

HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Rules Implementing the Health Care Professional Responsibility and Reporting  
Enhancement Act

Proposed New Rules: N.J.A.C. 8:30

Authorized By: Cathleen D. Bennett, Acting Commissioner, Department of Health in  
consultation with Elizabeth Connolly, Acting Commissioner, Department of  
Human Services and with the approval of the Health Care Administration Board.

Authority: N.J.S.A. 26:2H-12.2a and 2b; and the "Health Care Professional  
Responsibility and Reporting Enhancement Act," P.L. 2005, c. 83 (approved May  
3, 2005), particularly at § 19b (N.J.S.A. 45:1-41).

Calendar Reference: See Summary below for explanation of exception to calendar  
requirement.

Proposal Number: PRN 2015- .

**Submit written comments** by \_\_\_\_\_, 2015 electronically to

<http://www.nj.gov/health/legal/ecomments.shtml> or by regular mail to:

Joy L. Lindo, Director

Office of Legal and Regulatory Compliance

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there be any discrepancies between this document and the official version of the proposal or  
adoption, the official version will govern.

Office of the Commissioner

NJ Department of Health

PO Box 360

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The agency proposal follows:

### **Summary**

The Department of Health (Department) is proposing new rules at N.J.A.C. 8:30, Rules Implementing the Health Care Professional Responsibility and Reporting Enhancement Act, to implement P.L. 2005, c. 83 (approved May 3, 2005), the “Health Care Professional Responsibility and Reporting Enhancement Act” (Act). The Act directs the Division of Consumer Affairs in the Department of Law and Public Safety (Division) and the Department to adopt rules to implement the requirements of the Act. N.J.S.A. 45:1-41. Specifically, the Act requires the Department to prescribe the form of notification that health care entities are required to file containing information regarding health care professionals and to prescribe penalties for health care entities that fail to comply with the Act. N.J.S.A. 26:2H-12.2b at e and f. The proposed new rules would direct health care entities to the Division’s applicable requirements and would establish requirements and penalties by which the Department would ensure compliance.

Following is a summary of the proposed new rules.

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Proposed new N.J.A.C. 8:30-1.1 would provide the purpose and scope of the chapter, which is to implement the Act as it applies to health care entities.

Proposed new N.J.A.C. 8:30-1.2 would establish definitions of terms proposed for use in the chapter. Subsection (a) would establish that the proposed new rules would use the following terms as the Act defines them: “board,” “Division,” “health care entity,” “health care professional,” and “licensee.” Subsection (b) would establish definitions of the following terms: “Clearinghouse Coordinator,” “facility,” and “Medical Practitioner Review Panel.” The Act defines the term “entity” to include health care facilities licensed by the Department pursuant to the Health Care Facilities Planning Act, N.J.S.A. 26: 2H-1 et seq. and institutions licensed by other state agencies. The Department is proposing to establish a separate definition of the term, “facility,” to create a distinction between the health care facilities the Department licenses pursuant to the Health Care Facilities Planning Act, and institutions the Department regulates in a limited capacity pursuant to the Act.

Proposed new N.J.A.C. 8:30-1.3 would establish reporting requirements for health care entities. Subsection (a) would require health care entities to comply with the notification requirements at N.J.A.C. 13:45E-3.1. Subsection (b) would require health care entities to use the report required pursuant to N.J.A.C. 13:45E-5.1 when providing notification to the Clearinghouse Coordinator. Subsection (c) would require health care

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entities to cooperate with information requests from the Division, a board or the Medical Practitioner Review Panel. Subsection (d) would require health care entities to comply with N.J.A.C. 13:45E-3.3 in executing a joint report with a healthcare professional to the Clearinghouse Coordinator. Subsection (e) would require health care entities to comply with N.J.A.C. 13:45E-4.1 by providing a copy of a report submitted to the Clearinghouse Coordinator to a healthcare professional who is the subject of the report. Subsection (f) would require health care entities to provide a copy of the notice submitted to the Clearinghouse Coordinator to a staffing agency or healthcare services firm when the health care professional who is the subject of the notice is providing services to the health care entity pursuant to a contract with a staffing agency or health care services firm.

Proposed new N.J.A.C. 8:30-1.4 would establish procedures applicable to facilities that address inquiries about health care professionals and responses thereto. Subsection (a) would require facilities making inquiries pursuant to N.J.S.A. 26:2H-12.2c and N.J.A.C. 13:45E-6.1 to use the Health Care Facility Inquiry Regarding Health Care Professional form, to be incorporated by reference into the rule as Appendix A. Subsection (b) would allow a health care entity to use the Health Care Facility Inquiry Regarding Health Care Professional form in making inquiries to facilities and health care entities. Subsection (c) would require facilities responding to validly executed inquiries

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made pursuant to N.J.S.A. 26:2H-12.2c and N.J.A.C. 13:45E-6.1 to respond thereto within eight days of receipt of a validly executed request. Subsection (d) would require facilities to respond to requests made pursuant to N.J.S.A. 26:2H-12.2c and N.J.A.C. 13:45E-6.1 by health care entities other than facilities by means of a validly executed writing other than the form at Appendix A in accordance with the section, to use the form to respond, and to attach the writing or a copy thereof to the form.

Proposed new N.J.A.C. 8:30-1.5 would address the maintenance of records and disciplinary actions and would track the requirements of the Act. Subsection (a) would require the maintenance, for seven years after an occurrence, of all documented complaints of events related to patient care provided by, and records of disciplinary proceedings or actions against, a health care professional whom an entity has employed and/or with whom the entity has had an affiliation. Subsection (b) would identify the State entities to which the entity must provide access to these records. Subsection (c) would require an entity to maintain all records and source data relating to the entity's mortality, morbidity, complication, infection, and readmission for the preceding four years and would identify the State entities to which the entity must provide access to these records. Subparagraph (c)1 would make records subject to subsection (c) subject to the seven-year retention requirement in subsection (a) if the records relate to a specific health care professional.

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Proposed new N.J.A.C. 8:30-1.6 would establish penalties for violations of N.J.A.C. 8:30.

### **Social Impact**

The proposed new rules would have a social impact on health care entities and the public. Health care entities, like other employers, may shed problem employees without disclosing to prospective new employers that the employee was a problem employee. The proposed new rules would require health care entities, including health care facilities that the Department licenses, to comply with the standards at N.J.A.C. 13:45E for reporting health care professionals and disclosing information requested from an inquiring entity.

The proposed new rules, implementing the Act, in conjunction with the rules at N.J.A.C. 13:45E, would protect the public through a system designed to identify health care professionals whose conduct may adversely affect patient care.

### **Economic Impact**

The Department expects that the proposed new rules would have minimal economic impact on the public because they would not impose any additional direct costs on the State budget. The proposed new rules would not have an economic impact on patients. The proposed new rules would have an economic impact on the

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Department, which would incur staffing and administrative expenses to address violations of the rules. The proposed new rules would have an economic impact on health care entities, which would incur staffing, administrative, and recordkeeping expenses in order to comply, and penalties in the event of noncompliance. The Department is without sufficient information and experience in the implementation of this new law to estimate the costs of staffing, administrative, and recordkeeping expenses. The incurrence of penalties would depend on the nature of the offense as it relates to the penalty scale and amounts at proposed new N.J.A.C. 8:30-1.6.

### **Federal Standards Statement**

There are no Federal standards applicable to the proposed new rules. Therefore, no Federal standards analysis is required.

### **Jobs Impact**

The Department does not anticipate that the proposed new rules would result in an increase or decrease in the number of jobs available in the State.

### **Agriculture Industry Impact**

The proposed new rules would not have an impact on the agriculture industry.

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## **Regulatory Flexibility Analysis**

The proposed new rules would impose reporting, recordkeeping and compliance requirements on health care entities. Some of these health care entities are small businesses as defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq.

The Summary above describes the reporting, recordkeeping and compliance requirements that the proposed new rules would impose on health care entities. The Economic Impact describes the potential costs associated with compliance.

The Department does not anticipate that the proposed new rules would require small businesses that would be subject thereto to retain the services of professionals to comply.

The proposed new rules would not impose lesser or differing standards based on business size. The proposed new rules would establish standards that would be consistent, and the minimum standards necessary to comply, with the Act. The Act does not grant the Department discretion to impose lesser or differing standards based on business size but rather requires uniform application of the Act, and the rules promulgated pursuant thereto, to all health care entities, regardless of business size.

## **Housing Affordability Impact**

The proposed new rules would have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the proposed new

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rules would evoke a change in the average costs associated with housing because the rules only affect health care entities.

### **Smart Growth Development Impact**

The proposed new rules would have an insignificant impact on smart growth and there is an extreme unlikelihood that the proposed new rules would evoke a change in housing production in Planning Areas 1 or 2 or within designated centers under the State Development and Redevelopment Plan in New Jersey because the rules only affect health care entities.

**Full text** of the proposed new rules follows:

#### **TITLE 8**

#### **HEALTH**

#### **CHAPTER 30**

### **RULES IMPLEMENTING THE HEALTH CARE PROFESSIONAL RESPONSIBILITY AND REPORTING ENHANCEMENT ACT**

SUBCHAPTER 1. Rules Implementing the Health Care Professional Responsibility and Reporting Enhancement Act

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### 8:30-1.1 Purpose and scope

(a) This chapter implements the Health Care Professional Responsibility and Reporting Enhancement Act, P.L. 2005, c. 83 (approved May 3, 2005) (Act), and is to apply consistent with N.J.A.C. 13:45E.

(b) This chapter applies to all health care entities.

### 8:30-1.2 Definitions

(a) The following words and terms are defined in the Act at P.L. 2005, c. 83 at §§ 2 and/or 4 (N.J.S.A. 26:2H-12.2 and/or 45:1-28) and are used in this chapter as defined in the Act:

“Board”;

“Division”;

“Health care entity”;

“Health care professional”; and

“Licensee.”

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

“Clearinghouse Coordinator” means a “Health Care Professional Information Clearinghouse Coordinator” as N.J.S.A. 45:1-40 uses that term, and a “Clearing House Coordinator” as N.J.A.C. 13:45E defines that term.

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“Facility” means a health care facility licensed pursuant to N.J.S.A. 26:2H-1 et seq.

“Medical Practitioner Review Panel” or “review panel” means the Medical Practitioner Review Panel established pursuant to N.J.S.A. 45:9-19.8.

### 8:30-1.3 Reporting requirements

(a) A health care entity shall comply with the requirements of N.J.A.C. 13:45E-3.1 for notification to the Clearinghouse Coordinator.

(b) A health care entity shall use the form of report required pursuant to N.J.A.C. 13:45E-5.1 when providing notification to the Clearinghouse Coordinator.

(c) A health care entity shall cooperate with a request for information by the Division, a board, or the Medical Practitioner Review Panel.

(d) A health care entity shall comply with N.J.A.C. 13:45E-3.3 by executing a joint report to the Clearinghouse Coordinator with a healthcare professional.

(e) A health care entity shall comply with N.J.A.C. 13:45E-4.1 by providing a copy of a report filed with the Clearinghouse Coordinator to the health care professional who is the subject of the report.

(f) A health care entity shall provide a copy of the notice submitted to the Clearinghouse Coordinator in accordance with (a) above to a staffing agency or healthcare services firm when the health care professional who is the subject of the

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notice is providing services to the health care entity pursuant to a contract with a staffing agency or health care services firm.

8:30-1.4 Inquiry using, and response to, a Health Care Facility Inquiry Regarding Health Care Professional form; response time; response to non-form written requests

(a) A facility inquiring about a healthcare professional pursuant to N.J.S.A.

26:2H-12.2c and N.J.A.C. 13:45E-6:

1. Shall use the Health Care Facility Inquiry Regarding Health Care Professional form, CN-9, incorporated herein by reference as Appendix A and available from the Department's website at [www.nj.gov/health/forms](http://www.nj.gov/health/forms) ("inquiry form"), in making an inquiry to another facility; and

2. May use the inquiry form in making inquiries to health care entities other than facilities.

(b) A health care entity may use the inquiry form in making inquiries to facilities and health care entities.

(c) A facility that receives a validly executed inquiry form from any health care entity shall complete and return the form and any other information required pursuant to N.J.S.A. 26:2H-12.2c and N.J.A.C. 13:45E-6.1 to the inquiring health care entity within eight business days of receipt of the inquiry form.

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(d) A facility that receives a validly executed written request for information about a health care professional pursuant to N.J.S.A. 26:2H-12.2c and N.J.A.C. 13:45E-6.1 from a health care entity other than a facility by means of a writing made other than by use of the inquiry form shall respond to the request using the inquiry form in accordance with this section and attach the written request or a copy thereof to the inquiry form.

#### 8:30-1.5 Maintenance of records of complaints and disciplinary actions

(a) Unless another applicable law requires retention for a longer period, in which case (d) shall apply, a health care entity shall maintain and retain, for seven years from the date of the occurrence that triggered the creation of the record, all records of all documented complaints of events related to patient care provided by, and disciplinary proceedings or actions against, a health care professional:

1. Whom the health care entity employs and/or has employed; and/or
2. With whom the health care entity has and/or has had an affiliation.

(b) A health care entity shall make available to the Department, the Division, the board that licenses or otherwise authorizes the health care professional to practice, and the Medical Practitioner Review Panel, as applicable, upon request, records maintained and retained pursuant to (a) above, including records the entity has pertaining a health care professional created prior to January 12, 1990 (the effective date of the Professional Medical Conduct Reform Act of 1989, P.L. 1989, c. 300).

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(c) Unless another applicable law requires retention for a longer period, in which case (d) shall apply, a health care entity shall maintain and retain, for four years from the date of the occurrence that triggered the creation of the record, all records and source data relating to the entity's mortality, morbidity, complication, infection and readmission rates and shall make the records available to the Department, the Division, the board that licenses or otherwise authorizes the health care professional to practice, and the Medical Practitioner Review Panel, as applicable, upon request, provided:

1. A health care entity shall retain, in accordance with (a) above, records of the nature described in (c) above that relate to a specific health care professional.

(d) If another applicable law requires retention for a longer period than as provided above, that law shall control.

#### 8:30-1.6 Civil monetary penalties

(a) Pursuant to N.J.S.A. 26:2H-12.2b, health care entities are subject to the following penalties for failing to comply with this chapter:

1. \$500.00 per violation, which the Department may assess for each day of noncompliance it finds, for failing to notify the Clearinghouse Coordinator or failing to comply with a request for information from the Division or the Medical Practitioner Review Panel, as required by N.J.A.C. 8:30-1.3(b);

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2. \$250.00 per violation for failing to comply with N.J.A.C. 8:30-1.3(c);
3. \$1,000 per violation for failing to comply with N.J.A.C. 8:30-1.3(d);
4. \$250.00 per violation, which the Department may assess for each day of noncompliance it finds, for failing to respond in a timely and/or truthful manner to an inquiry submitted pursuant to N.J.A.C. 8:30-1.4;
5. \$500.00 per violation, which the Department may assess for each day of noncompliance it finds, for failing to comply with a request for records submitted pursuant to N.J.A.C. 8:30-1.5; and
6. Up to \$1,000 per violation for failing to maintain the records as required by N.J.A.C. 8:30-1.5.

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