

**KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
POLICIES AND PROCEDURES**

P&P 10: HIO Certificate of Authority

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Background:

- 1) Kansas Statutes Annotated 65-6831 charges the Kansas Department of Health and Environment (KDHE) with establishing and implementing the following:
 - a) a process by which an HIO may apply for and receive approval from the KDHE Secretary by demonstrating compliance with the KDHE HIO standards;
 - b) a process by which an approved HIO shall be reapproved on appropriate intervals by demonstrating continued compliance with the KDHE HIO standards; and
 - c) a process for the investigation of reported concerns and complaints regarding an approved HIO and imposition of appropriate remedial and proactive measures to address any identified deficiencies.
- 2) Under state law, an approved HIO enjoys certain benefits not available to other HIOs including, but not limited to, immunity from civil or criminal liability or any adverse administrative action relating to the use or disclosure of PHI; eligibility for financial support from the State of Kansas; and assistance or support from the State of Kansas in securing any other source of funding. Additionally, state agencies shall not interface with any non-approved HIO.
- 3) KDHE has established standards an HIO must satisfy to be eligible for a Certificate of Authority to operate an approved HIO in the State of Kansas in the following policies and procedures "Standards":
 - a) P&P 02: *Patient Notice and Restrictions on Access*
 - b) P&P 03: *HIO Participants and Data Sources*
 - c) P&P 04: *Conditions of Participation*
 - d) P&P 05: *User Access*
 - e) P&P 06: *Authentication*
 - f) P&P 07: *Audits and Identification of Unauthorized Access*
 - g) P&P 08: *HIO Complaints and Corrective Action*
 - h) P&P 09: *HIO Minimum Approval Standards*

- 4) KDHE has determined its goal of achieving statewide health information exchange can be achieved only if it approves HIOs fully committed to supporting all Kansas providers seeking to participate in health information exchange and those approved HIOs can achieve financial sustainability. KDHE recognizes an HIO must make a substantial financial investment to establish and maintain operations to support statewide health information exchange. Given the nature of the Kansas market, KDHE anticipates only a limited number of HIOs will be able to sustain operations, and that the establishment of multiple HIOs in the state may threaten the sustainability of the approved HIOs. Therefore, KDHE may find it necessary to limit the number of Certificates of Authority issued for approved HIOs based on market analysis.

Purpose:

To establish the process by which:

- 1) an HIO may apply to KDHE during a designated Application Period for a Certificate of Authority to operate as an approved HIO in the State of Kansas;
- 2) KDHE shall take action on such applications and issue or deny Certificates of Authority; and
- 3) KDHE shall monitor approved HIOs for compliance with the Standards while operating under a Certificate of Authority.

Policy:

1) Application and Approval Process

- a) KDHE may establish a timeframe (“Application Period”) within which it will accept and consider new applications from organizations seeking approved HIO status. For renewals of existing Certificates of Authority the application period shall commence 120 days before the expiration of an existing certificate of authority and conclude 60 days prior to expiration. Certificates of Authority for approved HIOs shall be granted for a period of two (2) years.
- b) KDHE may grant Temporary Certificates of Authority to HIOs desiring to establish health information exchange operations in the State prior to KDHE establishing a complete, formal application process. Such Temporary Certificates of Authority shall be granted for terms not to exceed one (1) year and shall be granted at the sole discretion of the KDHE Secretary upon its receipt of the applicant’s submission of an approved business plan and confirmation of the applicant’s agreement to follow the policies and directions of KDHE as developed. An approved HIO operating under such Temporary Certificate of Authority shall be required to apply for a Certificate of Authority under the procedure hereafter described to continue operations beyond the term of temporary authority granted.
- c) Prior to the beginning of any Application Period, KDHE shall prepare an application form as appropriate in light of health care industry demands, including technological capability, statewide technical infrastructure, and health information exchange in Kansas. The application form shall be substantially similar to the form attached as **Exhibit A (KDHE-HIT-10A)**. KDHE shall be available to potential applicants to answer questions and provide clarification regarding the application process. By no later than the last day of an Application Period, an HIO seeking

approved status from KDHE shall submit a completed application form accompanied by supporting documentation (the "Application"). The completed Application shall be submitted to KDHE electronically.

- d) KDHE shall review submitted applications and make written recommendations to the KDHE Secretary regarding the applicants.
- e) KDHE shall review each submitted Application for completeness within ten (10) business days of its receipt. Any Application deemed by KDHE to be substantially incomplete shall be rejected. If any requested information in a substantially complete Application is incomplete or unclear, KDHE shall request clarification or supplemental information from the applicant's identified contact person.
- f) Once KDHE deems an Application complete, KDHE shall conduct an initial review of the Application for compliance with the then-current Standards. KDHE shall communicate any identified concerns to the applicant's contact person for purposes of resolving those concerns. An applicant may revise or supplement its Application within a reasonable period of time for purposes of bringing it into compliance with the Standards. Upon completion of review, KDHE shall prepare a memorandum to the KDHE Secretary forwarding the completed application and comment on the applicant's compliance with the aforementioned standards.
- g) Following review of the application, the KDHE Secretary may:
 - i) issue or deny a Certificate of Authority to the applicant;
 - ii) schedule and conduct a public hearing to afford the opportunity for comment regarding the applicant; or
 - iii) request supplemental information from the applicant and/or supplemental analysis by KDHE staff regarding the impact of issuing the Certificate of Authority.

In the case of (ii) and (iii), the KDHE Secretary shall issue or deny a Certificate of Authority to the Applicant.

- h) A Certificate of Authority shall remain effective for a period of two (2) years, provided the HIO maintains compliance with the Standards as demonstrated through ongoing reviews (*see* Section 3 below).
- i) An applicant for a Certificate of Authority shall, upon written request from KDHE, provide in a timely manner sufficient documentation and other information to KDHE for purposes of (i) evaluating the applicant's compliance with P&P 09 - *HIO Minimum Approval Standards*, and (ii) conducting the analysis described in Section 1(g). Any such information an HIO deems as proprietary shall be made available to KDHE only. As necessary and appropriate, KDHE shall provide summaries of such information of the KDHE Secretary for purposes of decision-making with regard to issuance of a Certificate of Authority.

2) Ongoing Review Process and Renewal of Certificate of Authority

- a) An approved HIO shall be responsible for bringing its operations into compliance with any and all changes to the Standards during the effective period of its Certificate of Authority (or Temporary Certificate of Authority) within the time period specified by the KDHE Secretary in approving the revised standards.
- b) On a regular basis, KDHE shall review the operations and, as required, conduct on-site audits of each approved HIO operating under a Certificate of Authority (or Temporary Certificate of Authority) to determine the HIO's continued compliance with then-applicable Standards. An approved HIO shall, upon written request from KDHE, provide in a timely manner sufficient documentation and other information to KDHE for purposes of evaluating the approved HIO's compliance with the Standards. Any such information an HIO deems as proprietary shall be made available to KDHE only. As necessary and appropriate, KDHE shall provide summaries of such information to KDHE Secretary for purposes of decision-making with regard to maintenance of a Certificate of Authority or Temporary Certificate of Authority.
- c) If KDHE determines an approved HIO does not satisfy the Standards based on the information submitted, the KDHE Secretary shall issue a corrective action plan specifying the steps the approved HIO shall take within a specified period of time to bring its operations into full compliance with those standards. If the HIO fails to satisfy the corrective action plan within a reasonable period of time, the KDHE Secretary may terminate the HIO's Certificate of Authority (or Temporary Certificate of Authority) or otherwise impose restrictions or conditions on the approved HIO's operations. *See also P&P 08 – HIO Complaints and Corrective Action.*
- d) To renew a Certificate of Authority, an approved HIO shall submit a completed application for re-approval at least sixty (60) days prior to the expiration date of the Certificate on a form to be developed by KDHE. The review of an application for and the issuance of a renewal Certificate of Approval shall follow the same procedures outlined in Section 1 with regard to an initial application. A Temporary Certificate of Authority cannot be renewed.

3) Reporting Requirements

- a) An approved HIO shall submit complete and accurate written quarterly reports regarding its current operations and future plans as directed by the KDHE Secretary. Such reports shall include, at a minimum, timely disclosure of any material change to the information submitted by the approved HIO as part of its application for a Certificate of Authority (or Temporary Certificate of Authority). A material change includes but is not limited to changes in financials, ownership, marketing plans, pricing structure, services or primary technology vendor platform or items 1 through 11 of P&P 09: HIO Minimum Approval Standards. Approved HIOs are required to provide notification to KDHE within 30 calendar days of any substantial material change.
- b) Any material change reported by an approved HIO pursuant to Section 3(a) shall be forwarded to KDHE as soon as practical for consideration and recommendation to the KDHE Secretary regarding whether such change requires any corresponding

revision to the approved HIO's Certificate of Authority (or Temporary Certificate of Authority) and, if so, specification of such change. An approved HIO shall cooperate fully with such review by responding to inquiries and submitting requested documentation. The KDHE Secretary shall take action on any such recommendation as soon as practical.

- c) Notwithstanding the foregoing, a Certificate of Authority (including a Temporary Certificate of Authority) shall not be transferable from an approved HIO to another person or entity. If an approved HIO undergoes a change of ownership (as defined by 42 CFR 489.18), the new owner may operate as an approved HIO pending action on its application by the KDHE Secretary. In such circumstances, the KDHE recommendation shall be based on the adequacy of information submitted by the new owner demonstrating the new owner's ability to maintain compliance with all terms and conditions of the Certificate of Authority (or Temporary Certificate of Authority).

4) Confidentiality and Conflicts of Interest.

- a) KDHE shall regard all documents and other information furnished by an HIO as confidential business records of the HIO and shall properly safeguard such documents and information in its possession, custody, or control from any unauthorized use or disclosure. To the fullest extent permissible under the law, KDHE shall not produce such documents and information in response to a request made under the Kansas Open Records Act.
- b) Upon a good faith request by an applicant or approved HIO, KDHE shall restrict access to any documents or other information produced by the applicant or approved HIO only to KDHE directors, staff, and committee members who have no conflicts of interest, as determined under KDHE's Conflicts of Interest policy. The review and evaluation of such documents or other information in determining whether the applicant or approved HIO satisfies a specific standard specified herein shall be restricted to such individuals.

5) Appeals

An applicant for a Certificate of Authority or an approved HIO that is adversely impacted by a decision made by KDHE regarding such application or Certificate of Authority (including a Temporary Certificate of Authority) may appeal that decision to the KDHE Secretary. The KDHE Secretary shall consider such appeal, affording the applicant or approved HIO the opportunity to present evidence and submit an oral or written argument, and shall issue a written opinion. An adverse decision may be further appealed pursuant to the Kansas Judicial Review Act.

6) Assessments

An approved HIO shall pay such reasonable licensing or other fees or make other reasonable resource commitments as deemed necessary by the KDHE Secretary to sustain essential KDHE functions as defined by the Kansas Health Information Technology and Exchange Act.