
Palmetto Health	2.1	Is SCHIEx synonymous with the System?	Yes.
Palmetto Health	2.4	Is SCHIEx granted a perpetual license even after an entity no longer participates in SCHIEx and does this conflict with the termination provisions in the Business Associate Agreement? What data is required to be provided by the Participation Agreement?	Once a Participant terminates SCHIEx participation, no additional PHI will be provided by that Participant through SCHIEx to other Participants.
Palmetto Health	2.4	In line 8, after the word “by”, add the words “this Agreement and governed by...”. In the last line after the word “obligations,” and the words “in accordance with this Agreement and...”.	Change accepted.
Palmetto Health	3.1.a	In the first line, does the word “its” refer to SCHIEx or to the Participant?	Change accepted. The word “its” has been replaced with “SCHIEx”.

Commenter	Section	Comment	Response
Palmetto Health	3.1.a	In the last line before subsection (1), is the Participant required to have all of the following policies?	Yes, the Participant is required to have the listed policies.
Palmetto Health	3.1.a.2	Is the policy statement(s) regarding the “Purpose Specifications and Minimization” of data a SCHIEx policy that Participant could adopt?	SCHIEx Policies and Procedures (particularly Sections 4 and 5) contain information on these issues, but Participant may wish to be more detailed in its internal policies and procedures.
Palmetto Health	3.1.a	At the end of the section, add the words “or random as needed to ensure compliance.”	Change accepted.
Palmetto Health	3.h	What are “normal business hours?” This may not be sufficient give that health care is a 24/7 business.	SCHIEx Participants will have access to a 24/7 help desk through the Department of State Information Technology to address system performance issues. However, assistance with initial access and onboarding to SCHIEx will be available during normal business hours. Normal business hours are Monday through Friday from 8:30 am until 5:00 pm except for posted state holidays.
Palmetto Health	4.4	Persons other than employees may have access to SCHIEx through Participant, such as vendors, agents, ACO members, etc.	Comment accepted. Revised section to add the words “or other business relationship with the Participant.”
Palmetto Health	4.6	Termination or suspension of an individual Participant User login and/or passcode may be difficult to implement or monitor, and HR may not support.	No change. It is critical to the trust framework of SCHIEx that a Participant be able to terminate its Participant Users if a User violates SCHIEx requirements.
Palmetto Health	4.6	In the last line after the word “SCHIEx” add the words “per this Agreement or the Policy Manual.”	Change accepted.

Commenter	Section	Comment	Response
Palmetto Health	4.12	Does this section require all Business Associate Agreements of the Participant to comply with the SCHIEEx Policy Manual?	No. This only applies to Business Associate Agreements that relate to SCHIEEx.
Palmetto Health	5.1	Did not see a copy of the Individual User Agreement.	The sample agreement was not circulated for public comment. It will be incorporated in the SCHIEEx Policy Manual.
Palmetto Health	5.3.a	Who is responsible for managing the training program?	Training programs will be the responsibility of the Participant, but resources will be made available to Participants to assist with such programs.

Commenter	Section	Comment	Response
Palmetto Health	5.4	What are the services offered by SCHIEx?	<p>SCHIEx offers both the Core Network services required to engage in health information exchange and Optional Services that enable enhanced functionality. Core Services include the following: Record Locator Service (RLS), Master Patient Index (MPI), Terminology Services and Standards, Trusted Uniform Transport: Public Key Infrastructure (PKI) Certificate-based Encryption Scheme and Authentication of Exchange Participants, Audit Log of Document Transport between Exchange Participants, Quality Reporting for Federal EHR Meaningful Use Incentives, Public Health Reporting/ Immunization Registry, RX (Prescription) HUB, Provider Directory, Direct Messaging, and the NHIN Connect Gateway. Optional Services include the following services that SCHIEx may provide Participants who choose to contract and pay for such services in addition to the Core Services covered under the terms of the Participation Agreement: Provider Directory, Enhanced Direct Messaging, Clinical Viewer, EMR- Lite, E-prescribe, and Care Coordination Tools. Definitions for Core Services and Optional Services have been added to the Policy Manual. Both Core Services and Optional Services are subject to modification in order to meet ONC and CMS “meaningful use” requirements for health information exchange.</p>
Palmetto Health	5.5	This section appears to be a restatement of Sections 5.4 and 5.6	<p>No change. Section 5.5 is intended to make clear that access is limited to Participant Users who are properly identified to SCHIEx and who have been properly trained. This requirement is key to the trust framework of SCHIEx.</p>
Palmetto Health	5.6	Do not agree with this section. Participant should not be held responsible for the actions of its Participant Users.	<p>No change. Participant is responsible for the acts and omissions of its Participant Users and others who may access SCHIEx through the Participant.</p>

Commenter	Section	Comment	Response
Palmetto Health	5.7	Needs to be made consistent with Section 4.6 or let Section 4.6 stand on its own.	No change. These sections serve different purposes. Section 4.6 addresses termination of a Participant User’s access to SCHIEEx if the User violates SCHIEEx requirements. Section 5.7 addresses discipline of the Participant User in addition to termination of access to SCHIEEx. The Participant must appropriately discipline the Participant User in accordance with its disciplinary policies and procedures.
Palmetto Health	6	In line 3, revise language to allow automatic renewal for “additional one year terms”	Change accepted.
Palmetto Health	6	Change section references in last two lines.	Changes accepted. References corrected.
Palmetto Health	7	Change language to read “Participant and SCHIEEx agree to mutually execute a Business Associate Agreement.”	No change. There will be one standard Business Associate Agreement for SCHIEEx Participants and SCHIEEx. It is not practical for the State to have numerous contracts with varying terms.
Palmetto Health	8	SCHIEEx should notify Participants at least 90 days prior to the end of the term of any fee increases. SCHIEEx should invoice Participants for all fees which would then be due 30 days from receipt of the invoice.	Change accepted. The Agreement has been revised so that all Participant Agreements will terminate on December 31 st and renew annually on January 1 st . Any changes to the fee schedule will be posted 90 days prior to the end of the annual term. SCHIEEx will send Participants a subscription renewal notice via electronic mail 90 days prior to the end of the annual term.
Palmetto Health	9.3	What is the definition of a “Data Recipient?”	Language has been revised to state: “SCHIEEx grants to each Participant a non-exclusive, personal, nontransferable, limited license to use the software for access to or use of the system.”

Commenter	Section	Comment	Response
Palmetto Health	9.4	At the end of the section, which deals with copying software, add the words “except as needed for backup.”	No change. Participant may not copy software without SCHIEEx’s prior written consent.
Palmetto Health	9.6	Would need to see third-party agreements for software, hardware, and services before becoming a Participant.	Review of any necessary agreements with third-party vendors is the responsibility of the prospective Participant.
Palmetto Health	9.7	This section should be reciprocal. SCHIEEx should use similar reasonable efforts to ensure that it does not adversely impact a Participant’s operations.	Document already revised. The draft of this document released for public comment added a sentence to the end of this section to read as follows: “SCHIEEx must use similar reasonable efforts to ensure that it does not adversely impact Participant operations.”
Palmetto Health	11	SCHIEEx should indemnify Participants against claims of copyright infringement related to SCHIEEx and its services. Any indemnification provided by Palmetto Health must state that the indemnification is limited to State law on charitable entities.	This section was deleted in the draft released for public comment and replaced by a section entitled “LIABILITY” which provides that neither party is liable for the other party’s acts or failures to act. As a state entity, SCHIEEx will not indemnify Participants. Similarly, there is no requirement that Participants indemnify SCHIEEx.
RMC	11	Concerned that this section is an indemnity provision.	No change. There is no indemnity clause in the Agreement. This section was deleted in the draft released for public comment and replaced by a section entitled “LIABILITY” which provides that neither party is liable for the other party’s acts or failures to act. As a state entity, SCHIEEx will not indemnify Participants. Similarly, there is no requirement that Participants indemnify SCHIEEx.
Palmetto Health	13.1	Changes to the SCHIEEx Policy Manual should be binding in sixty (60) days rather than thirty (30) days.	Change accepted.

Commenter	Section	Comment	Response
Palmetto Health	15	What PHI must be made available via SCHIEEx? Will all PHI be available to all Participants?	Each Participant must determine what data or documents it will make available in its document repository and register in the SCHIEEx Statewide Document Registry for other SCHIEEx Participants to query and retrieve. This is part of the onboarding process as described in the SCHIEEx Interoperability Services Guide.
Palmetto Health	15	In line 6 after the word “Manual”, add the words “to include but not limited to the execution of a Business Associate Agreement.”	Change accepted. Revise section to provide that SCHIEEx shall ensure that the new Participant executes and becomes bound by “the Participation Agreement and the Business Associate Agreement provided in the SCHIEEx Policy Manual with the result that current Participants and the new Participant are all bound by identical Agreements.”
Palmetto Health	NOTICE (section will be numbered)	At the beginning of the section, add the words “Except as otherwise provided for in this Agreement.”	Change accepted. Section will be revised to read “Except as otherwise provided for in the SCHIEEx Policy Manual...”
Palmetto Health	New section 20	Add a new provision giving a Participant the right, at its own expense, to audit or inspect SCHIEEx.	No change. The Governing Authority, which has significant representation from healthcare providers, is responsible for overseeing SCHIEEx. SCHIEEx financial records will be audited as part of all applicable Budget and Control Board audits in accordance with State law.
Palmetto Health	New section 21	Add a new section regarding suspension and debarment of SCHIEEx, including provisions for certification by SCHIEEx that is not or proposed to be suspended or debarred by any state or federal agency, immediate notice to Participant of any suspension or debarment, and immediate termination of the Participation Agreement. SCHIEEx must also register on Participant’s vendor site.	No change. Under the terms of the Participation Agreement, the Agreement terminates upon performance by either party being rendered impossible.

