

Regulation 61-112

Implementation of Emergency Health Powers Act

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Table of Contents

Section 1. Scope and Purpose 1

Section 2. Definitions 1

Section 3. Declaration of Public Health Emergency; Roles of Agencies 2

Section 4. Personal and public health information 2

Section 5. Use of Real Property 3

Section 6. Personal property 4

Section 7. Response equipment and supplies 5

Section 8. Qualified health care providers 6

Section 9. Quarantine; Restrictions on travel and public assembly 7

Section 10. Human remains 8

Section 11. Severability 9

Section 1. Scope and Purpose

This regulation provides procedures for responding to the occurrence or imminent risk of a Qualifying Health Condition in a manner which is consistent with the authorities of S.C. Code Ann. Sections 44-1-110 through -140, the Emergency Health Powers Act (S.C. Code Ann. Section 44-4-10 *et seq.*), S.C. Code Ann. Sections 44-29-10 through -50, Regulations 61-16 and 61-20, and the State Emergency Response Plan with its supporting annexes, appendices, and Standard Operating Procedures. The regulation is intended to provide for timely recognition of sources or potential sources of disease, identification of victims or potential victims, delivery of health care, application of appropriate public health measures, and assurance of due process and personal privacy commensurate with the public health threat.

Section 2. Definitions

Unless otherwise defined below, terms in this regulation have the definitions set forth in S.C. Code Ann. Section 44-4-130, S.C. Code Ann. Section 44-29-10(C), and S.C. Code Ann. Regulation 61-20.

“Administer” — the direct application of a drug or device pursuant to a lawful order of a practitioner to the body of a patient by injection, inhalation, ingestion, topical application, or any other means.

“Commissioner” — the commissioner of the Department of Health and Environmental Control (DHEC) or his designee.

“Dispense” — the transfer of possession of one or more doses of a drug or device by a licensed pharmacist or person permitted by law, to the ultimate consumer or his agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. As an element of dispensing, the dispenser shall, before the actual physical transfer, interpret and assess the prescription order for potential adverse reactions or side effects, interactions, allergies, dosage, and regimen the dispenser considers appropriate in the exercise of his professional judgment, and the dispenser shall determine that the drug or device called for by the prescription is ready for dispensing. The dispenser shall also provide counseling on proper drug usage, either orally or in writing, as provided in this chapter. The actual sales transaction and delivery of a drug or device is not considered dispensing and the administration is not.

“Distribute” — the delivery of a drug or device other than by administering or dispensing.

“Emergency medical services” — the arrangement of personnel, facilities, and equipment for the delivery of health care services under emergency conditions.

“First Responder” — a health care worker, disaster relief worker, public safety officer, mortuary staff, or other individuals directly engaged in examining, treating or directing persons or animals during a Public Health Emergency.

“Initiating Event” — 1) the release of contaminants or infectious agents, 2) the spread of communicable disease, or 3) an accumulation of observations which lead to the conclusion that contamination may have been released, or that a communicable disease has begun to spread by either a natural or intentional event, with the potential for widespread public health impact. The existence of an Initiating Event may be inferred, based upon data and observations, and need not be a discrete event localized in time or place.

“Medical Supplies” — antitoxins, serums, vaccines, immunizing agents, antibiotics, and other pharmaceutical agents or medical supplies.

“Official List of Reportable Diseases” — the list published pursuant to S.C. Code Ann. Regulation 61-20 as amended from time to time.

“Route of Transmission” — the pathway by which an individual may be exposed to an infectious or communicable disease, or chemical or radiological contamination; includes consideration of physical pathways (aerosol, droplet, vapor, blood-borne, body fluids, or direct contact), biological pathways (human to human, animal to human, or other biological vectors), and receptor route (inhalation, ingestion, skin absorption).

“Strategic National Stockpile” or “SNS” — a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, airway maintenance supplies, and medical/surgical items. The SNS is designed to supplement and re-supply state and local public health agencies in the event of a national emergency anywhere and at anytime within the U.S. or its territories.

Section 3. Declaration of Public Health Emergency; Roles of Agencies

A. The Governor, in consultation with the Public Health Emergency Plan Committee, has the authority to declare a state of Public Health Emergency. DHEC will provide information and advice to the Committee and to the Governor before and after declaration of a state of Public Health Emergency.

B. It is inherent in the nature of public health emergencies that some actions must be taken before the declaration of a state of Public Health Emergency. Nothing in this regulation shall be construed to limit DHEC’s authority or obligation, before the declaration of a state of Public Health Emergency, to undertake such investigations or to take such actions pursuant to Code Sections 13-7-40 and -50, 44-1-80 and 44-1-140, 44-55-60, and 44-56-50 as may be necessary to detect, identify, and control the spread of communicable diseases or of biological, chemical, or radiological agents capable of causing disease or injury.

C. DHEC shall request the assistance of public safety agencies, coroners, medical examiners, professional licensing boards, professional associations, health care facilities, and vendors delivering goods and services to health care facilities and medical professionals to implement this regulation. Where specifically provided for by statute or regulation, such requests shall have the force of law.

Section 4. Personal and public health information

A. Medical Information

i. Upon declaration of a state of Public Health Emergency DHEC may by order amend the Official List of Reportable Conditions to include specific diseases or diagnostic criteria. DHEC may designate whether such reports are “Report Immediately” or “Urgently Reportable” and may provide telephone hot line numbers, electronic notification (email) addresses or other means of reporting as may be appropriate.

ii. Before declaration of a state of Public Health Emergency DHEC may by order amend the Official List of Reportable Conditions to include specific diseases or diagnostic criteria. DHEC may designate whether such reports are “Report Immediately” or “Urgently Reportable” and may provide telephone hot line numbers, electronic notification (email) addresses or other means of reporting as may be appropriate. Within twenty four hours of such order DHEC will provide the Governor and the Public Health Emergency Plan Committee with information upon which such order was based.

B. Non-Medical Information

If the Commissioner determines that individuals who have been in certain facilities, or at specific events, or in contact with certain individuals, objects, animals, or categories of individuals, have been or may have been exposed to contaminants or communicable diseases, he may by order require reports to be submitted to DHEC, which may include but not be limited to: passenger manifests; attendance rosters; lists of patrons of events, activities, or venues; and the like. The order shall include as much specificity as is reasonably available to limit the scope of the report.

C. Use and safeguarding

i. In order to investigate the causes and spread of communicable or epidemic disease, to prevent or control the spread of contamination or infectious diseases, and to protect the public health, the Commissioner may by order require collection of contact tracing information from individuals who have or may have been exposed to contaminants, infectious agents, or communicable diseases. To the extent that such information may be Protected Health Information, individuals carrying out such orders and collecting contact tracing information shall be deemed to be acting in accordance with the authority of Code Sections 44-1-80 and 44-4-560 for purposes of having access to such information.

ii. Other than in accordance with subsection (i) above, access to DHEC records containing protected health information of persons who have participated in medical testing, treatment, vaccination, isolation, or quarantine programs or efforts by DHEC during a public health emergency is limited to those persons having a legitimate need to provide treatment to the individual who is the subject of the health information; or to conduct epidemiological research; or to investigate the causes of transmission.

iii. Pursuant to Code Section 44-4-560(B)(3), protected health information otherwise exempt from disclosure by Section 44-4-560(A) may be included in petitions and other court documents required pursuant to Section 44-4-540.

iv. Pursuant to Code Section 44-4-560(B)(3) and (B)(5), DHEC may seek an ex parte court order for permission to disclose otherwise protected health information if necessary to locate individuals to limit the spread of contagion or to offer medical treatment. DHEC will include with the John Doe petition for such order a sealed affidavit stating with particularity the basis for believing that location of the specific individuals is necessary to protect the public health or the health of the individual and why disclosure of the identity or the protected health information is necessary.

Section 5. Use of Real Property

A. Use of Health Care Facilities

i. Coordination of assets

Upon declaration of a Public Health Emergency DHEC may require health care facilities to provide current information on patient census, available patient beds, and potential expansion capacity. Potential expansion capacity shall include vacant beds, rooms constructed but not placed into operation in accordance with a Certificate of Need, and rooms which could be adapted for multiple occupancy pursuant to subsection ii below. Health care facilities shall include such potential expansion capacity as separate line items in reports submitted for inclusion in the Regional Mass Casualty Response Plans. The means of reporting bed availability, facility problems, emergency department diversion, hospital pharmaceutical supplies, equipment, decontamination capability and other information necessary to coordinate a regional mass casualty response will be determined by DHEC and may include software or web page reporting mechanisms in current use and provided by DHEC. Hospitals may be required to report information with a predetermined frequency, or as requested within each hospital preparedness planning district.

ii. Suspension of hospital licensure requirements

Upon declaration of a state of Public Health Emergency, DHEC may by order suspend for the duration of the PHE so much of Regulations 61-15 and 61-16 as (1) restricts use of unlicensed beds or space; (2) restricts the conversion of single and double occupancy patient rooms to higher capacity (consistent with medically appropriate criteria); or (3) restricts establishment of wards, dormitories, or other spaces not designated as patient rooms.

B. Use of other real property

i. Upon declaration of a Public Health Emergency, DHEC may identify and notify public and private facilities to include but not be limited to hospitals, clinics, emergency medical services, outpatient treatment facilities, mortuaries, laboratories, and refrigerated storage facilities, that use of such facilities will be needed for the duration of the PHE to protect the public health.

ii. Operation of such facilities by the owners and operators is preferred. However, upon refusal by the owners or operators, or upon refusal to respond to DHEC's notification within a reasonable time not to exceed forty-eight hours, DHEC may apply for an *ex parte* court order authorizing DHEC, or its designee, to enter into said facility and take control for purposes of responding to the Public Health Emergency. Upon presentation, any public safety agency may execute such order. DHEC may apply for any such order to provide that designees operating facilities pursuant to court order shall be held harmless as to the owners or operators. After notice and opportunity for a hearing, DHEC may apply for an order continuing the *ex parte* order and setting the compensation, if any, due the owners and operators for such period of displacement.

C. Decontamination and sealing

i. DHEC may order decontamination of facilities to prevent the transmission of communicable diseases or to remove or neutralize biological, chemical, or radiological contaminants; such orders may include standard infection control techniques or other specific techniques as appropriate. DHEC may order decontamination of part or all of a facility or may order the sealing of part or all of a facility in lieu of decontamination. Sealed facilities shall be flagged or placarded in accordance with Regulation 61-20, Section 6; Regulation 61-20, Sections 8 and 9 apply.

ii. Orders requiring the sealing of facilities shall be reviewed regularly on a schedule commensurate with the nature of the contaminant, the scope and extent of the Public Health Emergency, and available resources.

Section 6. Personal property

A. DHEC may order decontamination, sealing, or destruction of equipment, foodstuffs, personal property, or any other material to limit the spread of communicable disease or contaminating agents. Such orders may apply to specific items or to classes of items.

B. Destruction may be ordered when decontamination is not practical or when exigent action is necessary to control the spread of contamination or communicable disease.

i. A petition for an order of destruction based on impracticality of decontamination shall be accompanied by one or more affidavits stating (1) the basis for determining the material to be contaminated; (2) if contamination cannot be confirmed by tests, the basis for believing the material to be contaminated

or potentially contaminated; (3) the risk to the public health if the material is neither decontaminated or destroyed; (4) alternatives such as decontamination or isolation which have been considered and the reasons they are not adequately protective of the public health.

ii. Nothing herein shall be construed to prohibit the immediate destruction without court order of a source of contamination or communicable disease when, in the professional judgment of DHEC staff, such action is necessary to prevent or limit the spread of contamination or disease. To the extent practicable, staff will record a description of the affected property, the location, and the basis for ordering immediate destruction.

C. If material can be sealed to eliminate it as a source of communicable disease or contamination with the possibility of decontamination after the Public Health Emergency abates, DHEC may order this as an option. Orders requiring sealing of material shall be reviewed regularly on a schedule commensurate with the nature of the contaminant, the scope and extent of the Public Health Emergency, and available resources.

D. Failure to comply with an order requiring decontamination or sealing of material may be grounds for seeking a court order requiring destruction of such material.

E. Animals

i. In consultation with the State Veterinarian, DHEC may issue orders requiring isolation, quarantine, or destruction of animals. Unless there is a clear medical or public health necessity, no animal shall be destroyed except by court order.

ii. Domestic pets: DHEC may by order allow persons to be accompanied by their pets in communal isolation or quarantine facilities, depending on the nature of the threat and the capacity of the facility. Alternatively DHEC may order establishment of pet holding areas or forbid pets in isolation or quarantine facilities.

iii. Non-domestic animals; farm animals; large animals: DHEC may by order allow owners or their representatives access to isolated animals for feeding or other necessary care; such access shall be upon such conditions as DHEC shall order.

Section 7. Response equipment and supplies

A. Possession and distribution

i. Pursuant to Code Section 44-4-330, DHEC may purchase antitoxins, serums, vaccines, immunizing agents, antibiotics, and other pharmaceutical agents or medical supplies (“Medical Supplies”). After declaration of a Public Health Emergency, and in accordance with Code Section 11-35-1570, the Commissioner or his designee may authorize others to make emergency procurements; provided, that such emergency procurements shall be made with as much competition as is practicable under the circumstances. A written determination of the basis for the emergency and for the selection of the particular contractor shall be included in the contract file.

ii. Strategic National Stockpile

a. DHEC has been designated as the entity responsible for distribution of SNS materials after transfer of SNS materials from CDC. DHEC shall name a consultant pharmacist to be responsible for establishing appropriate policies and procedures for the receipt, storage, dispensing, and distribution of

drugs from the SNS and for supervising a record-keeping system for those drugs. DHEC shall submit these policies, procedures, and record-keeping systems to the Board of Pharmacy for review and approval.

b. Upon notification that SNS materials are being sent to South Carolina and the declaration of a Public Health Emergency, DHEC shall notify the SC Board of Pharmacy and the SC Department of Labor, Licensing and Regulation of the impending arrival, distribution, and dispensing of SNS materials.

c. Provided that the Board of Pharmacy has approved the submitted policies, procedures and record-keeping systems, DHEC may proceed to distribute and dispense SNS materials.

d. Records with respect to receipt, storage, distribution and dispensing of SNS materials shall be retained for two years and shall be readily available for audit by the Board of Pharmacy, the Department of Labor, Licensing and Regulation, the DHEC Bureau of Drug Control, or a responsible Federal agency.

iii. DHEC may distribute, administer or dispense Medical Supplies either through its own employees, by instructions to wholesalers, or by allocation to health care providers for redistribution in accordance with directives issued by DHEC. In allocating Medical Supplies, DHEC will consider the amount on hand, the amount reasonably anticipated from other sources, and the population at risk. DHEC may allocate or deny Medical Supplies based on age, proximity to an initiating event or route of transmission, whether the individual is a First Responder, whether alternative personal protective measures are readily available, or other criteria of epidemiological significance.

iv. In allocating Medical Supplies to First Responders, DHEC may consider proximity to an initiating event or route of transmission in addition to other risk factors.

B. Orders affecting wholesale distribution

i. After declaration of a Public Health Emergency, DHEC may order manufacturers and distributors doing business in South Carolina to provide information on the amount, location and availability of Medical Supplies in South Carolina or in distribution chains serving South Carolina.

ii. In consultation with public health officials in neighboring states and with Federal officials, DHEC may direct distribution of Medical Supplies to designated health care providers. DHEC may direct designated health care providers to distribute or dispense Medical Supplies in accordance with criteria established by DHEC, which may include age, proximity to an initiating event or route of transmission, or other criteria of epidemiological significance.

C. Orders affecting retail distribution

DHEC may issue guidelines defining diagnostic criteria, risk factors and contraindications for the guidance of health care providers. The Commissioner may by order identify categories of individuals to whom Medical Supplies shall not be given.

Section 8. Qualified health care providers

A. Authorization to practice

i. Authorization of otherwise qualified health care professionals who are not licensed in South Carolina to render professional services during a public health emergency is the responsibility of the respective licensing board or entity. This may include students or interns as may be recommended by their faculty and approved by the respective licensing board.

ii. DHEC will consult with the Board of Medical Examiners, Board of Nursing, Board of Pharmacy, the State EMT Coordinator, and other licensing boards to determine what credentials will be required of otherwise qualified, but unlicensed, individuals before assignment in a response role. Upon declaration of a Public Health Emergency, DHEC may assign individuals after review of individual credentials but before confirmation from the professional licensing boards.

B. Conditions of licensure

i. If, during a Public Health Emergency, an individual health care provider unreasonably fails or refuses to perform vaccinations, treatment, examination, or testing of individuals, DHEC may submit evidence of such refusal to the appropriate licensing board for consideration in subsequent licensing decisions.

ii. DHEC may consider evidence of failure or refusal to allow vaccinations, treatment, examination or testing of individuals as a basis for revoking or denying renewal of facility licenses issued by DHEC. Revocation or denial of a license based in whole or in part on such grounds may be challenged as a contested case.

Section 9. Quarantine; Restrictions on travel and public assembly

A. Upon declaration of a Public Health Emergency in which there is a substantial likelihood of person-to-person transmission of disease or spread of contamination, DHEC may recommend to law enforcement authorities orders placing restrictions on public gatherings. Such recommendations shall be reasonably tailored to address the risk and may include limits on the number or age of individuals, restrictions on location, or restrictions on non-essential gatherings.

B. Upon declaration of a Public Health Emergency, DHEC may order closure of primary or secondary schools.

C. Quarantine and isolation

i. DHEC will provide notice to individuals in quarantine or isolation sufficient to inform them of (1) the basis for the order of quarantine or isolation; (2) the restrictions imposed by the order; (3) procedures for obtaining judicial review of the order; (3) notice of any hearings, appointment of counsel, or other court proceedings; (4) the findings of the court after any review of the order; (5) any testing, treatment or vaccination which is planned or available; (6) the location and hours of operation of facilities for the delivery of mail, food, fuel, medical treatment or supplies, and other necessities.

ii. (1) DHEC will by order establish criteria for allowing entry into and departure from quarantine or isolation facilities, which may include prohibitions against departure. The Commissioner may designate medical professionals to assist law enforcement personnel assigned to implement the quarantine order. (2) If quarantine has been established by geographical area, criteria for departure may include procedures for documenting that travelers have permission to enter the intended destination.

iii. DHEC will offer the reviewing court information, including best professional judgment, concerning risk of disease transmission and possible prophylactic measures for the court's consideration in establishing procedures for allowing quarantined or isolated individuals access to counsel and access to court proceedings consistent with public health and due process.

Section 10. Human remains

A. Upon declaration of a Public Health Emergency, DHEC will notify coroners, medical examiners, and funeral directors of specific procedures to be followed in handling and disposing of remains of individuals known or presumed to have died from or been exposed to contamination or communicable disease. This may include individuals determined to have died as a result of other causes, such as trauma, but who had been exposed prior to death.

B. Prior to disposal

i. Every person in charge of disposing of any human remains must maintain a written record of each set of human remains and all available information to identify the decedent and the circumstances of death and disposal. If the human remains cannot be identified, prior to disposal, a qualified person must, to the extent possible, take fingerprints and one or more photographs of the human remains, and collect a DNA specimen. The Commissioner may by order require collection of specific tissue samples or performance of specific tests. All information gathered under this paragraph must be promptly forwarded to DHEC. Identification must be handled by the agencies that have laboratories suitable for DNA identification.

ii. All human remains of a person who has died from an infectious disease must be clearly labeled with all available information to identify the decedent and the circumstances of death. Any human remains of a deceased person with an infectious disease must have an external, clearly visible tag indicating that the human remains are infected and, if known, the infectious disease. The person in charge of disposing of such human remains shall report to DHEC the identifying information and the date, means and place of disposal.

C. If DHEC concludes that there is no public health reason to require disposal within twenty-four hours of human remains of persons who have died of an infectious disease, DHEC shall so notify coroners, medical examiners, and funeral directors.

D. Mass graves: In the event of mass casualties in excess of the provisions of the State Emergency Operations Plan to provide for disposal, mass graves shall

i. not be located in floodways, wetlands, karst formations, or in unstable terrain;

ii. have at least two feet vertical separation above groundwater;

iii. be at least two hundred feet from the nearest property line, potable well, or irrigation well, and one hundred feet from surface waters (including ephemeral or seasonal streams);

iv. provided with daily cover to control vectors, hydrated lime, and absorbent material;

v. provided with adequate final cover, fencing and venting to minimize the need for long-term care.

vi. The corners of mass graves shall be marked with permanent monuments and the location recorded where title to real property is recorded.

vii. A permanent record of the names or other identifying information of all human remains shall be kept.

Section 11. Severability

Should any section, paragraph or other part of these regulations be declared invalid for any reason, the remainder shall not be affected.