

CHAPTER 94**ADMINISTRATION AND OPERATION OF THE NEW JERSEY COMMISSION ON SPINAL CORD RESEARCH, THE NEW JERSEY SPINAL CORD RESEARCH FUND, AND THE NEW JERSEY SPINAL CORD INJURY REGISTRY****Authority**

N.J.S.A. 52:9E-1 et seq., particularly 52:9E-5a, 8b and 10.

Source and Effective Date

R.2008 d.81, effective April 7, 2008.
See: 39 N.J.R. 738(a), 40 N.J.R. 1859(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 94, Administration and Operation of the New Jersey Commission on Spinal Cord Research, the New Jersey Spinal Cord Research Fund, and the New Jersey Spinal Cord Injury Registry, expires on April 7, 2015. See: 43 N.J.R. 1203(a).

Chapter Historical Note

Chapter 94, Administration and Operation of the New Jersey Commission on Spinal Cord Research, the New Jersey Spinal Cord Research Fund, and the New Jersey Spinal Cord Injury Registry, was adopted as new rules by R.2008 d.81, effective April 7, 2008. See: Source and Effective Date.

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SUBCHAPTER 1. GENERAL PROVISIONS**8:94-1.1 Purpose**

(a) The purpose of this chapter is to promote scientific research projects that focus on the treatment and cure of spinal cord injuries through grants made by the New Jersey Commission on Spinal Cord Research, established pursuant to N.J.S.A. 52:9E-3 (Commission), from the New Jersey Spinal Cord Research Fund.

(b) This chapter is intended to assist the Commission in funding scientific and medical research and other related activities that may lead to advances in the treatment and cure of spinal cord injuries by:

1. Encouraging and supporting meritorious spinal cord injury research in New Jersey;
2. Encouraging and supporting collaborations among New Jersey researchers and out-of-State researchers engaged in spinal cord injury research;
3. Fostering discoveries that will benefit New Jersey by reducing the cost of medical services for persons with spinal cord injuries;
4. Supporting the continued development and enhancement of New Jersey's public and private biomedical sector;
5. Establishing New Jersey as a leader in the field of spinal cord repair; and
6. Recruiting recognized leaders and promising new investigators to New Jersey to engage in spinal cord injury research.

(c) A further purpose of this chapter is the establishment and maintenance of a central registry of persons who sustain acute traumatic spinal cord injuries in New Jersey, which will serve as a resource for statistical, epidemiological and medical research.

8:94-1.2 Scope

This chapter provides for the administration and operation of the Commission; sets forth procedures for application, review and award of grants made from the New Jersey Spinal Cord Research Fund established pursuant to N.J.S.A. 52:9E-4; and sets forth procedures for the creation and operation of

the New Jersey Spinal Cord Injury Registry established pursuant to N.J.S.A. 52:9E-8. This chapter applies to the Commission, its administrative staff, grant applicants and recipients pursuant N.J.S.A. 52:9E-1 et seq., and health care facilities required to report cases of spinal cord injuries pursuant to N.J.S.A. 52:9E-8.

8:94-1.3 Definitions

The following words and terms, as used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

“Act” means the Spinal Cord Research Act, N.J.S.A. 52:93E-1 et seq.

“Approved research project” shall mean as defined at N.J.S.A. 52:9E-2a.

“ASIA” means the American Spinal Injury Association, which has endorsed the neurological impairment scale published in the International Standards for Neurological and Functional Classification of Spinal Cord Injury.

“Assault and homicide circumstances” means the variables (if available) that were precipitating factors of the spinal cord injury. These factors are defined by the National Violent Death Reporting System (NVDRS) version 2 coding manual, incorporated herein by reference, as amended and supplemented. To obtain a copy of the manual, contact the National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Mailstop K65, 4770 Buford Highway NE, Atlanta, GA 30341-3724.

“BLS/ALS dispatch” means the emergency medical services provided by trained and certified personnel, and includes Basic Life Support (BLS) and Advanced Life Support (ALS) services, as defined in N.J.A.C. 8:43G-12.13.

“Center for Health Statistics” or “CHS” means the Center for Health Statistics of the New Jersey Department of Health and Senior Services.

“Commission” shall mean as defined at N.J.S.A. 52:9E-2a.

“Department” or “DHSS” means the New Jersey Department of Health and Senior Services.

“Electronic submission of data” means the transfer of data from a computer used by a reporting health care facility, or provider to a computer specified by the Commission through the use of a modem, magnetic tape, magnetic disk, or the internet.

“Fiscal year” means the 12-month period beginning on July 1 and ending on June 30 of each year.

“Grant” means an award of funds by the Commission following a competitive grant submission and review process.

“Health care facility” or “facility” means a facility licensed by the Department of Health and Senior Services pursuant to P.L. 1971, c. 136 (N.J.S.A. 26:2H-1 et seq.), and any amendments thereto.

“Health care provider” or “provider” means a physician, podiatrist, dentist and/or chiropractor licensed pursuant to the provisions of Title 45 of the Revised Statutes.

“Hospital” means an institution, whether operated for profit or not, whether maintained, supervised or controlled by an agency of the government of the State or any county or municipality or not, which maintains and operates facilities for the diagnosis, treatment or care of two or more non-related individuals suffering from illness, injury or deformity and where emergency, out-patient, surgical, obstetrical, convalescent or other medical and nursing care is rendered for periods exceeding 24 hours, as defined in N.J.A.C. 8:43G-1.2.

“ICD-9 CM” refers to the International Classification of Diseases, Ninth Revision, Clinical Modification, incorporated herein by reference, as amended and supplemented. To obtain a copy of the ICD-9-CM contact the Centers for Disease Control and Prevention, National Center for Health Statistics, 3311 Toledo Road, Hyattsville, MD 20782.

“Institutional support services” shall mean as defined at N.J.S.A. 52:9E-2a.

“New Jersey Spinal Cord Research Fund” or “Fund” means the fund established pursuant to N.J.S.A. 52:9E-9. “Funds” as used in this chapter shall mean monies belonging to or drawn from the Fund.

“Qualifying research institution” shall mean as defined at N.J.S.A. 52:9E-2a.

“Registry Manager” means the entity or instrumentality designated to manage all aspects of the Spinal Cord Injury Registry by the New Jersey Commission on Spinal Cord Research and the Center for Health Statistics.

“Spinal cord injury” means an acute traumatic lesion of the neural elements in the spinal canal, resulting in temporary or permanent sensory deficit, motor deficit, or bowel/bladder dysfunction.

“Spinal Cord Injury Registry” or “Registry” means the central registry of persons who have sustained spinal cord injuries other than through disease, whether or not the injury results in a permanent disability, as established and maintained pursuant to the Act.

SUBCHAPTER 2. OPERATION OF THE COMMISSION

8:94-2.1 Operations and by-laws

(a) The Commission shall operate as a parliamentary body in accordance with Robert's Rules of Order and its duly adopted by-laws.

(b) The Commission shall issue and adopt by-laws governing its operations that establish and define its identity, enumerate its powers and duties, state requirements and terms of membership, procedures for meetings, requirements for quorums and voting, election and duties of officers and the executive director, conflicts of interest rules and code of ethics. Copies of such by-laws may be obtained in printed form from the Office of the Commission upon request.

8:94-2.2 Office of the Commission

(a) The Commission shall establish and maintain an administrative office (the "Office") and may hire such staff as it deems necessary to discharge its functions.

(b) The Office shall assist the Commission in the administration, operation and execution of the work of the Commission, including, but not limited to:

1. Arranging Commission meetings, activities and events;
2. Administering the Commission's grant solicitation, review and award procedures, grant progress and compliance; and
3. Preparing the annual report of the Commission, and such other documents required by N.J.S.A. 52:9E-4f and N.J.A.C. 8:94-2.1.

(c) The Office shall coordinate its activities with the Center for Health Statistics in creating and administering the Registry.

(d) The Commission may hire an Executive Director who shall be selected by the Commission, and who shall support the functions of the Office and staff. The Executive Director shall serve at the pleasure of the Commission, and under the direction of the Chairperson. Employment of the Executive Director shall be in the unclassified service of the State.

(e) The official address of the Commission and its Office is for all purposes as follows:

New Jersey Commission on Spinal Cord Research
Health and Agriculture Building, 4th Floor, Room
404
John Fitch Plaza, Market and Warren Streets
P.O. Box 360
Trenton, New Jersey 08625-0360
Tel: (609) 292-4055
Fax: (609) 943-4213

8:94-2.3 Meetings

(a) The Commission shall meet at least once a year for the election of officers or more frequently as specified in its by-laws.

(b) All such meetings shall be held in accordance with the provisions of the "Open Public Meetings Act," P.L. 1975, c. 231 (N.J.S.A. 10:4-6 et seq.)

8:94-2.4 Research program guidelines

(a) The Commission may from time to time issue, amend and revise research program guidelines (guidelines) to provide informational assistance and guidance to prospective applicants and the public in general concerning funding priorities, opportunities and parameters. Such guidelines shall be advisory only in nature and shall not be binding.

(b) Such guidelines shall be available for viewing or download on the Commission's website, and may also be obtained in printed form upon request from the Office of the Commission.

SUBCHAPTER 3. COMPETITIVE GRANT AWARDS
CYCLE**8:94-3.1 Notice of grant awards availability**

(a) The Commission shall initiate and implement a competitive grant awards cycle at least once annually, contingent upon availability of funds, by issuing a Notice of Grant Availability with respect to such cycle.

(b) Each Notice of Grant Availability shall be issued in accordance with and contain the information required by N.J.S.A. 52:14-34.4.

(c) Each Notice of Grant Availability shall be published in the New Jersey Register and the Department's annual Directory of Department of Health and Senior Services Grant Programs. The Notice of Grant Availability shall be available for viewing or download on the Commission's website, and in printed form from the Office of the Commission upon request. The Commission may take such other steps as it determines are necessary to ensure adequate notice to all potentially interested persons.

8:94-3.2 Criteria for applicants

(a) The Commission shall only consider and approve grant applications for spinal cord research projects made by qualifying research institutions, as defined in N.J.S.A. 52:9E-2(d).

(b) An institution seeking designation as a qualifying research institution shall submit a written request to the Commission indicating its intent to apply for research funding and requesting designation as a qualifying research institution designation.

1. The Commission may designate as a qualifying research institution any public or private academic institution, research organization or other entity, other than an individual person, established within the State of New Jersey and possessing a demonstrable capability to conduct grant-funded research.

2. The Commission may place such pre-conditions on the prospective designation of an entity as a qualifying research institution as it deems necessary or prudent prior to the award of funds to that institution.

(c) Principal investigators and other individuals applying for grants from the Fund must be affiliated with a qualifying research institution.

8:94-3.3 Types of grants

(a) The Commission may, at its discretion, designate specific types or classifications of grants that it has determined will best meet the overall purposes of the Commission as set forth in N.J.A.C. 8:94-1.1.

(b) The Commission may issue, withdraw or modify any grant type at any time, provided such action will not adversely affect any current grantee or applicant.

8:94-3.4 Grant application procedure

(a) Immediately following the publication of a Notice of Grant Availability, the Commission shall publish a grant application form for each type or classification of grant available as set forth in the Notice of Grant Availability.

1. Grant application forms will be available through the Commission's website at <http://www.state.nj.us/health/spinalcord/>.

2. All specifications and other requirements for each type of grant offered in the applicable Notice of Grant Availability will be incorporated in the grant application and on-line application process.

3. Printed copies of each grant application form may be obtained from the Office of the Commission upon request.

(b) Applicants must complete and submit all grant applications electronically using the Commission's on-line application form and process. Instructions for using the on-line form and process are available on-line or may be obtained from the Office upon request.

(c) Applicants must also submit one signed original application with original attachments, plus four copies to the Office of the Commission. Duplicate originals of attachments that cannot be legibly copied must be submitted as attachments to the required copies of each application.

(d) An application is deemed submitted upon successful completion of an on-line application and delivery of the physical original application and copies to the Office by the

time and date specified in the applicable Notice of Grant Availability for submission of applications.

8:94-3.5 Confidentiality

(a) All applications and accompanying materials shall be treated as confidential information of the applicant and shall not be disclosed by the Commission or its staff except as necessary to complete the review process or as may be required by law.

(b) All independent reviewers shall agree in writing to hold in confidence and not disclose any applications and related information disclosed to them except as necessary to complete the review process or as may be required by law.

(c) If an applicant believes any information or materials included in the grant application may be exempt from public disclosure obligations under N.J.S.A. 47:1A-1 et seq. or other public records access laws (exempt information), then, in addition to the grant application, the applicant shall submit a claim for exemption in a separate document specifying those aspects of the application that contain exempt information with an assertion of the legal basis of the claim or exemption. The Office shall be entitled to take action with respect to any such claim subject to the opinion of counsel.

8:94-3.6 Grant application review process

The grant application review process shall include an administrative review; an independent relevance review; an independent scientific merit review; and review and final decision by the Commission.

8:94-3.7 Administrative review

(a) The Office of the Commission shall conduct an administrative review of all submitted grant applications to determine compliance with the requirements of the Notice of Grant Availability, submission procedures, financial limitations, completeness, and accuracy.

(b) The Office may contact the applicant to resolve any issues concerning the application. Any application that cannot be satisfactorily corrected may be rejected.

(c) Applications successfully passing administrative review will be submitted for independent relevance review. All others shall be rejected with a brief statement provided to the applicant of the reasons for such action.

8:94-3.8 Independent relevance review

(a) The Office of the Commission (Office) shall designate an Independent Relevance Review Panel consisting of three individuals qualified by education and experience to make a finding of relevance for each grant application in light of the purposes set forth in N.J.A.C. 8:94-1.1, the Commission's mission, priorities, and research guidelines.

(b) Upon an affirmative finding of relevance, the Independent Relevance Review Panel shall instruct the Office to submit the application for independent evaluation of scientific merit by reviewers recommended by the Independent Relevance Review Panel.

(c) The Independent Relevance Review Panel shall reject all applications that it finds to have insufficient relevance, and shall provide a brief statement setting forth the reasons for its finding, which the Office shall forward to the applicant. Applications that are found by the Independent Relevance Review Panel to have insufficient relevance will be rejected, and will not be forwarded to the Independent Scientific Merit Review Panel for scientific merit review.

8:94-3.9 Scientific merit review

(a) The scientific merit review shall be conducted by an Independent Scientific Merit Review Panel consisting of peer scientists qualified by education and experience to render an independent and expert evaluation of the scientific value, importance and likelihood of success of each application.

(b) Applications found to be relevant by the Independent Relevance Review Panel shall be assigned to members of the Independent Scientific Merit Review Panel.

(c) Each panel member shall independently evaluate each assigned grant application and compile a preliminary score.

(d) Following completion of individual reviews, the Independent Scientific Merit Review Panel shall meet in a group session at a time and place specified by the Office of the Commission to determine a final score, funding recommendation and rationale with respect to each pending grant application. Applications not assigned a final numeric score by the Independent Scientific Merit Review Panel will not be submitted to the Commission for review.

8:94-3.10 Commission review and approval

(a) The Commission shall consider the rankings and recommendations of the Independent Scientific Merit Review Panel on each pending grant application and, by majority vote, decide whether or not to fund each application.

(b) Any Commission member who has any relationship, interest, association or other connection with a prospective grant recipient or sponsoring entity shall rescue himself or herself in accordance with the Commission's by-laws.

8:94-3.11 Grant award notification

(a) On or before the notification date set forth in the Notice of Grant Availability, the Office of the Commission (Office) shall send a written notice to each applicant, stating the Commission's decision and a summary of the reasons for the Commission's action.

(b) In the event an application is approved, the Office shall forward a grant award notice (Notice of Grant Award), a grant award package containing all relevant documents and information regarding the grant award, and instructions and requirements for execution and completion by the grantee.

(c) The grantee shall be responsible for completing the material contained in the grant award package and returning all such material to the Commission in a timely manner.

(d) Upon receipt of the completed grant award package, the Commission shall complete execution of all documents, take all remaining steps to finalize the award and forward a copy of the fully executed documents to the grantee.

8:94-3.12 Release of funds

(a) The Commission may release funds to a grantee in quarterly installments, or at its discretion, release funds to the grantee in the form of advance payments.

1. The Commission shall make its first payment of grant funds as specified in the Notice of Grant Award.

2. Subsequent payments shall be contingent upon the grantee's submission of properly documented quarterly expenditure reports, and availability of funds.

8:94-3.13 Responsibilities of grantees

(a) Grantees shall be responsible for compliance with all applicable State and Federal laws and regulations.

(b) Grantees shall be responsible for seeking and obtaining review and approval from their institutional review boards whenever and wherever required as a precondition for approval of research.

(c) The grantee and the principal investigator shall be legally and financially accountable for the proper use and application of all funds under the terms and conditions of the grant, compliance with all applicable laws and regulations, and the accuracy and validity of all scientific, financial and administrative information provided to the Commission.

(d) Each grantee shall submit to the Commission a final progress report within 60 days of the conclusion or other termination of the grant, and a final financial statement and expenditure report within 90 days of the conclusion or other termination of the grant, or as otherwise specified in the Notice of Grant Award or as directed by the Commission.

(e) Failure of any grantee to comply with this section shall be grounds for the denial of future grants, termination of funding, or such other action as the Commission deems appropriate.

8:94-3.14 Modification of grant award

(a) The grantee shall promptly notify the Commission in writing of any pending or actual events or circumstances that may materially affect the terms and conditions of the grant.

(b) The Commission shall determine whether and to what extent any such changes are or may be acceptable under the terms of the grant as originally awarded, or if modification of the terms of the grant will be required.

(c) The Commission may reject any changes it deems unacceptable, and may terminate further funding pursuant to N.J.A.C. 8:94-3.15, if an agreement on revised terms is not reached, or changes are made without the Commission's written consent.

(d) Neither the grantee nor the principal investigator may materially alter the research project as approved in the Notice of Grant Award without the express written agreement of the Commission and all other affected parties.

(e) If any amendment, modification, dissolution, or termination of grant award made pursuant to this section shall affect the amount of grant funding, the procedures at N.J.A.C. 8:94-3.16 shall apply.

(f) A grantee may request informal advice or opinion of the Commission or its Office on any issues that may arise concerning a grant, provided that any such opinions or recommendations made by the Commission or any of its staff or members shall be advisory only, and shall in no regard bind or place responsibility on the Commission.

8:94-3.15 Discontinuation and termination of grant

(a) If the Commission concludes that a grantee is or has become unable to meet the goals, objectives, terms, and conditions of the Notice of Grant Award, the Commission shall so inform the grantee in writing, specify the action and timing required to correct the problem, and state that failure to comply may result in amendment, modification, dissolution, or termination of the grant.

(b) Following receipt of such notice, the grantee shall act within the timeframe specified in the notice to address the issues noted by the Commission and provide evidence of its response.

(c) If a grantee fails to respond to a notice, fails to satisfactorily address the Commission's concerns or if the Commission concludes a problem is irremediable, the Commission may suspend or discontinue funding and terminate the grant award forthwith.

(d) If any amendment, modification, dissolution, or termination of grant award made pursuant to this section shall affect the amount of grant funding, the procedures in N.J.A.C. 8:94-3.16 shall apply.

8:94-3.16 Modification or reimbursement of grant funding

(a) If any amendment, modification, dissolution, or termination of a grant award shall affect the amount or application of grant funding, the Commission's determination shall specify in writing the manner in which, the amount and the extent to which:

1. The Commission shall reduce or withhold future scheduled disbursements; and

2. The grantee shall reimburse the Commission for previously disbursed funds.

SUBCHAPTER 4. THE SPINAL CORD INJURY REGISTRY**8:94-4.1 Operation**

The Registry shall be an electronic database managed and maintained by the Center for Health Statistics, DHSS, on behalf of the Commission pursuant to the Act and in furtherance of the purposes set forth in N.J.A.C. 8:94-1.1(c).

8:94-4.2 Reporting requirements

(a) Every hospitalization involving trauma resulting in spinal cord injury, as defined in N.J.A.C. 8:94-1.3, occurring in New Jersey shall be reported by each hospital ("reporting hospital") responsible for such hospitalization.

(b) Each reporting hospital shall designate an administrative contact person who shall have primary responsibility for complying with the provisions of this subchapter on behalf of the hospital. The reporting hospital shall submit the name, and contact information of such person to the Registry Manager.

(c) A health care facility other than a hospital or a health care provider may submit registry data on cases of spinal cord injury, regardless of etiology, provided the content and form of such data is compatible with the Registry.

(d) For each case of trauma resulting in spinal cord injury, the reporting hospital shall report such data as is required by the Registry Manager. The data required for each report shall include, at a minimum, the following:

1. Patient identifiers and demographics:

i. The patient's name, address and phone number;

ii. The patient's social security number;

iii. The patient's race, gender, age and date of birth;

iv. Ethnicity;

v. The medical record number and/or billing control number; and

- vi. The payment source;
- 2. BLS/ALS dispatch data:
 - i. The date and time of injury;
 - ii. The patient's location at time of injury;
 - iii. The cause of injury;
 - iv. The injury type;
 - v. The date and time of arrival of the first responder at the scene;
 - vi. Interventions at the scene and enroute to hospital;
 - vii. The date and time the patient departed scene; and
 - viii. The date and time the patient arrived at hospital;
- 3. Emergency room data:
 - i. The name of the admitting hospital;
 - ii. The date and time the patient arrived at the emergency room;
 - iii. Interventions at the emergency room;
 - iv. The date and time the patient was discharged from the emergency room;
 - v. The diagnosis at the time of discharge from the emergency room;
 - vi. The date and time the patient was admitted to the hospital;
 - vii. The date and time the patient was discharged from the hospital;
 - viii. The name and address of the facility the patient transferred to (if applicable);
 - ix. The reason for the transfer decision (if applicable); and
 - x. The responsible party for the transfer decision (if applicable);
- 4. Injury description and diagnoses:
 - i. The type of personal protective equipment;
 - ii. The motor vehicle position (if applicable);
 - iii. The injury context (work or sports related);
 - iv. The external cause of injury narrative;
 - v. The external cause of injury code (Ecode);
 - vi. Assault and/or homicide circumstances (if applicable);
 - vii. ICD-9 CM Volume I diagnosis code(s);
 - viii. Industry-standard spine-abbreviated injury score, if available;
 - ix. Industry-standard head-abbreviated injury score, if available; and
 - x. Industry-standard injury severity score, if available.
- 5. Physiological and/or neurological status:
 - i. Substances identified upon initial drug/alcohol screen;
 - ii. The level of spinal cord injury;
 - iii. The extent of spinal cord injury;
 - iv. The diagnostic indication for intracranial lesion;
 - v. The diagnostic indication for skull fracture;
 - vi. The level of consciousness;
 - vii. Glasgow Coma Scores (Eye, Motor, Verbal);
 - viii. Glasgow patient status factors;
 - ix. The ASIA Impairment Scale;
 - x. The ASIA Motor Score (Left, Right, Total);
 - xi. The ASIA Light Touch Sensory Score (Left, Right);
 - xii. The ASIA Pin Prick Sensory Score (Left, Right);
 - xiii. The total ASIA Sensory Score (Left Side);
 - xiv. The total ASIA Sensory Score (Right Side);
 - xv. The presence of anal contraction; and
 - xvi. The presence of anal sensitivity;
- 6. Treatment and outcomes:
 - i. ICD-9 CM Volume III procedure code(s);
 - ii. The administered medications;
 - iii. The use of injectable steroid(s);
 - iv. The time injectable steroid(s) administered;
 - v. The Glasgow Outcome Score;
 - vi. Functional independence measures/status at discharge (self-feeding, locomotion and expression);
 - vii. The patient disposition at discharge; and
 - viii. Autopsy findings, if any; and
- 7. Was the patient furnished a copy of the Registry enrollment form?

8:94-4.3 Time and form of submission

(a) Each reporting hospital shall submit registry data via electronic media using commercial trauma registry software provided by the Department, unless otherwise specified by the Registry Manager.

(b) A reporting hospital may contract with the Department or a private party to administer its reporting functions under the provision of this subchapter. A reporting hospital contracting with the Department shall reimburse the Department for the fair value of all such services rendered.

(c) A reporting hospital, including a hospital trauma center, shall be required to submit a report of a case of trauma resulting in spinal cord injury to the Registry Manager within 270 days following the close of the calendar quarter in which discharge occurred.

8:94-4.4 Provision of technical assistance, training, and contracting

DHSS may contract with any public or private party to discharge any or all of its responsibilities and obligations concerning the Spinal Cord Injury Registry, including, but not limited to, providing technical assistance and training on reporting, provided that such contracting entity shall be bound by and fully comply with the applicable provisions of the Act and this subchapter.

8:94-4.5 Access to information and records

(a) All communications and correspondence containing Registry data, including, but not limited to, mail, e-mail and faxes, will be deemed confidential, provided that no reporting hospital submitting information in accordance with provisions of the Act and this subchapter shall be deemed to be, or be held liable for, divulging confidential information.

(b) A reporting hospital shall allow authorized DHSS representatives, on behalf of the Commission, access to pertinent records and logs related to spinal cord injury as may be necessary to ensure, evaluate and audit compliance with the provisions of the Act and this subchapter.

(c) DHSS may from time to time publish statistics, analyses and reports based upon aggregate Registry data, in the ordinary course of its operations, in furtherance of the objectives of the Act and this subchapter or as may be otherwise required or authorized.

(d) DHSS may charge fees in accordance with N.J.S.A. 47:1A-2, to recover all expenses and costs, including costs associated with electronic data processing, duplication of reports, and complying with requests by public and private entities for summary Registry data compilation and analyses.

8:94-4.6 Audit, notice of violations, and enforcement actions

(a) A health care facility or health care provider's office shall be subject to audit at the discretion of the Commissioner by authorized representatives of the New Jersey Department of Health and Senior Services.

(b) The New Jersey Department of Health and Senior Services shall evaluate completeness and timeliness of re-

porting as specified by this chapter. Records which shall be reviewed shall include, but not be limited to: medical records, diagnostic tests, radiology, laboratory, and/or pathology reports, and discharge records.

(c) The audit shall be conducted during normal operating hours.

(d) A deficiency may be cited upon a determination that the health care facility or health care provider has not complied with the reporting requirements in this chapter.

(e) At the conclusion of the audit or within 10 business days thereafter, the New Jersey Department of Health and Senior Services shall provide the health care facility or health care provider with a written summary of any factual findings used as a basis to determine that reporting has not been complete or timely. This notice shall set forth the proposed assessment of civil monetary penalties, setting forth the specific reasons for the action. Such notice shall be served on a facility or health care provider, or its, his or her registered agent in person or by certified mail.

(f) A health care facility or health care provider shall have 30 business days in which to correct all deficiencies in its reporting that were discovered during the audit.

1. If a health care facility or health care provider fails to correct deficiencies in its reporting that were discovered during the audit within 30 days, the New Jersey Department of Health and Senior Services will act as registrar and shall charge the health care facility or health care provider for all costs related to these services, including, but not limited to, the retrieval of case information and the cost of the audit. This fee shall be based upon the fair market value of such services.

2. All checks for fees for the Department's audit services shall be made payable to "Treasurer, State of New Jersey" and forwarded to:

New Jersey Commission on Spinal Cord Research
New Jersey Department of Health and Senior
Services
PO Box 360
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Registry

8:94-4.7 Civil monetary penalties

(a) Pursuant to N.J.S.A. 52:9E-8 et. seq., and notwithstanding the provisions of N.J.A.C. 8:94-4.6(f)1, the Commission may assess a penalty for failure of a health care facility or health care provider to report pursuant to the provisions of this chapter, up to \$100.00 per unreported case of spinal cord injury.

(b) The Commission may decrease the penalties in (a) above based upon compliance history, the number and frequency of the deficiencies, the measures taken to mitigate or

prevent future deficiencies, the deterrent effect of the penalty, and/or other specific circumstances of the facility or violation.

8:94-4.8 Effective date of enforcement action

The assessment of civil monetary penalties shall become effective 30 days after the date of mailing or the date personally served, unless the health care facility or health care provider files with the Commission a written answer to the charges and gives written notice to the Commission of its desire for a hearing. In such a case, the assessment shall be held in abeyance until the administrative hearing has been conducted and a final decision is rendered by the Commission. Hearings shall be conducted in accordance with N.J.A.C. 8:94-4.10.

8:94-4.9 Failure to pay a penalty; remedies

(a) Upon receipt of a Notice of Proposed Assessment of a Penalty, a health care facility or health care provider shall have 30 days in which to notify the Commission of its request for a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

(b) The penalty will become due and owing upon the 30th day from receipt of the Notice of Proposed Assessment of Penalties if a notice requesting a hearing has not been received by the Commission. If a hearing has been requested, payment of the penalty is due 45 days after the issuance of a final agency decision by the Commission, if the Commission's assessment has not been withdrawn, rescinded, or reversed, and an appeal has not been timely filed with the Appellate Division pursuant to R. 2:2-3 of the New Jersey Court Rules.

(c) Failure to pay a penalty within 30 days of the date it is due and owing pursuant to (b) above may result in the in-

stitution of a summary civil proceeding by the State pursuant to the Penalty Enforcement Law, N.J.S.A. 2A:58-1 et seq.

8:94-4.10 Hearings

(a) Upon request, a hearing shall be afforded to a health care facility or health care provider pursuant to N.J.A.C. 8:94-4.9.

(b) A health care facility or health care provider shall notify the Commission, in writing, of its request for a hearing within 30 days of receipt of a Notice of Proposed Assessment of Penalties.

(c) The Commission shall transmit the hearing request to the Office of Administrative Law.

(d) Hearings shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

8:94-4.11 Settlement of enforcement actions

(a) A health care facility or health care provider may request that the matter be settled in lieu of conducting an administrative hearing concerning an enforcement action.

(b) If the Commission and the health care facility or health care provider agree on the terms of a settlement, a written agreement specifying these terms shall be executed.

(c) The Commission may agree to accept payment of penalties over a schedule not exceeding 18 months where a health care facility or health care provider demonstrates financial hardship.

(d) All funds received in payment of penalties shall be recovered by and in the name of the Commission and shall be deposited in the New Jersey Spinal Cord Research Fund.