**Section 689.40 Immunization Data Provided to the Registry**

a) Both demographic and immunization data shall be reported by providers participating in the Registry. Providers shall report all data elements for all immunizations administered. The following are the minimum data elements that shall be reported to the Registry:

1) Patient demographic information shall include, but is not limited to:

A) First and last names, and, if applicable, middle name;

B) Gender;

C) Date of birth;

D) Home mailing address;

E) Telephone number, if available;

F) Race;

G) Ethnicity; and

H) Any additional information as may be determined by the Department.

2) Patient immunization information shall include, but is not limited to:

A) Name of immunization;

B) Manufacturer of immunization;

C) Lot/serial number of immunization;

D) Type of immunization administered using industry standards such as vaccine groups, Health Level 7 codes, or current procedural terminology codes;

E) Date of administration of immunization;

F) Identity of provider site administering immunization;

G) If applicable, any contraindications or religious or medical exemptions; and

H) Any additional information as may be required by the Department.

b) The current and historical immunization records of all children and adults in Illinois may be included in the Registry without consent. An individual, parent or legal guardian or custodian may have a record locked from other providers at any time by completing the Opt-Out Form, which shall be maintained at the provider site (see Section 689.80).

c) All active providers who receive publicly funded vaccine shall use the Registry for submission of their immunization records to the Department. Failure of providers who receive publicly funded vaccine to use the Registry may result in suspension from participation in the publicly funded vaccine program. Participation in the Registry by all other authorized immunization providers is voluntary.

d) Providers shall report all COVID-19 immunizations administered in Illinois to the Registry. Reporting of all other immunizations by providers is voluntary, except as provided in 689.40(c) for publicly funded vaccine providers.

e) Data shall be provided electronically through the Department's web-based Registry system or through a secure electronic system integrated with the Registry via Health Level 7 (HL7) 2.3.1 format or higher.

f) Users shall provide an acceptable level of data quality, such as correct data fields, data accuracy, and enough information to correctly merge with existing clients. Data shall be reviewed to determine data quality. Any rejected records shall be resolved by the user in a timely way. The Department will suspend system privileges and take any action, as appropriate, including termination for any user that submits inaccurate data.

g) *The Department* will *distribute to health care providers, upon request, written information to be disseminated to patients that describes the* Registry. *The written information will include a description of the* Registry *and its purpose*, as well as the information concerning the opt-out option (see Section 689.80). (Section 15(c) of the Act)

(Source: Amended at 46 Ill. Reg. 2680, effective January 28, 2022)