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Document No. 4259

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Section 44-29-40

61-120. South Carolina Immunization Registry

**Synopsis:**

The South Carolina General Assembly amended S.C. Code Ann. Section 44-29-40 by 2010 Act No. 210. This Act created a South Carolina immunization registry into which immunizations shall be entered by health care providers.

This new regulation will implement this statutory provision. The regulation addresses the required entry of all immunizations given by health care providers into the South Carolina Immunization Information System (Registry). It is intended to facilitate health care workers giving the right vaccine to each child on time, preventing duplicate administration of the same vaccine, reduce costs of vaccine and immunization delivery, and thereby, reduce vaccine-preventable infections. Specific areas addressed in the regulation include definitions of terms, registration and reporting requirements, the schedule of implementation by providers, permitted uses and disclosures, compliance and enforcement, exceptions to the requirements, and severability.

A Notice of Drafting for this proposed regulation was published in the *State Register* on October 28, 2011. See Discussion below and Statement of Need and Reasonableness and Rationale herein.

Discussion of Regulation:

Section A provides a purpose and scope of the regulation.

Section B provides the definitions of key terms in the regulation.

Section C discusses registration and reporting requirements of the regulation.

Section D presents the schedule of implementation of the regulation. Providers are not expected to have to enter all immunizations given to all patients, in the beginning, but instead to phase them in over four years.

Section E presents the permitted uses and disclosures of registry information and the requirements for protecting confidentiality.

Section F presents provisions for promoting compliance and enforcement.

Section G provides for certain exceptions to the requirements when these are reasonable and do not compromise health and safety of patients.

Section H addresses the severability of portions of the regulation.

**Instructions:** Add new R.61-120, South Carolina Immunization Registry, to Chapter 61 regulations.

**Text:**

61-120. SOUTH CAROLINA IMMUNIZATION REGISTRY.

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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. Existing immunization providers shall register with the Department within ninety (90) days from the effective date of this regulation. New immunization providers, such as health care professionals and entities licensed or organized after the effective date of this regulation, 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 E.

D. Implementation Schedule.

 1. Immunization providers will enter all immunizations into the registry on the following schedule, according to the date of administration and date of birth of the immunized patient:

 a. All immunizations administered after December 31, 2013, or the effective date of this regulation, whichever is later, to children born after December 31, 2013, and to adults born before 1946;

 b. All immunizations administered after December 31, 2014, to children born after December 31, 2008, and to adults born before 1950;

 c. All immunizations administered after December 31, 2015 to children born after December 31, 2003 and to adults born before 1961;

 d. All immunizations administered after December 31, 2016.

 2. Immunizations administered before the designated dates are not required to be entered in the Registry, but may be entered voluntarily.

E. 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 a patient’s immunization record at the written request of a patient, or a parent or legal guardian of the patient if the patient is under eighteen (18) years of age;

 d. To investigate vaccine fraud;

 e. To prevent, investigate, and control outbreaks of vaccine preventable communicable diseases;

 f. To conduct epidemiological studies;

 g. 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;

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

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

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

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

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

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

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

 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.

F. 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 F.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.

G. 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.

H. 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.

**Fiscal Impact Statement:**

The Department estimates no additional costs will be incurred by the state or its political subdivisions by the implementation of the South Carolina Immunization Registry regulation.

**Statement of Need and Reasonableness:**

This statement of need and reasonableness (and Preliminary assessment report) was determined by staff analysis pursuant to S.C. Code Section 1-23-115(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: New Regulation 61-120, South Carolina Immunization Registry.

Purpose: The purpose of this regulation is to provide rules implementing S.C. Code Section 44-29-40 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.

Legal authority: S.C. Code Ann. Section 44-29-40 as amended in 2010.

Plan for Implementation: Upon approval by the Board of Health and Environmental Control, the General Assembly and publication in the State Register as a final regulation, this regulation will provide the detailed specifications for this immunization data collection and submission to the South Carolina Immunization Registry. The Department will also distribute detailed information on the regulation’s requirements via its Health Alert Network to all providers on that network.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

This regulation is needed and reasonable because its development will satisfy a legislative mandate pursuant to S.C. Code Ann. Section 44-29-40. This regulation is necessary to provide detailed specifications of all immunization administered by South Carolina health care providers to assure complete information is available for patient care throughout the state. An immunization registry (immunization information system) is an electronic database which contains all immunizations received by citizens of a jurisdiction, and which can be used exclusively by healthcare providers caring for a specific patient(s) to learn which immunizations that patient has received and is protected for, and which immunizations that child or adult needs at that provider visit to maintain protection. It will also tell the provider which immunizations a specific patient is missing so that the patient can be reminded to seek them. It will also tell state public health officials in which areas protection against a specific immunizable disease is low so that public health can be prepared for outbreaks and can promote higher immunization levels there.

Clearly, such an immunization information system will only be useful if most health providers enter the great majority of immunizations into the system. Otherwise, if a child is missing a vaccine according to the registry, it will not be known if the vaccine was truly not given, or was simply not entered in the system when given. This situation leads to duplication of immunizations since the provider wants to be sure the patient is protected; given the high cost of many vaccines this wastes substantial healthcare dollars, and in certain cases subjects the patient to risk of side effects from excess immunization. Thus there are clear and substantial benefits to health and economics of having a well-used immunization information system (registry). Scientific studies that have demonstrated this include the Journal of Public Health Management 2007, vol. 13 page 559; Public Health Reports 2002, vol. 117 page 386; and Pediatrics 2006, vol. 118, page 1293.

Most states in the United States have had functioning immunization information systems for 5-10 years that include the great majority of immunizations given within the state, but South Carolina’s system is currently less than 20 percent used. This level of completeness is too low to provide the benefits described above for patients and the health care providers. The agency has improved the system’s usability and provided substantial education and training efforts to increase usage, with incomplete success, even though pediatricians and family physicians agree that such a system is very beneficial to patient care. At least 16 states (as of August 2010) have solved this problem by requiring that providers use the system

DETERMINATION OF COSTS AND BENEFITS:

State and Agency Costs: The registry is fully developed and is ready to receive data from the providers. The ongoing cost of the registry is currently being covered by state and federal appropriations. No further resources are needed at this time to implement the registry for state operations.

External Costs: There will be a potential cost to vaccine providers depending on how they submit data for the registry. Currently, there are two basic options for submitting data into the registry.

 Option 1: The vaccine provider can key data into the registry through the internet. In this case, the only cost they would incur would be the staff time necessary to key the data. All other costs would be minimal. It is estimated that the providers would need an average of two to two and one-half minutes to key an individual vaccine administered to a single patient. The amount of the cost then would depend on the number of vaccinations provided.

 Option 2: If the provider is using an electronic system for maintaining their medical information and their current system allows for electronic (HL7) data transmission, the cost should be minimal. If they are using an electronic system that does not include electronic (HL7) data transmission, there will be a onetime cost for converting their system to allow for this information uploading. Estimates for this one time cost indicate the amount will be between $2,999 and $10,000. Systems could be set up at that time to automatically upload the data without additional cost for most providers. Some vendors may also charge a monthly maintenance fee to providers. If the provider chooses, they can submit data to the South Carolina Health Information Exchange (SCHIEX). This system is being configured to automatically submit immunization data into the registry so no additional cost would be incurred.

The agency is evaluating methods that can be used to assist in mitigating these costs to the providers. This may include a plan to reimburse electronic medical record vendors a non-recurring amount to cover their cost of development if they will distribute these modifications to the clients that use their system at little or no cost. This could be made available to vendors developing connections to SCHIEX as well for connections to the immunization registry. In addition, for those without an electronic medical record that can submit data, a plan is being evaluated to offer a centralized keying unit to be managed by the Department which would allow providers to submit data to the agency on paper forms for keying into the registry. If these plans are implemented, it is assumed that existing funds going to the agency would be utilized.

External Benefits: The ability to know the vaccinations that have been given to a patient is a significant benefit to the state, communities in South Carolina, insurance companies, the vaccination providers, and the patients. At the state and community level, coverage levels of vaccines can make a significant difference in public health decisions related to disease outbreak management which has the potential to save lives. The vaccine preventable disease burden would be greatly reduced with increased vaccine coverage rates. For the providers, there will be a reduction in duplicate doses of vaccine administered as well as being able to provide more effective interventions for individual patients. In addition, use of the registry by providers would allow for some cost savings due to a reduction in time needed to produce school certificates needed for children getting admission for schools and day cares which will reduce current administrative burdens.

For the patients, fewer duplicated vaccines mean less cost, for both out of pocket and deductibles for their insurance coverage plus they would be able to more easily find out what vaccinations they had received.

UNCERTAINTIES OF ESTIMATES:

The actual amount of computer system upgrade costs are not known as there are many different electronic medical record vendors which sell products in South Carolina and the choice of an electronic medical record is at the discretion of the medical provider. The agency is surveying the providers to better estimate these costs. In addition, the exact total number of vaccine providers in South Carolina has not been known up to this point in time.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

There will be no effect on the environment. The regulation will promote public health by improving knowledge and information regarding immunization coverage of vaccine preventable diseases, including rates and trends, in South Carolina. This will enable research on the causes, distribution, and prevention of vaccine preventable diseases and assist in the development of effective public health strategies.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

If the regulation is not implemented, the Department and the state of South Carolina would lose the opportunity to gain critically needed information about immunization coverage in South Carolina and to improve the health and quality of life of its citizens. Potential opportunities to understand and reduce the economic burden of vaccine preventable diseases to the state would also be lost.

**Statement of Rationale:**

This regulation implements the provisions of the S.C. Statewide Immunization Registry Law at S.C. Code Ann. Section 44-29-40.B.