

# Regulation 61-120

## South Carolina Immunization Registry

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<b>Statutory Authority:</b>	S.C. Code Section 44-29-40
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## **A. Purpose and Scope.**

The purpose of this regulation is to provide rules, implementing Section 44-29-40 of the S.C. Code of Laws, 1976, as amended, regarding the South Carolina Immunization Registry requirements for reporting immunizations occurring in South Carolina, implementation and operation of the registry, data elements to be collected, content of electronic forms and reports, and the procedures for disclosure of confidential registry information. This regulation will apply to all healthcare providers who give immunizations in South Carolina. Nothing in this regulation shall be construed to affect statutory or common law principles governing the liabilities of health care providers for acts or omissions of their employees, agents, or contractors. Nothing in this regulation shall be construed to conflict with any state law or regulation governing immunizations or to alter, add to, or eliminate any requirement of state law or regulation regarding the administration of immunizations or to regulate the practice of any of the health care professions.

## **B. Definitions.**

1. **AUTHORIZED USER** means an employee of an immunization provider who has been identified during the registration process as a user of the registry.
2. **DEPARTMENT** means the Department of Health and Environmental Control.
3. **IMMUNIZATION PROVIDER** means an individual health care provider licensed, certified, registered, or otherwise authorized by law to provide immunizations, and an organization, facility, or other entity that provides immunizations through such individual providers.
4. **PATIENT** means an individual who receives an immunization or other health care services.
5. **REGISTRY** means the data system for the collection, storage, and dissemination of information on immunizations administered in South Carolina established by the Department pursuant to Section 44-29-40.

## **C. Registration and Reporting Requirements.**

1. Immunization providers shall register with the Department for access to the Registry.
  - a. All immunization providers shall register with the Department before administering any immunizations for which reporting is required under the implementation schedule in this regulation. This section governs only the registration requirement and is not intended to prohibit or restrict the administration of immunizations by any person authorized by law to do so.
  - b. Authorized users shall complete training under schedules established by the Department in a format determined by the Department. The Department will contact registered users to schedule and provide the training and other needed activities in order to use the registry. Immunization providers will not be responsible for completing the reporting requirements of this regulation until necessary training and set up have been completed by the Department.
  - c. An immunization provider that is a facility or business entity administering vaccines through employees, agents, or contractors may register in its own name, and the employees, agents, and contractors of such facilities or business entities need not register individually. An immunization provider that is a business entity with multiple locations may register once as a single provider for more than one location. Individual immunization providers who practice in a group or with a facility or business entity may register individually or in the name of the group or facility or business entity.

2. Each immunization provider shall identify one or more employees who will be authorized users of the registry on behalf of the immunization provider.

a. All authorized users shall maintain the confidentiality of their individual access codes and passwords for the immunization registry and shall not share or exchange such codes with any other person, regardless of whether or not that other person is an authorized user.

b. Each immunization provider and authorized user shall be individually responsible for complying with this regulation and the user agreement. The immunization provider shall be responsible, according to existing principles of agency law, for its authorized users' access to the registry and uses and disclosures of registry information, and compliance with this regulation and the user agreement.

c. Immunization providers and authorized users shall enter into and comply with user agreements specifying terms of use and confidentiality and other obligations. A breach of a user agreement is a violation of this regulation.

3. The immunization provider shall notify the Department within fifteen (15) business days after an authorized user is terminated or leaves employment for any reason. The immunization provider shall not be liable for applicable statutory penalties for its authorized users' post-employment violations of this regulation, if the immunization provider has notified the Department that the authorized user is no longer employed. This regulation shall not be construed to affect the immunization provider's liability to any third party for acts or omissions of its employee or other authorized user.

4. Immunization providers shall report all immunizations administered to the registry within ten (10) business days of administration. Immunizations shall be reported in a standard electronic format specified by the Department via the internet at a website specified by the Department, or via the South Carolina Health Information Exchange or other method specified by the Department. An immunization provider that is a facility or business entity administering vaccines through employees, agents, or contractors shall report immunizations administered by its employees, agents, and contractors.

5. For each immunization administered, immunization providers shall report, at a minimum, the date of immunization; specific type of vaccine given; first and last name, gender, and date of birth of the person receiving the vaccine; and name of the registered immunization provider. The Department may require reporting of other data as needed to comply with federal requirements.

6. In the event of a state or federal declared disaster, state of emergency, or public health emergency, at the Department's discretion, immunization providers shall report to the Department information regarding administration or dispensing of certain drugs, medications, chemicals, vaccines, or biological products used in response to the declared disaster, state of emergency, or public health emergency.

7. Immunization providers in other states who administer immunizations in South Carolina must comply with the requirements of this regulation. Immunization providers who administer immunizations in other states to South Carolina residents are not required to register with or report immunizations administered out of state to the registry, but may register and report voluntarily. Out-of-state immunization providers who register voluntarily are subject to and must comply with the provisions of this regulation governing permitted uses and disclosures of registry information and compliance and enforcement as fully as if located in and administering immunizations in South Carolina.

8. Immunization providers who do not administer vaccines may register with the Department for access to the registry. Immunization providers who register under this paragraph and their authorized users are

subject to and will comply with all provisions of this regulation applicable to immunization providers and authorized users and may access and use registry information under Section D.

#### **D. Permitted Uses and Disclosures of Immunization Registry Information.**

1. Information in the immunization registry is confidential and shall be made available only to registered immunization providers through their authorized users. Immunizations providers who have registered for access to the registry may obtain information from the registry pertaining only to their own patients.

2. Immunization providers may use registry information for the following purposes:

- a. To provide care and treatment to their patients;
- b. To determine appropriate and needed immunizations for their patients;
- c. To generate reports to review their practice's coverage;
- d. To generate reminder and recall notices;
- e. To review their practice's immunizations for quality improvement purposes;
- f. To print a patient's immunization record;
- g. To print a South Carolina Certificate of Immunization for a patient for school and daycare attendance; and for
- h. Other uses specifically authorized by the Department.

3. Immunization providers and authorized users may not disclose identifying information obtained from the registry except as allowed or required by applicable law.

4. The Department may use registry information for public health purposes, including, but not limited to, the following:

- a. To determine appropriate and needed immunizations for patients;
- b. To print a patient's immunization record at the request or with permission of an immunization provider;
- c. To print a copy of an immunization record or a South Carolina Certificate of Immunization for a patient and at the written request of the patient, or a parent or legal guardian of the patient if the patient is under eighteen (18) years of age;
- d. To allow a patient, or a parent or legal guardian of the patient if the patient is under eighteen (18) years of age, to obtain a copy of the patient's immunization record through a Department authorized electronic Patient Portal;
- e. To investigate vaccine fraud;
- f. To prevent, investigate, and control outbreaks of vaccine preventable communicable diseases;

g. To conduct epidemiological studies;

h. To provide data that does not identify an individual either directly or indirectly for research and only if the researcher submits a research protocol describing, at a minimum: the intended use of the data, the methodology of the research project; why access to the information is necessary, and approval by an official Institutional Review Board;

i. To assure the quality of the data entered into the registry;

j. To review the quality of the immunization practices of immunization providers;

k. To publish aggregate data that does not identify an individual either directly or indirectly;

l. When deemed necessary by the Director in the event of a disaster, state of emergency, or public health emergency;

m. To perform repairs, maintenance, and updates of the Immunization registry;

n. To provide information needed by law enforcement officers and agencies in the investigation or prosecution of a crime;

o. To implement this regulation, including compliance assistance and enforcement activities; and

p. To provide immunization records to the Revenue and Fiscal Affairs Office so that it may provide these records to health plans of members and enrollees of the health plan who received immunizations during the time in which they were enrolled in the health plan. Each immunization record may only be used by health plans for public health and Healthcare Effectiveness Data and Information Set (HEDIS) purposes. Health plans shall enter into a data sharing agreement with the Department and the Revenue and Fiscal Affairs Office prior to receiving immunization records.

5. Uses and disclosures by immunization providers or authorized users of registry information not authorized by this section are prohibited. Nothing in this regulation authorizes an immunization provider or authorized user to make any use or disclosure of registry information that is otherwise prohibited by law.

## **E. Compliance and Enforcement.**

1. Immunization providers shall make immunization records available within a reasonable time to authorized representatives of the Department for inspection upon request.

2. For a violation of this regulation, the Department may:

a. Require an immunization provider or an authorized user to attend registry training;

b. Suspend or revoke access to the registry; or

c. Assess civil penalties as authorized by Section 44-1-150, S.C. Code of Laws, 1976, as amended.

3. A Department decision under Section E.2 may be appealed by an immunization provider or authorized user, pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.

## **F. Exceptions to Regulation.**

1. The Department may grant a waiver to a requirement of this regulation, in its discretion when an immunization provider demonstrates to the Department's satisfaction that compliance would cause substantial hardship, that the waiver would protect and promote the health and safety of patients, and that the requirement is not specifically mandated by statute.

2. A delay in reporting caused by an act of God, war, strike, riot, or other catastrophe as to which negligence or willfulness on the part of the immunization provider was not the proximate cause will not be considered a violation of this regulation, as long as the immunization provider reports as required at the earliest practicable time after the event or catastrophe.

## **G. Severability.**

If a court of competent jurisdiction rules any part of this regulation invalid or otherwise unenforceable, the remaining portions of this regulation shall remain in effect as if the invalid portions were not originally a part of this regulation.