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Document No. 5352

**DEPARTMENT OF PUBLIC HEALTH**

CHAPTER 60

Statutory Authority: 2023 Act No. 60, effective July 1, 2024

61‑3. The Practice of Selling and Fitting Hearing Aids.

61‑4. Controlled Substances.

61‑7. Emergency Medical Services.

61‑8. Immunization Requirements for School and Childcare Attendance.

61‑12. Standards for Licensing Abortion Clinics.

61‑13. Standards for Licensing Intermediate Care Facilities for Individuals with Intellectual Disabilities.

61‑15. Certification of Need for Health Facilities and Services.

61‑16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.

61‑17. Standards for Licensing Nursing Homes.

61‑19. Vital Statistics.

61‑20. Communicable Diseases.

61‑21. Sexually Transmitted Diseases.

61‑22. The Evaluation of Staff of Schools and Child Care Centers for Tuberculosis.

61‑24. Licensed Midwives.

61‑31. Health Care Cooperative Agreements.

61‑45. South Carolina Central Cancer Registry.

61‑75. Standards for Licensing Day Care Facilities for Adults.

61‑77. Standards for Licensing Home Health Agencies.

61‑78. Standards for Licensing Hospices.

61‑80. Neonatal Screening for Inborn Metabolic Errors and Hemoglobinopathies.

61‑84. Standards for Licensing Community Residential Care Facilities.

61‑91. Standards for Licensing Ambulatory Surgical Facilities.

61‑93. Standards for Licensing Facilities for Chemically Dependent or Addicted Persons.

61‑94. WIC Vendors.

61‑95. Medicaid Nursing Home Permits.

61‑97. Standards for Licensing Renal Dialysis Facilities.

61‑102. Standards for Licensing Birthing Centers for Deliveries by Midwives.

61‑103. Residential Treatment Facilities for Children and Adolescents.

61‑108. Standards for Licensing Freestanding or Mobile Technology.

61‑109. Standards for Permitting Body Piercing Facilities.

61‑111. Standards for Licensing Tattoo Facilities.

61‑112. Implementation of Emergency Health Powers Act.

61‑114. South Carolina Birth Defects Program.

61‑116. South Carolina Trauma Care Systems.

61‑118. South Carolina Stroke Care System.

61‑120. South Carolina Immunization Registry.

61‑122. Standards for Licensing In‑Home Care Providers.

61‑123. Critical Congenital Heart Screening on Newborns.

61‑125. Standards for Licensing Crisis Stabilization Unit Facilities.

**Synopsis:**

Pursuant to Section 14(B) of 2023 Act No. 60 (Act), the health‑related regulations currently under Chapter 61 – Department of Health and Environmental Control of the S.C. Code of Regulations are transferred to DPH. In accordance with this provision, DPH proposes transferring all the regulations listed above from Chapter 61 to the new Chapter 60 in the S.C. Code of Regulations, with the Chapter title of Department of Public Health. Additionally, DPH proposes amending references to the Department of Health and Environmental Control, including definitions, acronyms, email addresses, physical addresses, and other references in each listed regulation to conform to the provisions of 2023 Act No. 60. The Administrative Procedures Act, S.C. Code Section 1‑23‑120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the July 26, 2024, South Carolina State Register.

Section‑by‑Section Discussion of Amendments:

|  |  |  |
| --- | --- | --- |
| **Regulation/Section** | **Type of Change** | **Purpose** |
| **Chapter 60** | Add | Add Chapter 60 to the S.C. Code of Regulations |
| **R.61‑3** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section I(b) | Revision | Amend Department definition to mean Department of Public Health (DPH). |
| Section 101(e) | Revision | Amend Department reference to DPH. |
| Section 105(a) | Revision | Amend Department reference to DPH. |
| Section 204 | Revision | Amend Department reference to DPH. |
| **R.61‑4** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 102(d), (j), (k), and (u) | Revision | Amend Department definition to mean DPH and amend Department references to DPH. |
| Section 103 | Revision | Amend Department reference to DPH and remove Department mailing address. |
| Section 104 | Revision | Amend Department reference to DPH. |
| Section 109(b) and (d) | Revision | Amend Department reference to DPH. |
| Section 110(a) and (c) | Revision | Amend Department reference to DPH. |
| Section 202(a) | Revision | Amend Department reference to DPH. |
| Section 203(b) and (c) | Revision | Amend Department reference to DPH. |
| Section 304(a) | Revision | Amend Department reference to DPH. |
| Section 314(c) and (d) | Revision | Amend Department reference to DPH. |
| Section 317 | Revision | Amend Department reference to DPH and remove Department mailing address. |
| Section 319(a) | Revision | Amend Department reference to DPH. |
| Section 406(b) | Revision | Amend Department reference to DPH. |
| Section 407(c) | Revision | Amend Department reference to DPH. |
| Section 801(e) | Revision | Amend Department reference to DPH. |
| Section 809(a) | Revision | Amend Department reference to DPH. |
| Section 903 | Revision | Amend Department reference to DPH and remove Department mailing address. |
| Section 1001(a)(3) | Revision | Amend Department reference to DPH. |
| Section 1008 | Revision | Amend Department reference to DPH. |
| Section 1009(e) | Revision | Amend Department reference to DPH. |
| Section 1010 | Revision | Amend Department reference to DPH. |
| Section 1011 | Revision | Amend Department reference to DPH. |
| Section 1012(b) | Revision | Amend Department reference to DPH. |
| Section 1101(g) | Revision | Amend Department reference to DPH. |
| Section 1202(b)(4) | Revision | Amend Department reference to DPH. |
| Section 1404(a) | Revision | Amend Department reference to DPH and remove Department mailing address. |
| Section 1701(a) | Revision | Amend Department reference to DPH and remove Department mailing address. |
| Section 1702(a) and (b) | Revision | Amend Department reference to DPH and remove Department mailing address. |
| Section 1901 | Revision | Amend Department reference to DPH. |
| Section 1903 | Revision | Amend Department reference to DPH. |
| Section 1904 | Revision | Amend Department reference to DPH. |
| Section 1911(b) | Revision | Amend Department reference to DPH and remove Department mailing address. |
| Section 1917 | Revision | Amend Department reference to DPH. |
| Section 1920 | Revision | Amend Department reference to DPH. |
| Section 1921 | Revision | Amend Department reference to DPH. |
| **R.61‑7** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101(N) | Revision | Amend Department definition to mean DPH. |
| Section 1204(B) and (C) | Revision | Amend regulation number to reflect move to Chapter 60. |
| **R.61‑8** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| **R.61‑12** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.F | Revision | Amend Department definition to mean DPH. |
| Section 304.H | Revision | Amend to remove Department reference. |
| Section 403.A | Revision | Amend to update Department reference. |
| Section 403.A.2 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 803.A.1 | Revision | Amend Department unit reference to DPH. |
| Section 803.E | Revision | Amend Department reference to DPH. |
| Section 804 | Revision | Amend Department unit reference to DPH. |
| Part IX.A | Revision | Amend Department unit reference to DPH. |
| Part IX.B | Revision | Amend Department unit reference to DPH. |
| Part IX.B.1 | Revision | Amend Department reference to Department of Environmental Services. |
| Part IX.E | Revision | Amend Department unit reference to DPH. |
| **R.61‑13** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| **R.61‑15** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.5 | Revision | Amend Department definition to mean DPH. |
| Section 102.2 | Revision | Amend Department reference to DPH. |
| Section 301.2 | Revision | Amend Department reference to DPH and remove Department mailing address. |
| Section 303.1 | Revision | Amend Department reference to DPH. |
| **R.61‑16** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.D | Revision | Amend Department definition to mean DPH. |
| Section 702 | Revision | Amend Department email address to DPH. |
| Section 1302.B and C | Revision | Amend Department reference to DPH. |
| Section 1313.C | Revision | Amend Department reference to DPH. |
| Section 1402.A | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 1403 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 2003 | Revision | Amend Department email address to DPH. |
| **R.61‑17** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.Q | Revision | Amend Department definition to mean DPH. |
| Section 102.A.1 through 3 | Revision | Amend regulation numbers to reflect move to Chapter 60. |
| Section 201.C | Revision | Amend Department unit reference to DPH. |
| Section 703 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 804.B.8 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 1309.D | Revision | Amend regulation number to reflect move to Chapter 60. |
| **R.61‑19** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 100.K | Revision | Amend Department definition to mean DPH. |
| Section 100.CC | Revision | Amend regulation number to reflect move to Chapter 60. |
| **R.61‑20** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 1.A(1), (9), and (10) | Revision | Amend Department reference to DPH. Amend Department definition to mean DPH. Amend Director definition to reflect DPH. |
| Section 7 | Revision | Amend Department reference to DPH. |
| Section 13 | Revision | Amend Board and Department references to DPH and Director of DPH. |
| **R.61‑21** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section A(3) | Revision | Amend Department definition to mean DPH. |
| Section B | Revision | Amend Department reference to DPH. |
| Section L(2) | Revision | Amend Department reference to DPH. |
| **R.61‑22** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section II.B | Revision | Amend Department definition to mean DPH. |
| Section II.C | Revision | Amend Department reference to DPH. |
| Section III.A.4 and C.1 through 5 | Revision | Amend Department reference to DPH. |
| Section IV.A | Revision | Amend Department reference to DPH and remove Department mailing address. |
| Section IV.B | Revision | Amend form number for accuracy. |
| **R.61‑24** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section A.2.h | Revision | Amend Department definition to mean DPH. |
| Section O.3.d | Revision | Amend Department form and unit reference for accuracy. |
| Section P.1.a | Revision | Amend Commissioner reference to Director and Department reference to DPH. |
| **R.61‑31** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 102.4) | Revision | Amend Department definition to mean DPH. |
| Section 202(d).8 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 301 | Revision | Amend Department unit reference to DPH and remove Department mailing address. |
| Section 305 | Revision | Amend Department reference to DPH. |
| **R.61‑45** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section B.1, 9, 10, and 11 | Revision | Amend Department definition to mean DPH and amend Board and Department references to DPH. |
| Section C.1 through C.3.a through C.3.f | Revision | Amend Department references to DPH. |
| Section E | Revision | Amend Department reference and Department unit reference to DPH. |
| Section F.1 and 3 | Revision | Amend Department references to DPH. |
| Section G.3 through 5 | Revision | Amend Department references to DPH. |
| **R.61‑75** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.K | Revision | Amend Department definition to mean DPH. |
| Section 603 | Revision | Amend regulation number to reflect move to Chapter 60 and amend Department unit reference to DPH. |
| **R.61‑77** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.H | Revision | Amend Department definition to mean DPH. |
| **R.61‑78** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 100.J | Revision | Amend Department definition to mean DPH. |
| Section 704 | Revision | Amend regulation number to reflect move to Chapter 60. |
| **R.61‑80** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Table of Contents | Deletion | Amend to delete Department form references. |
| Section A | Revision | Amend Department reference to DPH. |
| Section B.5 through 8 | Revision | Amend Department definition to mean DPH and amend Department references to DPH. Amend Department unit reference for accuracy and amend Commissioner reference for Director. |
| Section H | Revision | Amend Department form references for accuracy and remove references to appendices. |
| Appendix A | Deletion | Amend to delete Department form. |
| Appendix B | Deletion | Amend to delete Department form. |
| Appendix C | Deletion | Amend to delete Department form. |
| **R.61‑84** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.P | Revision | Amend Department definition to mean DPH. |
| Section 102.A.1 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 603 | Revision | Amend regulation number to reflect move to Chapter 60. |
| **R.61‑91** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.R | Revision | Amend Department definition to mean DPH. |
| Section 102.A.1 through 4 | Revision | Amend regulation numbers to reflect move to Chapter 60. |
| Section 103.E.9 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 103.L.2 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 603 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 702.D.3 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 1007.A.2 | Revision | Amend regulation number to reflect move to Chapter 60. |
| **R.61‑93** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| **R.61‑94** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101(A) and (C) | Revision | Amend Department definition to mean DPH and amend Department references to DPH. Amend Department unit reference to DPH. |
| Section 801 | Revision | Amend administrative appeals to remove DHEC Board and conform to statute. |
| **R.61‑95** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.A | Revision | Amend Department definition to mean DPH. |
| Section 105.B | Revision | Amend Department unit reference to DPH and remove Department mailing address. |
| **R.61‑97** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.K | Revision | Amend Department definition to mean DPH. |
| Section 102.B.2 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 602.A | Revision | Amend regulation number to reflect move to Chapter 60 and amend Department unit reference to DPH. |
| **R.61‑102** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section A(1)(d) | Deletion | Remove Board definition as DHEC Board is no longer established. |
| Section A(1)(g) and (j) | Revision | Amend Department definition to mean DPH and amend Department references to DPH. |
| Section D(7)(b)(6) | Revision | Amend Department reference for DPH and clarify form number. |
| Section H(3)(e) | Revision | Amend Department reference to DPH. |
| Section L(1) and (2)(a) | Revision | Amend Department and Department unit reference to DPH and to SCDES. |
| **R.61‑103** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| **R.61‑108** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 101.M | Revision | Amend Department definition to mean DPH. |
| Section 101.P | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 102.A.1 through 4 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 102.I | Revision | Amend Department unit reference to SCDES. |
| Section 601.A.1 | Revision | Amend Department unit reference to DPH. |
| Section 601.B | Revision | Amend Department unit reference to DPH. |
| Section 602 | Revision | Amend Department unit reference to DPH and amend Department contact information for fire notifications and reports. |
| Section 603 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 604 | Revision | Amend Department unit reference to DPH. |
| Section 605 | Revision | Amend Department unit reference to DPH. |
| Section 606 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 607 | Revision | Amend Department unit reference to DPH. |
| Section 608.A and B | Revision | Amend Department unit reference to DPH. |
| Section 702.F and G | Revision | Amend Department unit reference to DPH. |
| Section 901.B | Revision | Amend Department unit reference to DPH. |
| Section 1001.D.4 | Revision | Amend Department unit reference to DPH. |
| Section 1006.E | Revision | Amend Department unit reference to DPH. |
| Section 1007.A.2 and B | Revision | Amend regulation number to reflect move to Chapter 60 and amend Department unit reference to DPH. |
| Section 1302.B.2 | Revision | Amend Department unit reference to DPH. |
| **R.61‑109** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 100.I | Revision | Amend Department definition to mean DPH. |
| **R.61‑111** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 100.K | Revision | Amend Department definition to mean DPH. |
| **R.61‑112** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 1 | Revision | Amend regulation numbers to reflect move to Chapter 60. |
| Section 2 | Revision | Amend regulation number to reflect move to Chapter 60. |
| Section 2, Commissioner Definition | Revision | Amend Commissioner definition to Director of DPH. |
| Section 3 | Revision | Amend Department references to DPH. |
| Section 4 | Revision | Amend Department references to DPH and amend Commissioner reference to Director. |
| Section 5 | Revision | Amend Department references to DPH and amend regulation numbers to reflect move to Chapter 60. |
| Section 6 | Revision | Amend Department references to DPH. |
| Section 7 | Revision | Amend Department references to DPH and amend Commissioner references to Director. |
| Section 8 | Revision | Amend Department references to DPH. |
| Section 9 | Revision | Amend Department references to DPH and amend Commissioner references to Director. |
| Section 10.A through C | Revision | Amend Department references to DPH and amend Commissioner references to Director. |
| **R.61‑114** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section A | Revision | Amend Department reference to DPH. |
| Section B.2 | Revision | Amend Department definition to mean DPH. |
| **R.61‑116** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 100.D | Revision | Amend Department definition to mean DPH. |
| **R.61‑118** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 100.F | Revision | Amend Department definition to mean DPH. |
| **R.61‑120** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section B.2 | Revision | Amend Department definition to mean DPH. |
| **R.61‑122** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| **R.61‑123** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |
| Section 102.A, B, and C | Revision | Amend Department definition to mean DPH and amend Department references to DPH. |
| **R.61‑125** |  |  |
| Regulation Number | Revision | Amend regulation number to move to Chapter 60. |

**Instructions:**

Amend the aforementioned regulations pursuant to each individual instruction provided with the text of the amendments below.

**Text:**

**Add Chapter 60 to the S.C. Code of Regulations**

**Chapter 60**

**Department of Public Health**

**61‑3. The Practice of Selling and Fitting Hearing Aids.**

Statutory Authority: 1976 Code Sections 40‑25‑30 et seq.

**Amend R.61‑3 regulation number** **and move to Chapter 60 to read:**

60‑3. The Practice of Selling and Fitting Hearing Aids.

**Amend R.61‑3.I(b) to read:**

(b) The Department: The South Carolina Department of Public Health.

**Amend R.61‑3, Section 101(e) to read:**

(e) Application for Examination Fee: An application for examination shall be accompanied by a check or money order made payable to the South Carolina Department of Public Health in the amount of fifty dollars ($50.00). It shall be understood by the applicant that the examination fee shall in no instance be refunded, applied as payment for temporary permit, or transferred to the license fee.

**Amend R.61‑3, Section 105(a) to read:**

(a) All fees shall be made payable to the South Carolina Department of Public Health and are not transferable.

**Amend R.61‑3, Section 204 to read:**

Conditions arising which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the South Carolina Department of Public Health.

**61‑4. Controlled Substances.**

Statutory Authority: S.C. Code Section 44‑53‑280(a).

**Amend R.61‑4 regulation number and move to Chapter 60 to read:**

60‑4. Controlled Substances.

**Amend R.61‑4, Section 102(d), (j), (k), and (u) to read:**

(d) Bureau Director. The Director of the Bureau of Drug Control, DPH.

(j) DPH. The South Carolina Department of Public Health.

(k) Director. Unless otherwise specified, the Director of the Department of Public Health.

(u) Long Term Care Facility (LTCF). Nursing home, intermediate care, mental care, or other facility or institution which provides extended health care to resident patients and is licensed as such by DPH or other appropriate State agency, which may further define the term for licensing and certification purposes.

**Amend R.61‑4, Section 103 to read:**

Information regarding procedures under these rules and special instructions supplementing these rules will be furnished upon request by writing to the Bureau of Drug Control, DPH.

**Amend R.61‑4, Section 104 to read:**

Registration and re‑registration fees shall be paid at the time when the application for registration is submitted for filing. Payment shall be made in the form of a personal, certified or cashier’s check, money order, credit card or online electronic payment, made payable to DPH. Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant.

**Amend R.61‑4, Section 109(b) and (d) to read:**

(b) An individual practitioner who is affiliated with one or more other individual practitioners in any legitimate and lawful form of business arrangement (i.e., partnership, professional association, etc.) shall be registered individually with DPH prior to engaging in any form of controlled substances activity, pursuant to the provisions of S.C. Code Ann. §§ 44‑53‑290 and 44‑53‑370(a)(1). With the written Power of Attorney of another affiliated practitioner within the group, any other affiliate individual practitioner may administer or dispense (other than by prescribing) controlled substances within the regular course of professional practice if and to the extent the practitioner granting the power of attorney has authorized. (For example, Dr. X and Dr. Y are partners; they shall be individually registered in order to utilize controlled substances in their practice; if Dr. X desired, he or she could issue Dr. Y a power of attorney to utilize Dr. X’s office stock of controlled substances to administer an injection of product CRx to Dr. Y’s Patient, Mrs. A. while she is in the office. Dr. Y may not, however, sign Dr. X’s name to prescriptions, nor may Dr. Y use Dr. X’s registration number to obtain stocks of controlled substances for himself or herself or his or her own office stock.) Any power of attorney, once granted, may be revoked by the grantor in writing. Nothing in this Section shall be construed to relieve the grantor of any power of attorney of any responsibility for the proper storage, record keeping, handling, or legitimate use of any controlled substances acquired by the grantor; nor shall anything be construed as relieving the grantee practitioner from full and complete responsibility for his or her actions conducted pursuant to the power of attorney or for controlled substances acquired or utilized pursuant to this paragraph.

(d) Individual practitioners permitted under the provisions of Federal Regulation 21 CFR § 1301.24 to dispense, administer, or prescribe controlled substances under the registration of a hospital or other institution which is registered, in lieu of personal registration, are prohibited from this practice by the provisions of S.C. Code Ann. §§ 44‑53‑290 and 44‑53‑370(a)(1). No prescriptions issued within this State shall be dispensed by any person registered with DPH unless the individual practitioner issuing the prescription holds a valid individual practitioner registration with DEA. Nothing shall prevent the dispensing of such prescriptions if they are co‑signed by an individual practitioner holding a valid individual registration with the DEA and DPH, providing that the co‑signing practitioner has established a valid practitioner‑patient relationship as set forth by §§ 1103 and 1204 of this Regulation prior to the dispensing of the controlled substance. Nothing in this paragraph shall preclude any pharmacy or dispensary operated by the Federal government on any property or enclave not subject to State jurisdiction from any act permitted under Federal law or regulation, nor shall it preclude the dispensing of out‑of‑state prescriptions as permitted by § 114 of this Regulation.

**Amend Section 110(a) and (c) to read:**

(a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service or Bureau of Prisons who is authorized to prescribe, dispense or administer, but not procure or purchase controlled substances in the course of his or her official duties, provided such prescribing, dispensing, and administering of controlled substances takes place upon a military reservation or other Federal enclave. Practitioners who issue prescriptions for controlled substances which are to be dispensed from governmental stocks shall be exempt from registration. Any practitioner who issues prescriptions for controlled substances which are to be dispensed from non‑governmental pharmacies or dispensaries shall register with DPH prior to issuing such prescriptions.

(c) Practitioners who register annually with DPH are granted an exemption to the fee requirement pursuant to Section 1303 of this regulation, provided that the request for exemption to the fee requirement is filed in writing with the Bureau Director. The written request must contain a military picture ID of the requestor, as well as documentation of the name and location of the military installation or hospital facility where the practitioner is located.

**Amend R.61‑4, Section 202(a) to read:**

(a) If the person is required to be registered, and is not so registered and is applying for registration;

(1) As a practitioner, pharmacy, mid‑level practitioner, animal control, animal shelter, health clinic, EMS, rescue squad, or hospice, he or she shall apply on the applicable DPH form or its electronic equivalent;

(2) As a narcotic treatment program, he or she shall apply on the applicable DPH form or its electronic equivalent;

(3) As a distributor, canine unit, researcher, exporter, importer, broker, analytical or forensic laboratory, manufacturer or hospital, he or she shall apply on the applicable DPH form or its electronic equivalent.

**Amend R.61‑4, Section 203(b) and (c) to read:**

(b) Practitioners registered with DPH desiring to perform incidental research on or with controlled substances under the provisions of S.C. Code Ann. § 44‑53‑300(c) are not required to furnish the formal protocol (except for narcotic substances as is required under Federal law), but shall instead provide a written summary of the proposed research, including the scope, the substance to be utilized, the number of research subjects (and their identity if protection from prosecution is desired), the duration of the research and the estimated usage of the controlled substance. Insofar as is practical, the dispensing of the controlled substance utilized in a valid research project shall be performed by the researcher or a particular dispenser or small group of dispensers in order to maintain adequate control. While not imperative to DPH, notice of any participating dispensaries or pharmacies should be made to the Bureau of Drug Control in order that inadvertent and unnecessary investigations of normally unusual dispensing practices may be avoided.

(c) DPH may require additional information or updating of protocols from time to time, but not more often than annually, unless a major change or deviation from previously submitted protocols or summaries is discovered. It is the responsibility of the person conducting the research project to notify DPH prior to any change in a protocol.

**Amend R.61‑4, Section 304(a) to read:**

(a) The Bureau Director, in his or her discretion, may grant provisional registration as a Researcher, Manufacturer, Distributor, Importer, or Exporter to any applicant, pending such applicant’s obtaining a registration under Federal law. The duration of such provisional registration shall not exceed one year, and may not be renewed. Upon the granting of Federal registration, the provisional registration may be converted to a permanent registration by DPH, which may renew such registration in the same manner as any other regular registration. If the Bureau Director does not find it in the public interest to grant a provisional registration, or to convert a provisional registration into a regular registration in the manner provided above, procedures set forth in S.C. Code Ann. § 44‑53‑320 for denial of registration shall be followed.

**Amend R.61‑4, Section 314(c) and (d) to read:**

(c) At any other hearing for the denial of a registration, DPH shall have the burden of proving that the requirements for such registration pursuant to the Act are not satisfied.

(d) At any hearing for the revocation or suspension of a registration, DPH shall have the burden of proving that the requirements of the Act for such suspension or revocation are satisfied.

**Amend R.61‑4, Section 317 to read:**

Any registrant may apply to modify his or her registration to authorize the handling of additional controlled substances or to change his or her name or address, by submitting a letter of request to the Bureau of Drug Control, DPH. The letter shall contain the registrant’s name, address, and registration number as printed on the Certificate of Registration, and the substances and/or schedules to be added to his or her registration or the new name or address and shall be signed in accordance with § 202(d). If the modification in registration is approved, the Bureau Director shall issue a new Certificate of Registration to the registrant, who shall maintain it with the old Certificate of Registration until expiration.

**Amend R.61‑4, Section 319(a) to read:**

(a) Upon the transfer of ownership of a controlling interest in any partnership, corporation, holding company, association, or other business entity holding a registration under the Act, which is not a personal registration as an individual or a proprietorship registration involving a single individual registrant, the registration held prior to any transfer of any controlling interest or controlling ownership shall terminate upon the effective date of the transfer, and a new registration shall be obtained if the business entity is to continue controlled substances activity. DPH may, in its discretion, permit a transferor‑registrant to permit the transferee to continue operation pursuant to a written power of attorney for a period of not more than 60 days, during the pendency of obtaining a new registration for the transferee.

**Amend R.61‑4, Section 406(b) to read:**

(b) The registrant shall notify the Bureau of Drug Control, DPH, of the loss or theft of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DEA Form 106 regarding such loss or theft.

**Amend R.61‑4, Section 407(c) to read:**

(c) Upon the second such diversion, the registrant shall be required to appear before the designated hearing officer of DPH to provide, under oath, the security measures that the registrant has effected and plans to effect in the future to prevent further diversion by theft.

**Amend R.61‑4, Section 801(e) to read:**

(e) DPH, upon a finding that a registrant has maintained inadequate records, or upon a finding that the registrant has a history of poor or inadequate record keeping, may, in its discretion, require perpetual inventories of all or a part on the controlled substances possessed or otherwise utilized or handled by such registrant (or an applicant for new registration having a history of record keeping deficiencies) as a condition for granting or renewing controlled substances registration. DPH, upon a finding that adequate record keeping has been maintained for two or more years, pursuant to a perpetual inventory requirement, may remove the requirement and permit the registrant to resume standard record keeping activities with or without a probationary period of registration, as DPH deems proper.

**Amend R.61‑4, Section 809(a) to read:**

(a) Each person registered or authorized by DPH to maintain and/or detoxify controlled substances users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:

**Amend R.61‑4, Section 903 to read:**

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his or her behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed (or was authorized to sign) the most recent application for registration or re‑registration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or re‑registration, and filing it with the power of attorney being revoked. The forms are available from Director of the Bureau of Drug Control, DPH.

**Amend R.61‑4, Section 1001(a)(3) to read:**

(3) Registered with DPH under the provisions of the Act.

**Amend R.61‑4, Section 1008 to read:**

DPH will not register any person to conduct an authorized maintenance program for drug dependent persons until approval of such program has been made by the appropriate federal agencies. Upon approval by these agencies, the Bureau of Drug Control shall accept the application for registration as complete.

**Amend R.61‑4, Section 1009(e) to read:**

(e) Any maintenance facility shall be approved by DPH and the appropriate federal agencies.

**Amend R.61‑4, Section 1010 title to read:**

1010. Approved Uses of Methadone in Hospitals. Methadone is Approved for the Following Uses for Inpatients of Hospitals Licensed by DPH.

Amend R.61‑4, Section 1011 to read:

(a) Prior approval by DPH for methadone use as set forth in § 1010 of this regulation is not required.

(b) Prior approval of DPH and registration as provided by Title 21, § 1301.22(a)(6) of the Code of Federal Regulations and S.C. Code Ann. § 44‑53‑290(i), is required of all persons desiring to operate a treatment program utilizing methadone (i.e., a “methadone maintenance program”).

(c) Prior approval by DPH in the manner set forth by § 1012 of this regulation is not required to dispense methadone to outpatients of a hospital licensed by DPH. Prior approval of DPH is not required for “take home” methadone preparations which are lawfully dispensed by a methadone maintenance treatment facility.

(d) Approvals by DPH, as required by §§ 1009 through 1012 of this regulation, may be granted by the Bureau of Drug Control in its discretion. If the Bureau finds that it cannot approve a request, the request shall be submitted to the Director, along with the Bureau’s reasons for non‑approval. The Director, in his or her discretion, may then approve or deny the request, but if he or she shall deny such request, the person making the request shall be entitled to a hearing to determine the public interest, in the manner provided for “contested cases” in the South Carolina Administrative Procedures Act.

(e) DPH may require further information from any applicant in order to obtain sufficient information to be utilized in approving or denying any request.

**Amend R.61‑4, Section 1012(b) to read:**

(b) The treating physician shall agree to maintain adequate records to substantiate the use of methadone as an analgesic for the patient and shall make such records available to DPH upon request.

**Amend R.61‑4, Section 1101(g) to read:**

(g) A prescription prepared in accordance with § 1003 written for a Schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII of the Social Security Act, or a hospice program which is licensed by DPH may be transmitted by the practitioner or the practitioner’s agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner’s agent shall note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and shall be maintained in accordance with § 603 (d). The written, signed, and voided prescription shall be maintained in the medical record of the patient.

**Amend R.61‑4, Section 1202(b)(4) to read:**

(4) Any such computerized system shall have the capability of producing a print‑out of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulation. For example, this would include a refill‑by‑refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both.) Such a print‑out shall indicate name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist and the number of the original prescription order. In any computerized system employed by a user pharmacy the central record‑keeping location shall be capable of sending the print‑out to the pharmacy within 48 hours, and if a DEA Special Agent or compliance Investigator or an Inspector from DPH requests a copy of such print‑out from the user pharmacy it shall, if requested to do so by the Agent, Investigator, or Inspector verify the print‑out transmittal capability of its system by documentation (e.g. postmark).

**Amend R.61‑4, Section 1404(a) to read:**

(a) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his or her South Carolina Controlled Substances Certificate of Registration to the Bureau of Drug Control, DPH. His or her Federal Controlled Substances Certificate of Registration and any un‑executed order forms shall be returned to the DEA, 1835 Assembly Street, Suite 1229, Columbia, SC 29201.

**Amend R.61‑4, Section 1701(a) to read:**

(a) Any person registered to conduct a bona fide research project with controlled substances under the Act who intends to maintain the confidentiality of those persons who are the subjects of such research, shall, upon registration or within a reasonable time thereafter, submit to the Bureau of Drug Control, DPH, a separate request for each research project involving controlled substances, which shall contain the following:

**Amend R.61‑4, Section 1702(a) and (b) to read:**

(a) Upon registration of a practitioner to engage in research in controlled substances under the Act, the Bureau of Drug Control, DPH, on its own motion or upon request in writing from the Director or from the practitioner, may exempt the registrant when acting within the scope of his or her registration, from prosecution under State or local laws for offenses relating to possession, distribution or dispensing of those controlled substances within the scope of his or her exemption. However, this exemption does not diminish any requirement of compliance with the Federal Food, Drug and Cosmetic Act (21 USC 301, et seq.) or with the Federal Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801, et seq.).

(b) All petitions for Grants of Exemption from Prosecution for the Researcher shall be addressed to the Director, Bureau of Drug Control, DPH, and shall contain the following:

**Amend R.61‑4, Section 1901 to read:**

All hospitals (except those owned and operated by the federal government) shall be registered with DPH in controlled substances schedules II through V inclusive.

**Amend R.61‑4, Section 1903 to read:**

A resident may prescribe or order the administration of controlled substances for patients within a hospital or residency training program, provided, that such resident has completed his or her course of study in a recognized college of medicine and has been duly licensed by the Board of Medical Examiners of South Carolina to practice medicine within this state, and has duly registered with DPH and the DEA under the respective Controlled Substances Acts.

**Amend R.61‑4, Section 1904 to read:**

The administrative head of the hospital as a registrant under the Controlled Substances Act is responsible for the proper safeguarding and handling of controlled substances within the hospital. Responsibility for storage, accountability, and proper dispensing of controlled substances from the pharmacy may be delegated to a pharmacist employed by the hospital. Likewise, the Director of Nursing is usually delegated the authority for proper storage at nursing stations, and use, as directed by physician orders. However, delegation of authority does not relieve the administrator of the hospital of supervisory responsibility to insure detection and correction or any diversion of mishandling. The administrator shall be certain that all possible control measures are observed, and that any suspected diversion or mishandling of controlled substances is reported immediately to the Bureau of Drug Control for investigation. The administrator is ultimately responsible that all thefts be reported to DPH pursuant to §§ 410 through 411 of this Regulation.

**Amend R.61‑4, Section 1911(b) to read:**

(b) Recurring shortages: In cases of recurring shortages or loss of significant quantities of controlled substances (several doses), a thorough investigation shall be made, making every effort to determine the reason for the shortages, and the person responsible for the shortage, if possible. A complete report of the incident and findings shall be made to the administrative authority of the hospital. Appropriate action shall be taken immediately to prevent recurrence. A copy of the report, including any findings resulting from the local investigations, and a theft report, as required by § 408, shall be forwarded to the Bureau of Drug Control, DPH.

**Amend R.61‑4, Section 1917 to read:**

The administrative head of the hospital shall, upon service of an inspection warrant by an inspector of the Bureau of Drug Control, DPH, or if such administrative head chooses, voluntarily without inspection warrant, (acting pursuant to the informed consent to inspection delineated as a condition of registration upon the application for registration and the registration certificate issued to the registrant by DPH) make available to such inspector all dispensing and administering records of controlled substances, for the purpose of audit of said controlled substances, as well as records of receipt and disposition of all controlled substances acquired by the hospital. Inspectors shall not divulge information contained on patient records that do not concern controlled substances or other drugs restricted to prescription use only.

**Amend R.61‑4, Section 1920 to read:**

These regulations are considered to be a general but minimal required control level in the opinion of the Bureau of Drug Control, DPH. More stringent control for the institution in question or special interpretations of these regulations may be approved by a special meeting with the Bureau of Drug Control, and the administrator or designated pharmacy and therapeutics committee of the respective hospital every 3 to 5 years when the need is felt for such clarification. The intent of Part 1900 of this regulation is to insure adequate control and accountability of controlled substances utilized in health care without duly hindering or restraining the delivery of such care. Accountability and an accurate audit at periodic intervals are the crux of the adequate control system.

**Amend R.61‑4, Section 1921 to read:**

At the request of the institution under examination and/or the Bureau of Drug Control, DPH, the S.C. Society of Hospital Pharmacists may furnish a recognized local authority on Institutional Medication Delivery and Control Systems to accompany the agent/or inspector and act as a consultant to the institution in question on rectifying flaws in the system under scrutiny.

**61‑7. Emergency Medical Services.**

Statutory Authority: S.C. Code Sections 44‑61‑10 et seq., 44‑78‑10 et seq., and 44‑80‑10 et seq.

**Amend R.61‑7 regulation number and move to Chapter 60 to read:**

60‑7. Emergency Medical Services.

**Amend R.61‑7, Section 101(N) to read:**

N. Department. The South Carolina Department of Public Health.

**Amend R.61‑7, Section 1204(B) and (C) to read:**

B. The EMS Agency shall store all medications in accordance with applicable state and federal laws. The EMS Agency shall maintain an inventory of the stock and distribution of all controlled substances in a manner that the disposition of any particular item is readily traced and pursuant to Regulation 60‑4, Controlled Substances.

C. The EMS Agency shall ensure controlled substances listed in Schedules II, III, IV, and V shall be stored in a double locked system and kept in a manner consistent with Regulation 60‑4 and federal Drug Enforcement Administration (DEA) regulations. The EMS Agency shall ensure medications are monitored and attended to prevent access by unauthorized individuals. The EMS Agency shall ensure expired or discontinued medications are not to be stored with current medications.

**61‑8. Immunization Requirements for School and Childcare Attendance.**

Statutory Authority: S.C. Code Sections 44‑29‑40(A) and 44‑29‑180 (2002 & Supp. 2012).

**Amend R.61‑8 regulation number and move to Chapter 60 to read:**

60‑8. Immunization Requirements for School and Childcare Attendance.

**61‑12. Standards for Licensing Abortion Clinics.**

Statutory Authority: S.C. Code Sections 44‑7‑130 and 260; 44‑41‑10 et seq.; and 44‑93‑100.

**Amend R.61‑12 regulation number and move to Chapter 60 to read:**

60‑12. Standards for Licensing Abortion Clinics.

**Amend R.61‑12, Section 101.F to read:**

F. Department. The South Carolina Department of Public Health.

**Amend R.61‑12, Section 304.H to read:**

H. Products of conception resulting from the abortion procedure must be managed in accordance with requirements for pathological waste pursuant to R.61‑105, Infectious Waste Management Regulations. All contaminated dressings and/or similar waste shall be properly disposed of in accordance with R.61‑105.

**Amend R.61‑12, Section 403.A to read:**

A. The following shall be reported to the Department:

**Amend R.61‑12, Section 403.A.2 to read:**

2. A fetal death when the fetus has completed or passed the age or weight requiring a report, pursuant to the standards in Department R. 60‑19, Vital Statistics.

**Amend R.61‑12, Section 803.A.1 to read:**

1. When construction is contemplated either for new buildings, additions or major alterations to existing buildings, the facility must contact the Department to discuss code and regulation requirements that apply to that project. Plans and specifications shall be submitted to the Department for review. Where the Standard Building Code or other regulations require fire‑rated walls or other fire‑rated structural elements, these plans and specifications shall be prepared by an architect registered in the State of South Carolina and shall bear his/her seal.

**Amend R.61‑12, Section 803.E to read:**

E. One complete set of as‑built drawings shall be filed with DPH.

**Amend R.61‑12, Section 804 introductory paragraph to read:**

When an existing structure is contemplated for licensure it must meet the same building code requirements as a “new” facility (see Section 803.A). If an expansion or renovation to an existing facility is contemplated, the facility must contact the Department to discuss code and regulatory requirements that apply to that project. The following shall be submitted to the Department:

**Amend R.61‑12, Part IX.A to read:**

A. Plans and construction must be approved by the Department.

**Amend R.61‑12, Part IX.B to read:**

B. The facility shall submit a completed application for license on forms that shall be furnished by the Department. The following documents shall be submitted with the application:

**Amend R.61‑12, Part IX.B.1 to read:**

1. Final construction approval of both water and wastewater systems by the S.C. Department of Environmental Services (includes satisfactory laboratory reports of water samples).

**Amend R.61‑12, Part IX.E to read:**

E. The Department shall inspect the facility and require compliance with these regulations.

**61‑13. Standards for Licensing Intermediate Care Facilities for Individuals with Intellectual Disabilities.**

Statutory Authority: S.C. Code Section 44‑7‑260.

**Amend R.61‑13 regulation number and move to Chapter 60 to read:**

60‑13. Standards for Licensing Intermediate Care Facilities for Individuals with Intellectual Disabilities.

**61‑15. Certification of Need for Health Facilities and Services.**

Statutory Authority: S.C. Code Sections 44‑7‑110 through 44‑7‑340.

**Amend R.61‑15 regulation number and move to Chapter 60 to read:**

60‑15. Certification of Need for Health Facilities and Services.

**Amend R.61‑15, Section 101.5 to read:**

5. **Department.** The S.C. Department of Public Health.

**Amend R.61‑15, Section 102.2 to read:**

2. Until January 1, 2027, a person or health care facility as defined in this Regulation is required to obtain a Certificate of Need from the Department of Public Health before undertaking any of the following:

**Amend R.61‑15, Section 301.2 to read:**

2. A non‑refundable filing fee of five hundred dollars ($500) shall be received by the S.C. Department of Public Health, within twenty (20) calendar days of the public notification pursuant to Section 201 and the Certificate of Need application pursuant to Section 301.1.

**Amend R.61‑15, Section 303.1 to read:**

1. When the application is determined to be complete, the Department shall invoice the applicant, by certified mail, for the Certificate of Need application fee. The applicant shall have fifteen (15) calendar days from the date of receipt of the invoice to pay the fee by valid check or credit card made payable to the S.C. Department of Public Health. Should the application fee not be received from the applicant within fifteen (15) calendar days from receipt of the Department’s invoice, the application will be considered withdrawn.

**61‑16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.**

Statutory Authority: S.C. Code Sections 44‑7‑110 through 44‑7‑394, 44‑37‑40, 44‑37‑50, and 63‑7‑40.

**Amend R.61‑16 regulation number and move to Chapter 60 to read:**

60‑16. Minimum Standards for Licensing Hospitals and Institutional General Infirmaries.

**Amend R.61‑16, Section 101.D to read:**

D. Department: The South Carolina Department of Public Health.

**Amend R.61‑16, Section 702 to read:**

Should a facility experience a loss of an essential service such as cooling, potable water, or electrical power, the facility shall notify the Department by email to HQEP@dph.sc.gov or other email address prescribed by the Department after ensuring the safety of the patients, but not to exceed twenty‑four (24) hours from the loss of service.

**Amend R.61‑16, Section 1302.B and C to read:**

B. The facility shall request that the maternity patient, the father, or the primary caregiver view the video. Those persons whom the facility requests to view the video shall sign a document prescribed by the Department of Public Health stating that they have been offered an opportunity to view the video.

C. The facility shall only use a video approved by the Director, or his/her designee, of the Department of Public Health.

**Amend R.61‑16, Section 1313.C to read:**

C. Level I and II hospitals shall review all live births or fetal/neonatal deaths in which the neonate weighed at least 350 grams and less than 1500 grams, utilizing the Department’s Very Low Birthweight Self‑monitoring Tool. Each completed self‑monitoring DPH form shall be retained by the facility and a copy made available to the Department as specified in the self‑monitoring tool.

**Amend R.61‑16, Section 1402.A to read:**

A. For inpatient newborns a licensee shall be responsible for filing a birth certificate for all live births occurring in the licensed facility (see Regulation 60‑19 for definition of live birth). The record should be filed as prescribed within five (5) days of delivery per Regulation 60‑19.

**Amend R.61‑16, Section 1403 to read:**

Filing of a death certificate shall be in accordance with Regulation 60‑19 and the S.C. Code of Laws.

**Amend R.61‑16, Section 2003 to read:**

The Facility shall immediately notify the Department by email to firewatch@dph.sc.gov or other email address prescribed by the Department regarding any fire, regardless of size or damage that occurs in the facility, and followed by a complete written report to include fire department reports, if any, to be submitted within a time period determined by the facility, but not to exceed 7 business days.

**61‑17. Standards for Licensing Nursing Homes.**

Statutory Authority: S.C. Code Section 44‑7‑260.

**Amend R.61‑17 regulation number and move to Chapter 60 to read:**

60‑17. Standards for Licensing Nursing Homes.

**Amend R.61‑17, Section 101.Q to read:**

Q. Department. The South Carolina Department of Public Health.

**Amend R.61‑17, Section 102.A.1 through 3 to read:**

1. Regulation 60‑4, Controlled Substances;

2. Regulation 60‑19, Vital Statistics;

3. Regulation 60‑20, Communicable Diseases;

**Amend R.61‑17, Section 201.C to read:**

C. Compliance with Building Standards. Licensed facilities shall be allowed to continue utilizing the previously‑licensed structure without building modification and shall comply with the remainder of the standards within this regulation. Proposed facilities for which the licensee has received written approval from the Department prior to the effective date of this regulation shall be allowed to comply with the previously‑approved building standards and shall comply with the remainder of the standards within this regulation. Existing facilities are not required to modify square footage of resident rooms, sitting areas, and maximum number of beds in resident rooms. (II)

**Amend R.61‑17, Section 703 to read:**

All cases of reportable diseases, animal bites, any occurrences such as epidemic outbreaks or poisonings, or other unusual occurrences that threaten the health and safety of residents or staff shall be reported in accordance with R.60‑20.

**Amend R.61‑17, Section 804.B.8 to read:**

8. Facilities shall comply with R.60‑19 with regard to vital statistics.

**Amend R.61‑17, Section 1309.D to read:**

D. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.60‑4. (I)

**61‑19. Vital Statistics.**

Statutory Authority: S.C. Code Sections 44‑63‑10 et seq.

**Amend R.61‑19 regulation number and move to Chapter 60 to read:**

60‑19. Vital Statistics.

**Amend R.61‑19, Section 100.K to read:**

K. Department. The South Carolina Department of Public Health.

**Amend R.61‑19, Section 100.CC to read:**

CC. Midwife. A person licensed by the State of South Carolina who provides midwifery services as defined in Regulation 60‑24, Licensed Midwives.

**61‑20. Communicable Diseases.**

Statutory Authority: S.C. Code Sections 44‑1‑110, 44‑1‑140 and 44‑29‑10 et seq.

**Amend R.61‑20 regulation number and move to Chapter 60 to read:**

60‑20. Communicable Diseases.

**Amend R.61‑20, Section 1.A(1), (9), and (10) to read:**

(1) “Authorized Health Officer” means an individual designated by the Director of the South Carolina Department of Public Health or his or her designee as an individual who may act as a health officer pursuant to these regulations.

(9) “Department” means the South Carolina Department of Public Health.

(10) “Director” means the Director of the South Carolina Department of Public Health.

**Amend R.61‑20, Section 7 to read:**

Whenever the Department determines that a building, place or premises may pose a risk to the public health, the Department shall cause a Public Health Notice to be placed upon the outside entrance or entrances of the building, place or premises in order to warn the public of the risk. The Public Health Notice shall be in a manner comparable to the following:

“These premises may pose a risk to the public health and may not be again occupied until order of the S.C. Department of Public Health. This notice must not be removed under penalty of law, except by an Authorized Health Officer.”

**Amend R.61‑20, Section 13 to read:**

Nothing contained in these regulations shall be construed to prevent any city, town or county from making such health laws as they may think necessary for the preservation of public health; provided that said laws are not inconsistent with the laws approved by the Department of Public Health. It shall be the duty of any city, town or county proposing a health law to at once furnish the Department of Public Health with a copy of any proposed law for the approval of the Director of the Department of Public Health before it shall become law.

**61‑21. Sexually Transmitted Diseases.**

Statutory Authority: S.C. Code Sections 44‑1‑110, 44‑1‑140 and 44‑29‑10 et seq.

**Amend R.61‑21 regulation number and move to Chapter 60 to read:**

60‑21. Sexually Transmitted Diseases.

**Amend R.61‑21, Section A(3) to read:**

(3) Department ‑The South Carolina Department of Public Health.

**Amend R.61‑21, Section B to read:**

Sexually transmitted diseases are declared to be contagious, infectious, communicable, and dangerous to the public health. Sexually transmitted diseases include all diseases or infections spread through person‑to‑person sexual contact which are included in the annual Department of Public Health List of Reportable Diseases.

**Amend R.61‑21, Section L(2) to read:**

(2) If a prisoner is suffering from HIV infection, AIDS or any sexually transmitted disease for which there is no cure, the prisoner’s medical condition shall not be a reason for further confinement. It is the recommendation of the Department that no prisoner be confined beyond the expiration of his/her sentence simply because he/she is infected with HIV or any other sexually transmitted disease for which there is no cure. When it is known to the prison or jail that a prisoner to be released is infected with HIV, or any other STD upon the release of the infected prisoner, the facility from which the prisoner has been released shall provide the prisoner with the telephone number and address of the local health department of the prisoner’s anticipated county of residence. Prior to the release of the prisoner, the prison or jail must also provide the Department of Public Health with the name, release date, sex, date of birth, race, and, if available, address and other locating/identifying information concerning the prisoner. The Department may then require the infected prisoner to report for counseling and/or other related services.

**61‑22. The Evaluation of Staff of Schools and Child Care Centers for Tuberculosis.**

Statutory Authority: S.C. Code Sections 44‑29‑150, 44‑29‑160, 44‑29‑170.

**Amend R.61‑22 regulation number and move to Chapter 60 to read:**

60‑22. The Evaluation of Staff of Schools and Child Care Centers for Tuberculosis.

**Amend R.61‑22, Section II.B to read:**

B. “Department” means the South Carolina Department of Public Health.

**Amend R.61‑22, Section II.C to read:**

C. “DPH 1420” means the form designated by the Department for documenting and certifying tuberculosis evaluation, including results of Approved TB Screening Tests, disposition and preventive measures.

**Amend R.61‑22, Section III.A.4 to read:**

4. Certification of tuberculosis evaluation, including disposition and preventive treatment, shall be documented on DPH 1420 and retained in the files of the school, kindergarten, nursery or day care center for infants and children where the person works.

**Amend R.61‑22, Section III.C.1 through 5 to read:**

1. Every school, kindergarten, nursery or day care center for infants and children shall maintain a completed DPH 1420 for each employee and shall make such records available for review by representatives of the Department upon request. Records may be maintained in an individual facility or in a centralized office, such as in a school district office.

2. For persons who are not employed directly by a school, kindergarten, nursery or day care center, but who work in these settings, the person’s employer shall maintain a completed DPH 1420 and shall make such records available for review upon request by representatives of the Department as well as representatives of any school, kindergarten, nursery or day care center in which the person works.

3. If an employee moves or transfers directly to another public or private school, kindergarten, nursery or day care center for infants and children such that employment in any of these work settings remains uninterrupted, no additional routine screening or evaluation for tuberculosis shall be required beyond that which is described above, provided the employee has a completed DPH 1420, which should be transferred to the new place of employment.

4. If an employee works in more than one school, kindergarten, nursery or day care center for infants and children, each facility shall maintain a separate copy of the individual’s completed DPH 1420 unless kept in a centralized office governing all places of employment.

5. Any employee who does not have proper documentation on file that he or she is free of TB disease shall be excluded from working in any school, kindergarten, nursery or day care center for infants and children until written certification by a licensed physician is received and documented on DPH 1420 declaring that the individual does not have tuberculosis in an active stage.

**Amend R.61‑22, Section IV.A to read:**

A. Questions regarding these guidelines may be addressed to personnel of the county health departments or the regional offices of the Department of Public Health. Questions which cannot be resolved at the local level may be referred to the Tuberculosis Control Program, Department of Public Health.

**Amend R.61‑22, Section IV.B to read:**

B. Employees may obtain tuberculosis evaluations and certifications from private physicians. Certification forms (DPH 1420) are available, upon request, from the Department.

**61‑24. Licensed Midwives.**

Statutory Authority: S.C. Code Sections 44–1–140, 40–33–30, 44–37–40, 44–37–50, and 44–89–10 et seq.

**Amend R.61‑24 regulation number and move to Chapter 60 to read:**

60‑24. Licensed Midwives.

**Amend R.61‑24, Section A.2.h to read:**

h. Department. The S.C. Department of Public Health.

**Amend R.61‑24, Section O.3.d to read:**

d. Reporting Mortalities. The midwife shall report any maternal or infant death to the Department within 48 hours. This report requires information concerning the death, to include sex, weight, date and place of delivery, pregnancy history, obstetric procedures, complications of labor and/or delivery, method of delivery, congenital anomalies of the fetus, and cause of death.

**Amend R.61‑24, Section P.1.a to read:**

a. The Director of the Department shall appoint a Midwifery Advisory Council which shall meet at least annually for the purpose of reviewing and advising the Department regarding matters pertaining to the training, practices, and regulation of midwives in South Carolina. The Council shall consist of three licensed midwives, one consumer of midwife care, two certified nurse‑midwives, one physician active in perinatal care, and one member‑at‑large. Each member shall be appointed for a three‑year term of office.

**61‑31. Health Care Cooperative Agreements.**

Statutory Authority: S.C. Code Sections 44‑7‑500 through 44‑7‑590.

**Amend R.61‑31 regulation number and move to Chapter 60 to read:**

60‑31. Health Care Cooperative Agreements.

**Amend R.61‑31, Section 102.4) to read:**

4) “Department” means the Department of Public Health.

**Amend R.61‑31, Section 202(d).8 to read:**

8. that the parties understand that the issuance of a Certificate of Public Advantage does not exempt any of the parties from compliance with the provisions of Regulation 60‑15, Certification of Need for Health Facilities and Services.

**Amend R.61‑31, Section 301 to read:**

Two copies of the application, and the filing fee set forth in Section 509 shall be submitted to the S.C. Department of Public Health.

**Amend R.61‑31, Section 305 to read:**

Upon receipt of a completed application, the Department shall forward a copy of the application to the S. C. Attorney General. After review in accordance with SC Code § 44‑7‑550, the Attorney General may advise the Department in writing to approve or deny the application. If no report is received from the Attorney General within thirty days, the Department will consider that as a recommendation to approve the request. If the Attorney General recommends denial of the Certificate of Public Advantage, the Department will consider the reasons therefor. The Attorney General’s opinion is advisory and DPH is responsible for rendering the final decision.

**61‑45. South Carolina Central Cancer Registry.**

Statutory Authority: 1976 Code Sections 44‑35‑10 et seq.

**Amend R.61‑45 regulation number and move to Chapter 60 to read:**

60‑45. South Carolina Central Cancer Registry.

**Amend R.61‑45, Section B.1, 9, 10, and 11 to read:**

1. “South Carolina Central Cancer Registry (SCCCR)” means the population‑based cancer data system for the collection, storage, maintenance, analysis, and dissemination of all cancer cases occurring in South Carolina, diagnosed after December 31, 1995, under the administration of the South Carolina Department of Public Health (DPH).

9. “Department” or DPH means the South Carolina Department of Public Health.

10. “DPH Cancer Control Advisory Committee (CCAC)” means the multidisciplinary committee that advises DPH on professional issues pertaining to cancer prevention, detection, care, and surveillance. This includes all SCCCR activities.

11. “Surveillance Subcommittee” means the subcommittee of the DPH Cancer Control Advisory Committee that is comprised of statewide representation of cancer researchers, the South Carolina Medical Association, the South Carolina Hospital Association, and the South Carolina Budget and Control Board Office of Research and Statistics. This subcommittee has the specific responsibility to determine the appropriateness of requests for confidential data release from the SCCCR.

**Amend R.61‑45, Section C.1 through C.3.a through f to read:**

1. Reportable cancer cases, as defined, which are initially diagnosed after December 31, 1995 shall be reported to DPH within six months of initial diagnosis.

2. All health care providers that diagnose and/or treat cancer patients in the State are responsible for reporting cancer cases to DPH, unless those health care providers are already reporting to a regional cancer registry.

3. Responsibility for Reporting:

a. Hospitals with existing cancer registries shall designate an appropriate person to be responsible for reporting all SCCCR reportable cases to DPH.

b. Hospitals without a cancer registry shall designate the Director of Health Information Management or the functional equivalent employee to be responsible for reporting all SCCCR reportable cases to DPH.

c. The Director or the functional equivalent of each independent pathology laboratory and private component of a hospital pathology laboratory shall be responsible for reporting the results of examination of tissue specimens and/or hematology examinations to DPH. Pathologic and hematologic reports indicating the diagnosis of cancer, that have not been previously reported from that laboratory, shall be reported.

d. Physicians shall report to DPH all new cancer cases diagnosed in their offices that are not referred to a hospital in the State for treatment.

e. The Director of functional equivalent of each freestanding surgical or treatment center shall be responsible for reporting all new cancer cases to DPH.

f. Every health care provider shall allow representatives of DPH upon demand to access, obtain, and copy information from all medical, pathological, and other pertinent records and logs related to cancer cases, as necessary for fulfilling the functions of the SCCCR. Adequate space shall be provided as needed to DPH staff for record review at South Carolina health care facilities.

**Amend R.61‑45, Section E introductory paragraph to read:**

All health care providers shall provide to DPH at least the following data items on all reportable cancer cases in accordance with standard definitions as listed in the current edition of the NAACCR Standards for Cancer Registries, Volume II, Data Standards and Data Dictionary obtained from the NAACCR. The current edition of NAACCR standards can be obtained from DPH:

**Amend R.61‑45, Section F.1 and 3 to read:**

1. The information to be reported shall be provided on forms supplied by DPH. The forms must be completed entirely. Supplemental information can be supplied for forms that cannot be completed entirely by submitting copies of pertinent medical information to include, at a minimum, pathology reports, history and physical, discharge summary, and radiographic reports.

3. Reportable cases from facilities served by the SCCCR field staff shall be collected in a manner determined by DPH.

**Amend R.61‑45, Section G.3 through 5:**

3. The DPH CCAC shall advise and make recommendations to the Department about the issues related to cancer surveillance, including all Central Cancer Registry activities. A subcommittee of the CCAC called the Surveillance Subcommittee shall have specific responsibility to determine the appropriateness of requests for confidential data release. Membership of this subcommittee shall consist of statewide representation of cancer researchers, the South Carolina Medical Association, the South Carolina Hospital Association, and the South Carolina Budget and Control Board Office of Research and Statistics. Strict criteria set forth in the SCCCR Data Release Protocol written in coordination with the South Carolina Budget and Control Board Office of Research and Statistics Principles and Protocol for Release of Health Data shall be utilized to review each data release request. This Subcommittee also assures the DPH Internal Review Board approval when appropriate in order to assure protection of human subjects.

4. Each applicant requesting access to confidential information will follow the procedure outlined in the SCCCR Data Release Protocol, completing the application and providing the required information, documentation, and assurances. The applicant shall provide, at no cost to the SCCCR, a reprint of each publication using Registry information. Any report or published papers must acknowledge DPH and the SCCCR and data must only be published according to its intended purpose on the application for data release.

5. Requests for non‑confidential data as specified in the SCCCR Data Release Protocol will be processed by SCCCR staff, subject to the confidentiality provisions set forth in DPH regulations.

**61‑75. Standards for Licensing Day Care Facilities for Adults.**

Statutory Authority: S.C. Code Section 44‑7‑260.

**Amend R.61‑75 regulation number and move to Chapter 60 to read:**

60‑75. Standards for Licensing Day Care Facilities for Adults.

**Amend R.61‑75, Section 101.K to read:**

K. Department. The South Carolina Department of Public Health.

**Amend R.61‑75, Section 603 to read:**

The Facility shall immediately report animal bites, diseases, and infections in accordance with Regulation 60‑20, Communicable Diseases, to the Department. The Facility shall maintain documentation of reported animal bites, diseases, and infections in the Participant records.

**61‑77. Standards for Licensing Home Health Agencies.**

Statutory Authority: S.C. Code Sections 44‑69‑10 et seq.

**Amend R.61‑77 regulation number and move to Chapter 60 to read:**

60‑77. Standards for Licensing Home Health Agencies.

**Amend R.61‑77, Section 101.H to read:**

H. Department. The South Carolina Department of Public Health.

**61‑78. Standards for Licensing Hospices.**

Statutory Authority: S.C. Code Sections 44‑71‑10 et seq., and 44‑7‑110 et seq.

**Amend R.61‑78 regulation number and move to Chapter 60 to read:**

60‑78. Standards for Licensing Hospices.

**Amend R.61‑78, Section 100.J to read:**

J. Department. The South Carolina Department of Public Health (DPH).

**Amend R.61‑78, Section 704 to read:**

A Hospice providing Inpatient Services shall notify the appropriate county health department of all cases of diseases and animal bites required to be reported in accordance with Regulation 60‑20, Communicable Diseases.

**61‑80. Neonatal Screening for Inborn Metabolic Errors and Hemoglobinopathies.**

Statutory Authority: S.C. Code Section 44‑37‑30.

**Amend R.61‑80 regulation number and move to Chapter 60 to read:**

60‑80. Neonatal Screening for Inborn Metabolic Errors and Hemoglobinopathies.

**Delete R.61‑80, Table of Contents, Appendices A through C:**

|  |  |
| --- | --- |
| Contents: | |
| Section A. | Purpose and Scope |
| Section B. | Definitions |
| Section C. | Testing |
| Section D. | Collection of Specimen |
| Section E. | Assurance of Diagnosis and Follow‑Up |
| Section F. | Storage of Specimen |
| Section G. | Use of Stored Specimen |
| Section H. | Forms |
| Section I. | Enforcement Provision |

**Amend R.61‑80, Section A to read:**

This regulation establishes rules implementing provisions of Section 44‑37‑30 of the South Carolina Code of Laws, 1976, as amended, regarding testing of newborn children for inborn metabolic errors and hemoglobinopathies. The Department of Public Health has been given the legislative mandate to promulgate rules and regulations for screening for inborn metabolic errors and hemoglobinopathies and to ensure compliance with the screening of every child born in South Carolina. The responsibilities of the various agencies, institutions and persons involved in the screening process are defined. Procedures for storage and use of blood specimens and maintenance of confidentiality are included.

**Amend R.61‑80, Section B.5 through 8 to read:**

5. Department—shall mean the South Carolina Department of Public Health.

6. Laboratory—shall mean the South Carolina Department of Public Health Laboratory.

7. Bureau of Maternal and Child Health—shall mean an organizational unit of the South Carolina Department of Public Health.

8. Official Departmental Instructions—shall mean detailed instructions approved by the Director of the South Carolina Department of Public Health or his designee under which the public and private health care providers, including hospitals, laboratories, clinics, physicians and their staffs screen all children born in South Carolina for designated Inborn Metabolic Errors and Hemoglobinopathies.

**Amend R.61‑80, Section H to read:**

1. Newborn Screening Program Parental Statement of Religious Objection (Religious Objection Form): The Religious Objection Form shall be completed if the parents refuse newborn screening for inborn metabolic errors and hemoglobinopathies for their child based upon religious convictions.

2. Authorization to Release Information Relative to Newborn Screening for Inborn Metabolic Errors and Hemoglobinopathies (Information Release Form): The Information Release Form may be completed as needed for release of information regarding newborn screening for inborn metabolic errors and hemoglobinopathies to persons other than those specified elsewhere in this regulation.

3. Blood Sample Storage Options, Screening for Inborn Metabolic Errors and Hemoglobinopathies (Blood Sample Storage Options Form): The Blood Sample Storage Options Form shall be completed if the parents or legal guardians do not agree to have their child’s specimen stored and potentially released for confidential, anonymous scientific study.

**Delete R.61‑80, Appendix A:**

**Delete R.61‑80, Appendix B:**

**Delete R.61‑80, Appendix C:**

**61‑84. Standards for Licensing Community Residential Care Facilities.**

Statutory Authority: S.C. Code Section 44‑7‑260.

**Amend R.61‑84 regulation number and move to Chapter 60 to read:**

60‑84. Standards for Licensing Community Residential Care Facilities.

**Amend R.61‑84, Section 101.P to read:**

P. Department. The S.C. Department of Public Health (DPH).

**Amend R.61‑84, Section 102.A.1 to read:**

1. R.60‑20, Communicable Diseases;

**Amend R.61‑84, Section 603 to read:**

All cases of diseases and animal bites which are required to be reported to the appropriate county health department shall be accomplished in accordance with R.60‑20.

**61‑91. Standards for Licensing Ambulatory Surgical Facilities.**

Statutory Authority: S.C. Code Section 44‑7‑260.

**Amend R.61‑91 regulation number and move to Chapter 60 to read:**

60‑91. Standards for Licensing Ambulatory Surgical Facilities.

**Amend R.61‑91, Section 101.R to read:**

R. Department. The S.C. Department of Public Health (DPH).

**Amend R.61‑91, Section 102.A.1 through 4 to read:**

1. R.60‑4, Controlled Substances;

2. R.60‑12, Standards for Licensing Abortion Clinics;

3. R.60‑16, Standards for Licensing Hospitals and Institutional General Infirmaries;

4. R.60‑20, Communicable Diseases;

**Amend R.61‑91, Section 103.E.9 to read:**

9. Abortions shall not be performed in an ambulatory surgical facility unless it is also licensed as an abortion clinic pursuant to R.60‑12.

**Amend R.61‑91, Section 103.L.2 to read:**

2. Ambulatory surgical services or procedures provided in licensed hospitals (such services remain within the purview of R.60‑16);

**Amend R.61‑91, Section 603 to read:**

All cases of diseases that are required to be reported to the appropriate county health department shall be accomplished in accordance with R.60‑20.

**Amend R.61‑91, Section 702.D.3 to read:**

3. Rubber stamp signatures are not permitted on orders for medications listed as “controlled substances” pursuant to R.60‑4.

**Amend R.61‑91, Section 1007.A.2 to read:**

2. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.60‑4.

**61‑93. Standards for Licensing Facilities for Chemically Dependent or Addicted Persons.**

Statutory Authority: S.C. Code Sections 44‑7‑260 et seq.

**Amend R.61‑93 regulation number and move to Chapter 60 to read:**

60‑93. Standards for Licensing Facilities for Chemically Dependent or Addicted Persons.

**61‑94. WIC Vendors.**

Statutory Authority: S.C. Code Section 43‑5‑930.

**Amend R.61‑94 regulation number and move to Chapter 60 to read:**

60‑94. WIC Vendors.

**Amend R.61‑94, Section 101(A) and (C) to read:**

(A) DPH or Department. The South Carolina Department of Public Health.

(C) State WIC Program (“Program”). The WIC Services Program in the South Carolina Department of Public Health.

**Amend R.61‑94, Section 801 to read:**

All vendors have the opportunity to request a fair hearing (administrative review) regarding certain adverse actions taken by the Department. The vendor must provide the Department with a written fair hearing request within fifteen (15) calendar days of the receipt of the notice of the adverse action. The written request must list the actions with which the vendor disagrees, as well as reasons the vendor disagrees with these actions. If the vendor does not request a hearing within the fifteen (15) calendar‑day period following notification, the Department’s decision becomes final.

A decision of the Department imposing disqualification, penalties, or requiring a vendor to refund monies for overcharging may be appealed pursuant to the state Administrative Procedures Act.

**61‑95. Medicaid Nursing Home Permits.**

Statutory Authority: S.C. Code Sections 44‑7‑80 through 44‑7‑90.

**Amend R.61‑95 regulation number and move to Chapter 60 to read:**

60‑95. Medicaid Nursing Home Permits.

**Amend R.61‑95, Section 101.A to read:**

A. Department ‑ “Department” means the Department of Public Health.

**Amend R.61‑95, Section 105.B to read:**

B. The application, to be filed upon forms provided by the Department, shall be forwarded to the Department of Public Health. The application shall set forth at least the following:

**61‑97. Standards for Licensing Renal Dialysis Facilities.**

Statutory Authority: S.C Code Sections 44‑7‑260 et seq.

**Amend R.61‑97 regulation number and move to Chapter 60 to read:**

60‑97. Standards for Licensing Renal Dialysis Facilities.

**Amend R.61‑97, Section 101.K to read:**

K. Department. The South Carolina Department of Public Health.

**Amend R.61‑97, Section 102.B.2 to read:**

2. Renal dialysis services provided in licensed hospitals (such services remain within the purview of R.60‑16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries).

**Amend R.61‑97, Section 602.A to read:**

A. Reportable Diseases. The Facility shall report cases of reportable diseases in accordance with Regulation 60‑20, Communicable Diseases, and any occurrences, such as epidemic outbreaks or poisonings or other unusual occurrence, which threaten the welfare, safety or health of Patients or personnel shall be reported immediately to the Department.

**61‑102. Standards for Licensing Birthing Centers for Deliveries by Midwives.**

Statutory Authority: S.C. Code Sections 44‑89‑60 and 44‑7‑260.

**Amend R.61‑102 regulation number and move to Chapter 60 to read:**

60‑102. Standards for Licensing Birthing Centers for Deliveries by Midwives.

**Delete R.61‑102, Section A(1)(d) and recodify remaining definitions:**

**Amend R.61‑102, Section A(1)(g) and (j) to read:**

(g) Department means the South Carolina Department of Public Health (DPH).

(j) Licensing agency means DPH.

**Amend R.61‑102, Section D(7)(b)(6) to read:**

(6) Test results and date specimen was collected for PKU and hypothyroid newborn screening test. (Exempt only when parents object because of religious convictions; then file copy of executed “Statement of Religious Objection Form,” DPH Form 1804 with newborn record.)

**Amend R.61‑102, Section H(3)(e) to read:**

(e) One complete set of as built drawings shall be filed with DPH.

**Amend R.61‑102, Section L(1) and (2)(a) to read:**

Prior to admission of patients to, and issuance of a license for new facilities or additional stations, the following actions must be accomplished and documentation furnished at the final inspection:

(1) Plans and construction must be approved by DPH.

(2) The facility shall submit a completed Application for License on forms which shall be furnished by the Department. The following documents shall be submitted with the application:

(a) Final construction approval of both water and wastewater systems by the South Carolina Department of Environmental Services (SCDES). (Includes satisfactory laboratory reports of water samples taken by SCDES.)

**61‑103. Residential Treatment Facilities for Children and Adolescents.**

Statutory Authority: S.C. Code Section 44‑7‑260.

**Amend R.61‑103 regulation number and move to Chapter 60 to read:**

60‑103. Residential Treatment Facilities for Children and Adolescents.

**61‑108. Standards for Licensing Freestanding or Mobile Technology.**

Statutory Authority: S.C. Code Ann. Section 44‑7‑265 (1976, as amended).

**Amend R.61‑108 regulation number and move to Chapter 60 to read:**

60‑108. Standards for Licensing Freestanding or Mobile Technology.

**Amend R.61‑108, Section 101.M to read:**

M. Department. The S.C. Department of Public Health (DPH).

**Amend R.61‑108, Section 101.P to read:**

P. Freestanding or Mobile Technology. Medical equipment which is to be used for diagnosis or treatment and is owned or operated by a person, other than a health care facility (as defined in S.C. Code Ann. § 44‑7‑130 (1976, as amended)), for which the total cost is in excess of that prescribed by R.60‑15 and for which specific standards or criteria are prescribed in the State Health Plan.

**Amend R.61‑108, Section 102.A.1 through 4 to read**:

1. R.60‑4, Controlled Substances;

2. R.60‑15, Certification of Need for Health Facilities and Services;

3. R.60‑16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries;

4. R.60‑20, Communicable Diseases;

**Amend R.61‑108, Section 102.I to read:**

I. Registered Equipment. Licensees utilizing equipment that is required to be registered by the S.C. Department­ of Environmental Services pursuant to S.C. Code Sections 13‑7‑10 et seq. shall not be licensed until such equipment is properly registered.

**Amend R.61‑108, Section 601.A.1 to read:**

A. A record of each incident and/or accident occurring in the equipment location area involving patients

or staff members shall be retained.

1. Serious incidents/accidents and/or medical conditions as defined below and any illness resulting in death or inpatient hospitalization shall be reported via telephone to the next‑of‑kin or responsible party immediately and in writing to the Department within 10 days of the occurrence.

**Amend R.61‑108, Section 601.B to read:**

B. Reports made to the Department shall contain at a minimum: facility name, patient age and sex, date of incident/accident, location, extent/type of injury, and means of treatment, e.g., hospitalization.

**Amend R.61‑108, Section 602 to read:**

602. Fire/Disasters (II). The Department shall be notified immediately via email to firewatch@dph.sc.gov or other email address prescribed by the Department regarding any fire occurring at the equipment location and followed by a complete written report to include fire department reports, if any, submitted within a time period determined by the policies and procedures, but not to exceed 10 days from the occurrence of the fire.

**Amend R.61‑108, Section 603 to read:**

All cases of diseases that are required to be reported to the appropriate county health department shall be reported in accordance with R.60‑20.

**Amend R.61‑108, Section 604 to read:**

The Department shall be notified in writing by the licensee of freestanding technology within 10 days of any change in on‑site manager. The notice shall include at a minimum the name of the newly appointed individual, documented qualifications as required by Section 502, and the effective date of the appointment.

**Amend R.61‑108, Section 605 to read:**

Licensees, if required by the Department to submit a "Joint Annual Report," shall complete and return this report within the time period specified by the Department.

**Amend R.61‑108, Section 606 to read:**

In accordance with R.60‑4, any licensee whose licensed equipment is housed in a facility registered with the Department’s Bureau of Drug Control shall report any theft or significant loss of controlled substances to the Bureau of Drug Control upon discovery of the loss/theft. Pursuant to S.C. Code Ann. § 40‑43‑91 (1976, as amended), any licensee whose licensed equipment is housed in a facility permitted by the S.C. Board of Pharmacy shall report the loss or theft of controlled substances or devices within thirty working days of the discovery of the loss/theft to the S.C. Board of Pharmacy.

**Amend R.61‑108, Section 607 to read:**

The Department shall be notified in writing by the licensee within 10 days of any change, upgrade and/or replacement of licensed equipment.

**Amend R.61‑108, Section 608.A and B to read:**

A. Prior to the permanent closure of a business where equipment is licensed, the Department shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the Department shall be notified of the provisions for the maintenance of the records. On the date of closure, the current original license shall be returned to the Department.

B. When a business where equipment is licensed temporarily closes, the Department shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but is not limited to: the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current standards to the equipment prior to its usage. If the location is closed for a period longer than one year, and there is a desire to re‑open, the licensee shall re‑apply to the Department and shall be subject to all licensing requirements at the time of that application.

**Amend R.61‑108, Section 702.F and G to read:**

F. Upon discharge of a patient, the record shall be completed within 60 days and filed in an inactive/closed file maintained by the licensee. Prior to the closing of an equipment location for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations and other applicable law. The licensee shall notify the Department, in writing, describing these arrangements and the location of the records.

G. Records of patients shall be retained for at least six years following the discharge of the patient. Records of minors shall be retained until after the expiration of the period of election following achievement of majority as prescribed by statute. Other documents required by this regulation, e.g., fire drills, shall be retained at least 12 months or until the next Department inspection.

**Amend R.61‑108, Section 901.B to read:**

B. The licensee shall develop and post in a conspicuous place in a public area a grievance/complaint procedure to be exercised on behalf of the patients that includes the address and phone number of the Department and a provision prohibiting retaliation should the grievance right be exercised.

**Amend R.61‑108, Section 1001.D.4 to read:**

4. Contents of each section of the kit/cart shall be listed and maintained on or in the kit/cart, and shall correspond to the list. Documentation of monthly checks of expiration dates of medications and supplies is to be retained for a period of two years or until the Department’s next inspection, whichever is longer.

**Amend R.61‑108, Section 1006.E to read:**

E. Records shall be maintained of all stock controlled substances that indicate an accounting of all items received and/or administered in such a manner that the disposition of each dose of any particular item may be readily traced. Records shall be maintained for a minimum of two years or until the next inspection by the Department.

**Amend R.61‑108, Section 1007.A.2 and B to read:**

2. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.60‑4.

B. Destruction records shall be retained by the facility for at least two years or until the Department’s next inspection.

**Amend R.61‑108, Section 1302.B.2 to read:**

2. A record of the inspections made prior to each use of the anesthesia equipment, as well as a record of all service and repair performed on all anesthesia machines, vaporizers, and ventilators, shall be maintained and retained for a minimum of two years or until the next Department inspection.

**61‑109. Standards for Permitting Body Piercing Facilities.**

Statutory Authority: 1976 Code Sections 44‑32‑10 et seq.

**Amend R.61‑109 regulation number and move to Chapter 60 to read:**

60‑109. Standards for Permitting Body Piercing Facilities.

**Amend R.61‑109, Section 100.I to read:**

I. Department. The South Carolina Department of Public Health.

**61‑111. Standards for Licensing Tattoo Facilities.**

Statutory Authority: S.C. Code Sections 44‑34‑10 et seq.

**Amend R.61‑111 regulation number and move to Chapter 60 to read:**

60‑111. Standards for Licensing Tattoo Facilities.

**Amend R.61‑111, Section 100.K to read:**

K. Department. The South Carolina Department of Public Health.

**61‑112. Implementation of Emergency Health Powers Act.**

Statutory Authority: 2002 SC Code Ann. Sections 44‑1‑140; 44‑4‑100 et seq. (Supp. 2003).

Related Authority: SC Code Ann. Section 25‑1‑440 (Supp. 2003).

**Amend R.61‑112 regulation number and move to Chapter 60 to read:**

60‑112. Implementation of Emergency Health Powers Act.

**Amend R.61‑112, Section 1 to read:**

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 60‑16 and 60‑20, 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.

**Amend R.61‑112, Section 2 to read:**

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 60‑20.

**Amend R.61‑112, Section 2, Commissioner Definition to read:**

“Director” — the Director of the Department of Public Health (DPH) or his designee.

**Amend R.61‑112, Section 3 to read:**

A. The Governor, in consultation with the Public Health Emergency Plan Committee, has the authority to declare a state of Public Health Emergency. DPH 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 DPH’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. DPH 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.

**Amend R.61‑112, Section 4 to read:**

A. Medical Information

i. Upon declaration of a state of Public Health Emergency DPH may by order amend the Official List of Reportable Conditions to include specific diseases or diagnostic criteria. DPH 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 DPH may by order amend the Official List of Reportable Conditions to include specific diseases or diagnostic criteria. DPH 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 DPH 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 Director 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 DPH, 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 Director 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 DPH records containing protected health information of persons who have participated in medical testing, treatment, vaccination, isolation, or quarantine programs or efforts by DPH 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), DPH 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. DPH 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.

**Amend R.61‑112, Section 5 to read:**

A. Use of Health Care Facilities

i. Coordination of assets

Upon declaration of a Public Health Emergency DPH 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 DPH and may include software or web page reporting mechanisms in current use and provided by DPH. 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, DPH may by order suspend for the duration of the PHE so much of Regulations 60‑15 and 60‑16 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, DPH 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 DPH’s notification within a reasonable time not to exceed forty‑eight hours, DPH may apply for an *ex parte* court order authorizing DPH, 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. DPH 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, DPH 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. DPH 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. DPH 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 60‑20, Section 6; Regulation 60‑20, 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.

**Amend R.61‑112, Section 6 to read:**

A. DPH 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 DPH 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, DPH 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, DPH 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: DPH 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 DPH may order establishment of pet holding areas or forbid pets in isolation or quarantine facilities.

iii. Non‑domestic animals; farm animals; large animals: DPH 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 DPH shall order.

**Amend R.61‑112, Section 7 to read:**

A. Possession and distribution

i. Pursuant to Code Section 44‑4‑330, DPH 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 Director 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. DPH has been designated as the entity responsible for distribution of SNS materials after transfer of SNS materials from CDC. DPH 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. DPH 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, DPH 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, DPH 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 DPH Bureau of Drug Control, or a responsible Federal agency.

iii. DPH 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 DPH. In allocating Medical Supplies, DPH will consider the amount on hand, the amount reasonably anticipated from other sources, and the population at risk. DPH 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, DPH 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, DPH 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, DPH may direct distribution of Medical Supplies to designated health care providers. DPH may direct designated health care providers to distribute or dispense Medical Supplies in accordance with criteria established by DPH, which may include age, proximity to an initiating event or route of transmission, or other criteria of epidemiological significance.

C. Orders affecting retail distribution

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

**Amend R.61‑112, Section 8 to read:**

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. DPH 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, DPH 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, DPH may submit evidence of such refusal to the appropriate licensing board for consideration in subsequent licensing decisions.

ii. DPH 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 DPH. Revocation or denial of a license based in whole or in part on such grounds may be challenged as a contested case.

**Amend R.61‑112, Section 9 to read:**

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, DPH 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, DPH may order closure of primary or secondary schools.

C. Quarantine and isolation

i. DPH 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 necessaries.

ii. (1) DPH will by order establish criteria for allowing entry into and departure from quarantine or isolation facilities, which may include prohibitions against departure. The Director 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. DPH 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.

**Amend R.61‑112, Section 10.A through C to read:**

A. Upon declaration of a Public Health Emergency, DPH 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 Director 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 DPH. 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 DPH the identifying information and the date, means and place of disposal.

C. If DPH 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, DPH shall so notify coroners, medical examiners, and funeral directors.

**61‑114. South Carolina Birth Defects Program.**

Statutory Authority: S.C. Code Sections 44‑44‑10 through 44‑44‑160.

**Amend R.61‑114 regulation number and move to Chapter 60 to read:**

60‑114. South Carolina Birth Defects Program.

**Amend R.61‑114, Section A to read:**

This regulation establishes standards for implementing provisions of Sections 44‑44‑10 through 44‑44‑160 of the South Carolina Code of Laws, 1976, as amended, regarding the public health monitoring of birth defects identified in children up to two years of age in South Carolina. The Birth Defects Act of 2004 established the South Carolina Birth Defects Program (SCBDP) within the Department of Public Health. The Department has been given the legislative mandate to promulgate regulations for public health monitoring of birth defects and to ensure compliance with the public health monitoring of children born in South Carolina. The responsibilities of the various agencies, institutions and persons involved in public health surveillance and monitoring of birth defects are defined. Procedures for public health surveillance and monitoring, use of data, and maintenance of confidentiality are included.

**Amend R.61‑114, Section B.2 to read:**

2. “Department” means the South Carolina Department of Public Health.

**61‑116. South Carolina Trauma Care Systems.**

Statutory Authority: S.C. Code Sections 44‑61‑510 et seq.

**Amend R.61‑116 regulation number and move to Chapter 60 to read:**

60‑116. South Carolina Trauma Care Systems.

**Amend R.61‑116, Section 100.D to read:**

D. Department. The South Carolina Department of Public Health (DPH).

**61‑118. South Carolina Stroke Care System.**

Statutory Authority: S.C. Code Sections 44‑61‑610 et seq.

**Amend R.61‑118 regulation number and move to Chapter 60 to read:**

60‑118. South Carolina Stroke Care System.

**Amend R.61‑118, Section 100.F to read:**

F. Department. The South Carolina Department of Public Health (“DPH”).

**61‑120. South Carolina Immunization Registry.**

Statutory Authority: S.C. Code Section 44‑29‑40.

**Amend R.61‑120 regulation number and move to Chapter 60 to read:**

60‑120. South Carolina Immunization Registry.

**Amend R.61‑120, Section B.2 to read:**

2. DEPARTMENT means the Department of Public Health.

**61‑122. Standards for Licensing In‑Home Care Providers.**

Statutory Authority: S.C. Code Sections 44‑70‑10 et seq.

**Amend R.61‑122 regulation number and move to Chapter 60 to read:**

60‑122. Standards for Licensing In‑Home Care Providers.

**61‑123. Critical Congenital Heart Screening on Newborns.**

Statutory Authority: 1976 Code Sections 44‑37‑70 et seq.

**Amend R.61‑123 regulation number and move to Chapter 60 to read:**

60‑123. Critical Congenital Heart Screening on Newborns.

**Amend R.61‑123, Section 102.A, B, and C to read:**

A. Birthing facility. An inpatient or ambulatory health care facility licensed by the Department of Public Health that provides birthing and newborn care services.

B. Department. The South Carolina Department of Public Health.

C. Department Approved Screening. A critical congenital heart defects screening approved by the Department of Public Health as an alternative to pulse oximetry screening based on standards set forth by the United States Secretary of Health and Human Services’ Advisory Committee on Heritable Disorders in Newborns and Children, the American Heart Association, and the American Academy of Pediatrics.

**61‑125. Standards for Licensing Crisis Stabilization Unit Facilities.**

Statutory Authority: S.C. Code Section 44‑7‑260.

**Amend R.61‑125 regulation number and move to Chapter 60 to read:**

60‑125. Standards for Licensing Crisis Stabilization Unit Facilities.

**Fiscal Impact Statement:**

Implementation of these regulatory amendments will not require additional resources. There is no anticipated additional cost by the Department or state government due to any requirements of these regulations.

**Statement of Rationale:**

The Department proposes amending the DPH regulations to conform to 2023 Act No. 60 (Act). Pursuant to Section 14(B) of the Act, the health‑related regulations currently under Chapter 61 – Department of Health and Environmental Control of the S.C. Code of Regulations are transferred to DPH. In accordance with this provision, DPH proposes transferring all the regulations listed above from Chapter 61 to the new Chapter 60 in the S.C. Code of Regulations, with the Chapter title of Department of Public Health. Additionally, DPH proposes amending references to the Department of Health and Environmental Control, including definitions, acronyms, email addresses, physical addresses, and other references in each listed regulation to conform to the provisions of 2023 Act No. 60.