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HISTORY OF LEGISLATIVE ACTIONS

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VERSIONS OF THIS BILL

Xx/xx/2024

A BILL

TO AMEND THE SOUTH CAROLINA CODE OF LAWS BY ENACTING THE "SOUTH CAROLINA HEALTH INFORMATION ANALYTICS ACT" BY ADDING CHAPTER 140 TO TITLE 44 SO AS TO CREATE AND SUPPORT AN OPERATIONAL PERMANENT ADVISORY ORGANIZATION CALLED "THE SOUTH CAROLINA HEALTH INFORMATION ORGANIZATION (SCHIO) , AND A HEALTH INFORMATION DATABASE WITH A ROBUST TOOLKIT CALLED "THE SOUTH CAROLINA INFORMATION AND ANALYTICS SYSTEM, WITH SUPPORTING CONSTRAINTS USAGE PROTOCOLS, AND DEPENDENCIES. .

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. This act shall be known and may be cited as the "South Carolina Health Information Analytics Act".

SECTION 2. Title 44 of the S.C. Code is amended by adding:

CHAPTER 140

South Carolina Health Information Analytics Act

Section 44-140-10. Principles of the chapter:

(A) Independence. Ensure that potential biases and potential conflicts of interest are minimized, balanced, or otherwise managed in the design and implementation of all processes, practices, and policies related to the Act.

(B) Integration. In order to establish the cause of symptoms and adverse effects, the Covid-19 era has demonstrated that healthcare data must include (1) the analysis of the pharmaceutical product for purity and functionality (2) the evaluation of the quality of the manufacturing process (3) full access to a patient's health history, including all pharmaceuticals given to the patient, along with the dates, lot information, and place of administration, (4) mortician, medical examiner, and autopsy results for designated infectious diseases

(C) Functionality. A full suite of analytic tools, from those commonly used to experimental, must be integrated into the system.

(D) Transparency. All processes, practices, and policies related to the healthcare data are developed in the spirit of openness, shall be clearly articulated, and shall be available to interested persons or entitie; any deviations from them must be documented and justified.

(E) Fairness. All processes, practices, and policies related to the databases are designed and implemented in a fair manner.

(F)Protection of confidentiality. The design and implementation of the the healthcare database shall protect the confidentiality of individually identifiable information while enabling traceback to patients when adverse effects are detected that should be addressed by other patients that have the same medical situation

(G) Timeliness. New snapshots of data should be available on approximately a weekly basis in order to capture early signals of adverse effects as well as new disease outbreaks.

Section 44-140-20.Objectives of the chapter:

(A) Re-establish integrity and trust in public health in South Carolina.

(B) Remove the dependency on the federal government and transparently provide data and analysis support for pharmaceutical effectiveness and adverse effects which will support public health in South Carolina.

(C) Establish a executive body and a healthcare database that will be free of influence from any government agency or any healthcare organization.

(D) Establish a culture in the medical community that questions whether health problems are associated with pharmaceuticals as either unintended consequences or adverse effects which threatens public health. Provide funding to study and identify these threats.

(E) Have access to reliable and timely health data to protect the citizens from Constitutional overreach by the federal government and manipulation, incompetence, and poor policy recommendations regarding health and education by the executive branch of state government. Additional state initiatives are necessary to ensure that citizens of all ages can critically assess information in general, but especially information related to their own and their family's health.

(F) To protect SC citizens from Corporate and Institutional overreach, manipulation, incompetence, and poor policy recommendations regarding health.

(G) To protect the informed consent ethic, and basic human rights

Section 44-140-30.Definitions:

For the purposes of the chapter:

(A) "SCHIO" means a governance agency called the South Carolina Health Information Organization. It's overall characteristics will be that of a RHIO: "A health information

organization that brings together health scientists, database analysts, program managers, manufacturing experts, to establish a healthcare database within a defined geographic area and governs health information aggregation and analytics tool integration in a secure environment for that database, all for the purpose of improving health and care in that region."

(B) "HIT" means Health Information Technology. See https://www.hhs.gov/hipaa/for-professionals/special-topics/health-information-technology/index.html

(C) "SCHIAS" means South Carolina Health Information and Analysis System.

(D) "Designated pharmaceutical" is a pharmaceutical that has been designated by the SCHIO as requiring analysis, evaluation, tracking, or other actions to understand and assure pharmaceutical or protocol quality, effectiveness, or adverse effects with respect to a particular infectious disease or human organ malady.

(E) "Stakeholder" in this endeavor is the South Carolina citizen; it is not any healthcare organization or government entity, with the exception that the medical committees of the South Carolina Medical committees are the representatives of the stakeholder.

(F) "Program Manager" is a role in the SCHIO and is a professional, PMI certified project manager. The individual in this role is not required to have experience with projects in the healthcare domain, but is required to have experience with complex projects where the individual human participants and organizations have little project management maturity as defined by the PMI.

(G) "Program Dependencies" are entities that this Act depends on for successful implementation of this Act. These include, but aren't limited to hospital systems that have implemented EPIC for patient records; mortuaries, County Coroner offices, and pharmaceutical manufacturers and their suppliers, and locations that sell or administer target pharmaceuticals.

Section 44-140-40.South Carolina Health Information Organization

(A) The South Carolina Health Information Organization (SCHIO) shall be established to create and manage a health information technology (HIT) database and infrastructure and all policies related to its lifecycle, standards, use, and contents

(B) SCHIO shall report directly to the Secretary of Health and Policy (44-12-20, Bill 915)

(C) SCHIO membership shall

a. Not include anyone who has or has had a business financial relationship with a pharmaceutical company.

b. Not include anyone who has a current relationship with a healthcare organization

c. Include one member from the House 3M, Medical Affairs subcommittee

d. Include one member from the Senate Medical Affairs committee

e. Include a PMI certified Program Manager that does not have and has not had a relationship with the South Carolina Department of Administration or other state

organization

f. Include a Senior Biologics Director from the University of South Carolina who's demonstrated skill has been the analysis and characterization of pharmaceuticals in general and the n1-ΨxRNA/LPN pharmaceuticals in particular.

g. Include a Senior Manufacturing Quality Director whose professional experience includes auditing pharmaceutical manufacturing facilities, including suppliers and logistics, for Good Manufacturing Practice.

h. Include a Senior Scientific Director with expertise in biostatistics and operations research, whose skill is recognized world-wide, and who has not been an advocate of the failed Covid-19 management strategies of the world, federal, or state healthcare organizations

i. Include a Senior Technology Director from Clemson who is a member of the Electrical and Computer Engineering Department with skills in informatics, cyber systems, security, and artificial intelligence in healthcare.

j. Include two recognized analysts who have demonstrated skill in analyzing Covid-19 data for adverse effects and communicating those analyses using web dashboards.

k. Include a Senior Pathologist with experience in infectious disease pathology

l. Include a representative from the hospital systems of in the state

m. Include a representative of the County Coroners of the state

n. Include a representative of the embalmers of the state

o. Include a representative of the medical examiners of the state

p. Include a public communications specialist without ties to the pharmaceutical or healthcare industries or the SC government

q. Include a representative from the SC Public Health Department who has not directed any of the DHEC response during the Covid-19 era

r. Include a staff representative of the Governor's office who has not been involved in the governor's office response during the Covid-19 era

(D) Each member shall be nominated and appointed by consensus of the House and Senate Medical Committees for a period of three years, with an opportunity for one renewal.

(E) The SCHIO shall have public meetings each quarter to report on progress and analytical results

(F) The SCHIO shall establish priorities for all data extraction protocols based on the historical health record and future infectious and/or pharmaceutical development predictions

(G) The SCHIO shall establish priorities for design and development

(H) The Office of the Secretary of Health and Policy will provide Financial Management for this Act.

Section 44-140-50.

(A) Title: **The South Carolina Health Information and Analysis System**

(B) A Health Information Database (HIT), called the South Carolina Health Information and Analysis System (SCHIAS), will be designed, established, and maintained according to the guidance of the SCHIO.

(C) The database will be an integration of the 5 databases described in Sections 44-140-60, 44-140-70, 44-140-80, 44-140-90, and 44-140-100.

(D) The analysis system will provide access to the integrated database and be comprised of analytic tools commonly used for healthcare and manufacturing data analysis as well as various prototype and experimental tools.

(E) All Program Dependencies must supply data requested by the SCHIO.

(F) The database will be maintained by a central information technology organization associated with Clemson University that has expertise in complex, cyber-secure systems.

(G) The system will add data on a weekly basis from the various databases described in 44-140-40-B. Extreme security will be employed to assure the data can not be corrupted, destroyed or manipulated during transfer.

(H) The system will archive data after three years and the archive will retain data for a period designated by the SCHIO.

(I) The system will be open access after registration by any user. Qualifications for use will be determined by the SCHIO, but access should not be restricted to healthcare organizations and government agencies; individuals with relevant interest must be allowed complete access.

Section 44-140-60.

(A) Title: **Manufacturing Lot Quality and Logistics History Database**

(B) This database contains the quality and logistics history data for every lot of a designated pharmaceutical administered to or used by South Carolinians.

(C) They must be supplied by any pharmaceutical manufacturer distributing a designated pharmaceutical in South Carolina or by the governmental organization responsible for logistics.

(D) They must be supplied to the administrator of this database by any pharmaceutical manufacturer of a designated pharmaceutical if it is administered to a patient while out-of-state.

Section 44-140-70.

(A) Title: **Manufacturing Vial Quality Sampling Database**

(B) The Manufacturing Vial Quality Sampling data consists of the results of quality sampling of vials or other packaging implementation by SCHIO designated quality assurance

organizations

(C) Sampling can be at various locations in the logistics process of the designated pharmaceutical, as determined by the SCHIO, but must include sampling vials at the point of administration to a patient.

(D) The sampling procedure must implement a quality sampling process that dynamically adjusts the sampling quantity of product at a location and at other locations, depending on the results.

(E) Sampling protocols must include designated pharmaceutical product "halt distribution" and "recall" protocols, the details of which are defined by the SCHIO.

(F) Sampling and quality services should be contractor selected by the SCHIO.

Section 44-140-80.

(A) Title: **Manufacturing Good Quality Management Database**

(B) The data in this database consists of the results of good quality management audit reports of pharmaceutical manufacturers as designated by the SCHIO.

(C) The format, audit protocols, and details of the data required are as designated by the SCHIO

(D) The audit shall be performed by the SCHIO or by a selected contractor.

Section 44-140-90.

(A) Title: **Patient EPIC EMR Database**

(B) These data consist of ICD codes and patient notes, and time designations as defined by the SCHIO for a designated pharmaceutical.

(C) Data shall include all information on the administration of the designated pharmaceutical to the patient.

(D) Data should include all informed consent forms along with the information provided for consent at the time the patient signed the form. If the data are not available in the EPIC database, then the SCHIO shall establish a process for obtaining said data and entering it into this database.

(E) The patient is anonymized but can be back-traced to the attending physician related to the patient note associated with an examination.

(F) The data shall be provided by every healthcare facility in the state operating EPIC EMR.

Section 44-140-100.

(A) Title: **Post-Mortem Database**

(B) The data in this database come from the following sources, each location of which shall provide the data to the database administrator in a cyber-secure manner for any patient who died after administration of designated pharmaceuticals or protocols and had ICD code sequences and/or

combinations or death certificate entries designated by SCHIO

a. Embalmer data: procedure and data defined by the SCHIO for the designated pharmaceutical or protocol

b. Medical examiner data: procedure and data defined by the SCHIO for the designated pharmaceutical or protocol

c. Coroner data: procedure and data defined by the SCHIO for the designated pharmaceutical or protocol

SECTION 5. If any section, subsection, paragraph, subparagraph, sentence, clause, phrase, or word of this act is for any reason held to be unconstitutional or invalid, such holding shall not affect the constitutionality or validity of the remaining portions of this act, the General Assembly hereby declaring that it would have passed this act, and each and every section, subsection, paragraph, subparagraph, sentence, clause, phrase, and word thereof, irrespective of the fact that any one or more other sections, subsections, paragraphs, subparagraphs, sentences, clauses, phrases, or words hereof may be declared to be unconstitutional, invalid, or otherwise ineffective.

SECTION 6. This act takes effect upon approval by the Governor.

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