

**62J.498 HEALTH INFORMATION EXCHANGE.**

Subdivision 1. **Definitions.** The following definitions apply to sections 62J.498 to 62J.4982:

- (a) "Clinical transaction" means any meaningful use transaction that is not covered by section 62J.536.
- (b) "Commissioner" means the commissioner of health.
- (c) "Direct health information exchange" means the electronic transmission of health-related information through a direct connection between the electronic health record systems of health care providers without the use of a health data intermediary.
- (d) "Health care provider" or "provider" means a health care provider or provider as defined in section 62J.03, subdivision 8.
- (e) "Health data intermediary" means an entity that provides the infrastructure to connect computer systems or other electronic devices used by health care providers, laboratories, pharmacies, health plans, third-party administrators, or pharmacy benefit managers to facilitate the secure transmission of health information, including pharmaceutical electronic data intermediaries as defined in section 62J.495. This does not include health care providers engaged in direct health information exchange.
- (f) "Health information exchange" means the electronic transmission of health-related information between organizations according to nationally recognized standards.
- (g) "Health information exchange service provider" means a health data intermediary or health information organization that has been issued a certificate of authority by the commissioner under section 62J.4981.
- (h) "Health information organization" means an organization that oversees, governs, and facilitates the exchange of health-related information among organizations according to nationally recognized standards.
- (i) "HITECH Act" means the Health Information Technology for Economic and Clinical Health Act as defined in section 62J.495.
- (j) "Major participating entity" means:
- (1) a participating entity that receives compensation for services that is greater than 30 percent of the health information organization's gross annual revenues from the health information exchange service provider;
  - (2) a participating entity providing administrative, financial, or management services to the health information organization, if the total payment for all services provided by the participating entity exceeds three percent of the gross revenue of the health information organization; and
  - (3) a participating entity that nominates or appoints 30 percent or more of the board of directors of the health information organization.
- (k) "Meaningful use" means use of certified electronic health record technology that includes e-prescribing, and is connected in a manner that provides for the electronic exchange of health information and used for the submission of clinical quality measures as established by the Center for Medicare and Medicaid Services and the Minnesota Department of Human Services pursuant to sections 4101, 4102, and 4201 of the HITECH Act.

(l) "Meaningful use transaction" means an electronic transaction that a health care provider must exchange to receive Medicare or Medicaid incentives or avoid Medicare penalties pursuant to sections 4101, 4102, and 4201 of the HITECH Act.

(m) "Participating entity" means any of the following persons, health care providers, companies, or other organizations with which a health information organization or health data intermediary has contracts or other agreements for the provision of health information exchange service providers:

(1) a health care facility licensed under sections 144.50 to 144.56, a nursing home licensed under sections 144A.02 to 144A.10, and any other health care facility otherwise licensed under the laws of this state or registered with the commissioner;

(2) a health care provider, and any other health care professional otherwise licensed under the laws of this state or registered with the commissioner;

(3) a group, professional corporation, or other organization that provides the services of individuals or entities identified in clause (2), including but not limited to a medical clinic, a medical group, a home health care agency, an urgent care center, and an emergent care center;

(4) a health plan as defined in section 62A.011, subdivision 3; and

(5) a state agency as defined in section 13.02, subdivision 17.

(n) "Reciprocal agreement" means an arrangement in which two or more health information exchange service providers agree to share in-kind services and resources to allow for the pass-through of meaningful use transactions.

(o) "State-certified health data intermediary" means a health data intermediary that:

(1) provides a subset of the meaningful use transaction capabilities necessary for hospitals and providers to achieve meaningful use of electronic health records;

(2) is not exclusively engaged in the exchange of meaningful use transactions covered by section 62J.536; and

(3) has been issued a certificate of authority to operate in Minnesota.

(p) "State-certified health information organization" means a nonprofit health information organization that provides transaction capabilities necessary to fully support clinical transactions required for meaningful use of electronic health records that has been issued a certificate of authority to operate in Minnesota.

**Subd. 2. Health information exchange oversight.** (a) The commissioner shall protect the public interest on matters pertaining to health information exchange. The commissioner shall:

(1) review and act on applications from health data intermediaries and health information organizations for certificates of authority to operate in Minnesota;

(2) provide ongoing monitoring to ensure compliance with criteria established under sections 62J.498 to 62J.4982;

(3) respond to public complaints related to health information exchange services;

(4) take enforcement actions as necessary, including the imposition of fines, suspension, or revocation of certificates of authority as outlined in section 62J.4982;

(5) provide a biennial report on the status of health information exchange services that includes but is not limited to:

(i) recommendations on actions necessary to ensure that health information exchange services are adequate to meet the needs of Minnesota citizens and providers statewide;

(ii) recommendations on enforcement actions to ensure that health information exchange service providers act in the public interest without causing disruption in health information exchange services;

(iii) recommendations on updates to criteria for obtaining certificates of authority under this section; and

(iv) recommendations on standard operating procedures for health information exchange, including but not limited to the management of consumer preferences; and

(6) other duties necessary to protect the public interest.

(b) As part of the application review process for certification under paragraph (a), prior to issuing a certificate of authority, the commissioner shall:

(1) hold public hearings that provide an adequate opportunity for participating entities and consumers to provide feedback and recommendations on the application under consideration. The commissioner shall make all portions of the application classified as public data available to the public at least ten days in advance of the hearing. The applicant shall participate in the hearing by presenting an overview of their application and responding to questions from interested parties;

(2) make available all feedback and recommendations gathered at the hearing available to the public prior to issuing a certificate of authority; and

(3) consult with hospitals, physicians, and other professionals eligible to receive meaningful use incentive payments or subject to penalties as established in the HITECH Act, and their respective statewide associations, prior to issuing a certificate of authority.

(c) When the commissioner is actively considering a suspension or revocation of a certificate of authority as described in section 62J.4982, subdivision 3, all investigatory data that are collected, created, or maintained related to the suspension or revocation are classified as confidential data on individuals and as protected nonpublic data in the case of data not on individuals.

(d) The commissioner may disclose data classified as protected nonpublic or confidential under paragraph (c) if disclosing the data will protect the health or safety of patients.

(e) After the commissioner makes a final determination regarding a suspension or revocation of a certificate of authority, all minutes, orders for hearing, findings of fact, conclusions of law, and the specification of the final disciplinary action, are classified as public data.

**History:** 2010 c 336 s 6

**62J.4981 CERTIFICATE OF AUTHORITY TO PROVIDE HEALTH INFORMATION EXCHANGE SERVICES.**

Subdivision 1. **Authority to require organizations to apply.** The commissioner shall require an entity providing health information exchange services to apply for a certificate of authority under this section. An applicant may continue to operate until the commissioner acts on the application. If the application is denied, the applicant is considered a health information organization whose certificate of authority has been revoked under section 62J.4982, subdivision 2, paragraph (d).

Subd. 2. **Certificate of authority for health data intermediaries.** (a) A health data intermediary that provides health information exchange services for the transmission of one or more clinical transactions necessary for hospitals, providers, or eligible professionals to achieve meaningful use must be registered with the state and comply with requirements established in this section.

(b) Notwithstanding any law to the contrary, any corporation organized to do so may apply to the commissioner for a certificate of authority to establish and operate as a health data intermediary in compliance with this section. No person shall establish or operate a health data intermediary in this state, nor sell or offer to sell, or solicit offers to purchase or receive advance or periodic consideration in conjunction with a health data intermediary contract unless the organization has a certificate of authority or has an application under active consideration under this section.

(c) In issuing the certificate of authority, the commissioner shall determine whether the applicant for the certificate of authority has demonstrated that the applicant meets the following minimum criteria:

- (1) interoperate with at least one state-certified health information organization;
- (2) provide an option for Minnesota entities to connect to their services through at least one state-certified health information organization;
- (3) have a record locator service as defined in section 144.291, subdivision 2, paragraph (i), that is compliant with the requirements of section 144.293, subdivision 8, when conducting meaningful use transactions; and
- (4) hold reciprocal agreements with at least one state-certified health information organization to enable access to record locator services to find patient data, and for the transmission and receipt of meaningful use transactions consistent with the format and content required by national standards established by Centers for Medicare and Medicaid Services. Reciprocal agreements must meet the requirements established in subdivision 5.

Subd. 3. **Certificate of authority for health information organizations.** (a) A health information organization that provides all electronic capabilities for the transmission of clinical transactions necessary for meaningful use of electronic health records must obtain a certificate of authority from the commissioner and demonstrate compliance with the criteria in paragraph (c).

(b) Notwithstanding any law to the contrary, a nonprofit corporation organized to do so may apply for a certificate of authority to establish and operate a health information organization under this section. No person shall establish or operate a health information organization in this state, nor sell or offer to sell, or solicit offers to purchase or receive advance or periodic consideration in conjunction with a health information organization or health information contract unless the organization has a certificate of authority under this section.

(c) In issuing the certificate of authority, the commissioner shall determine whether the applicant for the certificate of authority has demonstrated that the applicant meets the following minimum criteria:

- (1) the entity is a legally established, nonprofit organization;
- (2) appropriate insurance, including liability insurance, for the operation of the health information organization is in place and sufficient to protect the interest of the public and participating entities;
- (3) strategic and operational plans clearly address how the organization will expand technical capacity of the health information organization to support providers in achieving meaningful use of electronic health records over time;
- (4) the entity addresses the parameters to be used with participating entities and other health information organizations for meaningful use transactions, compliance with Minnesota law, and interstate health information exchange in trust agreements;
- (5) the entity's board of directors is composed of members that broadly represent the health information organization's participating entities and consumers;
- (6) the entity maintains a professional staff responsible to the board of directors with the capacity to ensure accountability to the organization's mission;
- (7) the organization is compliant with criteria established under the Health Information Exchange Accreditation Program of the Electronic Healthcare Network Accreditation Commission (EHNAC) or equivalent criteria established by the commissioner;
- (8) the entity maintains a record locator service as defined in section 144.291, subdivision 2, paragraph (i), that is compliant with the requirements of section 144.293, subdivision 8, when conducting meaningful use transactions;
- (9) the organization demonstrates interoperability with all other state-certified health information organizations using nationally recognized standards;
- (10) the organization demonstrates compliance with all privacy and security requirements required by state and federal law; and
- (11) the organization uses financial policies and procedures consistent with generally accepted accounting principles and has an independent audit of the organization's financials on an annual basis.

(d) Health information organizations that have obtained a certificate of authority must:

- (1) meet the requirements established for connecting to the Nationwide Health Information Network (NHIN) within the federally mandated timeline or within a time frame established by the commissioner and published in the State Register. If the state timeline for implementation varies from the federal timeline, the State Register notice shall include an explanation for the variation;
- (2) annually submit strategic and operational plans for review by the commissioner that address:
  - (i) increasing adoption rates to include a sufficient number of participating entities to achieve financial sustainability; and

(ii) progress in achieving objectives included in previously submitted strategic and operational plans across the following domains: business and technical operations, technical infrastructure, legal and policy issues, finance, and organizational governance;

(3) develop and maintain a business plan that addresses:

(i) plans for ensuring the necessary capacity to support meaningful use transactions;

(ii) approach for attaining financial sustainability, including public and private financing strategies, and rate structures;

(iii) rates of adoption, utilization, and transaction volume, and mechanisms to support health information exchange; and

(iv) an explanation of methods employed to address the needs of community clinics, critical access hospitals, and free clinics in accessing health information exchange services;

(4) annually submit a rate plan to the commissioner outlining fee structures for health information exchange services for approval by the commissioner. The commissioner shall approve the rate plan if it:

(i) distributes costs equitably among users of health information services;

(ii) provides predictable costs for participating entities;

(iii) covers all costs associated with conducting the full range of meaningful use clinical transactions, including access to health information retrieved through other state-certified health information exchange service providers; and

(iv) provides for a predictable revenue stream for the health information organization and generates sufficient resources to maintain operating costs and develop technical infrastructure necessary to serve the public interest;

(5) enter into reciprocal agreements with all other state-certified health information organizations to enable access to record locator services to find patient data, and transmission and receipt of meaningful use transactions consistent with the format and content required by national standards established by Centers for Medicare and Medicaid Services. Reciprocal agreements must meet the requirements in subdivision 5; and

(6) comply with additional requirements for the certification or recertification of health information organizations that may be established by the commissioner.

**Subd. 4. Application for certificate of authority for health information exchange service providers.** (a) Each application for a certificate of authority shall be in a form prescribed by the commissioner and verified by an officer or authorized representative of the applicant. Each application shall include the following:

(1) a copy of the basic organizational document, if any, of the applicant and of each major participating entity, such as the articles of incorporation, or other applicable documents, and all amendments to it;

(2) a list of the names, addresses, and official positions of the following:

(i) all members of the board of directors, and the principal officers and, if applicable, shareholders of the applicant organization; and

(ii) all members of the board of directors, and the principal officers of each major participating entity and, if applicable, each shareholder beneficially owning more than ten percent of any voting stock of the major participating entity;

(3) the name and address of each participating entity and the agreed-upon duration of each contract or agreement if applicable;

(4) a copy of each standard agreement or contract intended to bind the participating entities and the health information organization. Contractual provisions shall be consistent with the purposes of this section, in regard to the services to be performed under the standard agreement or contract, the manner in which payment for services is determined, the nature and extent of responsibilities to be retained by the health information organization, and contractual termination provisions;

(5) a copy of each contract intended to bind major participating entities and the health information organization. Contract information filed with the commissioner under this section shall be nonpublic as defined in section 13.02, subdivision 9;

(6) a statement generally describing the health information organization, its health information exchange contracts, facilities, and personnel, including a statement describing the manner in which the applicant proposes to provide participants with comprehensive health information exchange services;

(7) financial statements showing the applicant's assets, liabilities, and sources of financial support, including a copy of the applicant's most recent certified financial statement;

(8) strategic and operational plans that specifically address how the organization will expand technical capacity of the health information organization to support providers in achieving meaningful use of electronic health records over time, a description of the proposed method of marketing the services, a schedule of proposed charges, and a financial plan that includes a three-year projection of the expenses and income and other sources of future capital;

(9) a statement reasonably describing the geographic area or areas to be served and the type or types of participants to be served;

(10) a description of the complaint procedures to be used as required under this section;

(11) a description of the mechanism by which participating entities will have an opportunity to participate in matters of policy and operation;

(12) a copy of any pertinent agreements between the health information organization and insurers, including liability insurers, demonstrating coverage is in place;

(13) a copy of the conflict of interest policy that applies to all members of the board of directors and the principal officers of the health information organization; and

(14) other information as the commissioner may reasonably require to be provided.

(b) Within 30 days after the receipt of the application for a certificate of authority, the commissioner shall determine whether or not the application submitted meets the requirements for completion in paragraph (a), and notify the applicant of any further information required for the application to be processed.

(c) Within 90 days after the receipt of a complete application for a certificate of authority, the commissioner shall issue a certificate of authority to the applicant if the commissioner

determines that the applicant meets the minimum criteria requirements of subdivision 2 for health data intermediaries or subdivision 3 for health information organizations. If the commissioner determines that the applicant is not qualified, the commissioner shall notify the applicant and specify the reasons for disqualification.

(d) Upon being granted a certificate of authority to operate as a health information organization, the organization must operate in compliance with the provisions of this section. Noncompliance may result in the imposition of a fine or the suspension or revocation of the certificate of authority according to section 62J.4982.

**Subd. 5. Reciprocal agreements between health information exchange entities.** (a) Reciprocal agreements between two health information organizations or between a health information organization and a health data intermediary must include a fair and equitable model for charges between the entities that:

(1) does not impede the secure transmission of transactions necessary to achieve meaningful use;

(2) does not charge a fee for the exchange of meaningful use transactions transmitted according to nationally recognized standards where no additional value-added service is rendered to the sending or receiving health information organization or health data intermediary either directly or on behalf of the client;

(3) is consistent with fair market value and proportionately reflects the value-added services accessed as a result of the agreement; and

(4) prevents health care stakeholders from being charged multiple times for the same service.

(b) Reciprocal agreements must include comparable quality of service standards that ensure equitable levels of services.

(c) Reciprocal agreements are subject to review and approval by the commissioner.

(d) Nothing in this section precludes a state-certified health information organization or state-certified health data intermediary from entering into contractual agreements for the provision of value-added services beyond meaningful use.

(e) The commissioner of human services or health, when providing access to data or services through a certified health information organization, must offer the same data or services directly through any certified health information organization at the same pricing, if the health information organization pays for all connection costs to the state data or service. For all external connectivity to the respective agencies through existing or future information exchange implementations, the respective agency shall establish the required connectivity methods as well as protocol standards to be utilized.

**Subd. 6. State participation in health information exchange.** A state agency that connects to a health information exchange service provider for the purpose of exchanging meaningful use transactions must ensure that the contracted health information exchange service provider has reciprocal agreements in place as required by this section. The reciprocal agreements must provide equal access to information supplied by the agency as necessary for meaningful use by the participating entities of the other health information service providers.

**History:** 2010 c 336 s 7



**62J.4982 ENFORCEMENT AUTHORITY; COMPLIANCE.**

Subdivision 1. **Penalties and enforcement.** (a) The commissioner may, for any violation of statute or rule applicable to a health information exchange service provider, levy an administrative penalty in an amount up to \$25,000 for each violation. In determining the level of an administrative penalty, the commissioner shall consider the following factors:

- (1) the number of participating entities affected by the violation;
- (2) the effect of the violation on participating entities' access to health information exchange services;
- (3) if only one participating entity is affected, the effect of the violation on the patients of that entity;
- (4) whether the violation is an isolated incident or part of a pattern of violations;
- (5) the economic benefits derived by the health information organization or a health data intermediary by virtue of the violation;
- (6) whether the violation hindered or facilitated an individual's ability to obtain health care;
- (7) whether the violation was intentional;
- (8) whether the violation was beyond the direct control of the health information exchange service provider;
- (9) any history of prior compliance with the provisions of this section, including violations;
- (10) whether and to what extent the health information exchange service provider attempted to correct previous violations;
- (11) how the health information exchange service provider responded to technical assistance from the commissioner provided in the context of a compliance effort; and
- (12) the financial condition of the health information exchange service provider including, but not limited to, whether the health information exchange service provider had financial difficulties that affected its ability to comply or whether the imposition of an administrative monetary penalty would jeopardize the ability of the health information exchange service provider to continue to deliver health information exchange services.

The commissioner shall give reasonable notice in writing to the health information exchange service provider of the intent to levy the penalty and the reasons for it. A health information exchange service provider may have 15 days within which to contest whether the facts found constitute a violation of sections 62J.4981 and 62J.4982, according to the contested case and judicial review provisions of sections 14.57 to 14.69.

(b) If the commissioner has reason to believe that a violation of section 62J.4981 or 62J.4982 has occurred or is likely, the commissioner may confer with the persons involved before commencing action under subdivision 2. The commissioner may notify the health information exchange service provider and the representatives, or other persons who appear to be involved in the suspected violation, to arrange a voluntary conference with the alleged violators or their authorized representatives. The purpose of the conference is to attempt to learn the facts about the suspected violation and, if it appears that a violation has occurred or is threatened, to find a way to

correct or prevent it. The conference is not governed by any formal procedural requirements, and may be conducted as the commissioner considers appropriate.

(c) The commissioner may issue an order directing a health information exchange service provider or a representative of a health information exchange service provider to cease and desist from engaging in any act or practice in violation of sections 62J.4981 and 62J.4982.

(d) Within 20 days after service of the order to cease and desist, a health information exchange service provider may contest whether the facts found constitute a violation of sections 62J.4981 and 62J.4982 according to the contested case and judicial review provisions of sections 14.57 to 14.69.

(e) In the event of noncompliance with a cease and desist order issued under this subdivision, the commissioner may institute a proceeding to obtain injunctive relief or other appropriate relief in Ramsey County District Court.

**Subd. 2. Suspension or revocation of certificates of authority.** (a) The commissioner may suspend or revoke a certificate of authority issued to a health data intermediary or health information organization under section 62J.4981 if the commissioner finds that:

(1) the health information exchange service provider is operating significantly in contravention of its basic organizational document, or in a manner contrary to that described in and reasonably inferred from any other information submitted under section 62J.4981, unless amendments to the submissions have been filed with and approved by the commissioner;

(2) the health information exchange service provider is unable to fulfill its obligations to furnish comprehensive health information exchange services as required under its health information exchange contract;

(3) the health information exchange service provider is no longer financially solvent or may not reasonably be expected to meet its obligations to participating entities;

(4) the health information exchange service provider has failed to implement the complaint system in a manner designed to reasonably resolve valid complaints;

(5) the health information exchange service provider, or any person acting with its sanction, has advertised or merchandised its services in an untrue, misleading, deceptive, or unfair manner;

(6) the continued operation of the health information exchange service provider would be hazardous to its participating entities or the patients served by the participating entities; or

(7) the health information exchange service provider has otherwise failed to substantially comply with section 62J.4981 or with any other statute or administrative rule applicable to health information exchange service providers, or has submitted false information in any report required under sections 62J.498 to 62J.4982.

(b) A certificate of authority shall be suspended or revoked only after meeting the requirements of subdivision 3.

(c) If the certificate of authority of a health information exchange service provider is suspended, the health information exchange service provider shall not, during the period of suspension, enroll any additional participating entities, and shall not engage in any advertising or solicitation.

(d) If the certificate of authority of a health information exchange service provider is revoked, the organization shall proceed, immediately following the effective date of the order of revocation, to wind up its affairs, and shall conduct no further business except as necessary to the orderly conclusion of the affairs of the organization. The organization shall engage in no further advertising or solicitation. The commissioner may, by written order, permit further operation of the organization as the commissioner finds to be in the best interest of participating entities, to the end that participating entities will be given the greatest practical opportunity to access continuing health information exchange services.

**Subd. 3. Denial, suspension, and revocation; administrative procedures.** (a) When the commissioner has cause to believe that grounds for the denial, suspension, or revocation of a certificate of authority exist, the commissioner shall notify the health information exchange service provider in writing stating the grounds for denial, suspension, or revocation and setting a time within 20 days for a hearing on the matter.

(b) After a hearing before the commissioner at which the health information exchange service provider may respond to the grounds for denial, suspension, or revocation, or upon the failure of the health information exchange service provider to appear at the hearing, the commissioner shall take action as deemed necessary and shall issue written findings and mail them to the health information exchange service provider.

(c) If suspension, revocation, or administrative penalty is proposed according to this section, the commissioner must deliver, or send by certified mail with return receipt requested, to the health information exchange service provider written notice of the commissioner's intent to impose a penalty. This notice of proposed determination must include:

- (1) a reference to the statutory basis for the penalty;
- (2) a description of the findings of fact regarding the violations with respect to which the penalty is proposed;
- (3) the nature and amount of the proposed penalty;
- (4) any circumstances described in subdivision 1, paragraph (a), that were considered in determining the amount of the proposed penalty;
- (5) instructions for responding to the notice, including a statement of the health information exchange service provider's right to a contested case proceeding and a statement that failure to request a contested case proceeding within 30 calendar days permits the imposition of the proposed penalty; and
- (6) the address to which the contested case proceeding request must be sent.

**Subd. 4. Coordination.** (a) The commissioner shall, to the extent possible, seek the advice of the Minnesota e-Health Advisory Committee, in the review and update of criteria for the certification and recertification of health information exchange service providers when implementing sections 62J.498 to 62J.4982.

(b) By January 1, 2011, the commissioner shall report to the governor and the chairs of the senate and house of representatives committees having jurisdiction over health information policy issues on the status of health information exchange in Minnesota, and provide recommendations on further action necessary to facilitate the secure electronic movement of health information

among health providers that will enable Minnesota providers and hospitals to meet meaningful use exchange requirements.

**Subd. 5. Fees and monetary penalties.** (a) The commissioner shall assess fees on every health information exchange service provider subject to sections 62J.4981 and 62J.4982 as follows:

- (1) filing an application for certificate of authority to operate as a health information organization, \$10,500;
- (2) filing an application for certificate of authority to operate as a health data intermediary, \$7,000;
- (3) annual health information organization certificate fee, \$14,000;
- (4) annual health data intermediary certificate fee, \$7,000; and
- (5) fees for other filings, as specified by rule.

(b) Administrative monetary penalties imposed under this subdivision shall be credited to an account in the special revenue fund and are appropriated to the commissioner for the purposes of sections 62J.498 to 62J.4982.

**History:** 2010 c 336 s 8