HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

Hospital Licensing Standards

Renal Dialysis

Staffing Requirements for Inpatient Dialysis Services

Proposed Amendment: N.J.A.C. 8:43G-30.6

Authorized By: Jeffrey A. Brown, Acting Commissioner, Department of Health, in consultation with the Health Care Administration Board.

Authority: N.J.S.A. 26:2H-1 et seq., particularly N.J.S.A. 26:2H-5.

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

Proposal Number: PRN 2025-

Submit written comments by , 2025, electronically to

www.nj.gov/health/legal/ecomments.shtml or by regular mail postmarked by

, 2025, to:

Kimberly E. Jenkins, Director

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

The official versions of any Departmental rulemaking activity (notices of proposal or adoption) are published in the New Jersey Register and/or the New Jersey Administrative Code. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

Summary

N.J.A.C. 8:43G, Hospital Licensing Standards, at Subchapter 30, Renal Dialysis, establishes standards applicable to hemodialysis and peritoneal dialysis units in hospitals. N.J.A.C. 8:43G-30.6, Staffing requirements for inpatient dialysis services, at paragraph (a)1, requires a nephrologist to be present during the initiation of a patient's first inpatient dialysis treatment.

On May 30, 2023, the Department of Health (Department) received a petition for rulemaking from Shaunak Dwivedi, D.O. (petitioner). 55 N.J.R. 1761(b) (August 7, 2023) (Notice of Receipt of Petition for Rulemaking). The petitioner requested that the Department amend N.J.A.C. 8:43G-30.6(a) to remove the requirement that a nephrologist be present during the initiation of a patient's first inpatient dialysis treatment.

The Department published a notice of action on the petition for rulemaking announcing that the Department had reviewed, and determined to grant, the petition, and initiate rulemaking. 56 N.J.R. 1202(a) (July 1, 2024). In announcing its determination, the Department stated that it had spoken "with physicians licensed in New Jersey, specializing in nephrology, who confirmed that [not requiring a nephrologist to be present during a patient's initial dialysis treatment would be] reasonable and appropriate in most situations[; had] examined the regulations of over 20 other states, ... and found that [none] had a similar requirement[; had determined that the] requirement is unique and [not consistent with standards in] other states [or the] Federal [regulation] at Title 42 Chapter 4, Subchapter G, Part 494, Conditions for Coverage for End-Stage Renal Disease Facilities, [which does] not require a nephrologist to be

present[; and, for these reasons, had] determined to grant the petition for rulemaking [and would propose] to eliminate the requirement that a nephrologist be present during the initiation of a patient's first hospital inpatient dialysis treatment." *Id.* at 1203.

The Department further notes that the requested change would provide consistency across its rules for renal dialysis staffing in other health care facility types under the Department's regulatory jurisdiction. The staffing rule governing the provision of renal dialysis services in ambulatory care facilities, N.J.A.C. 8:43A-24.7, Dialysis staffing, does not require a nephrologist to be present upon a patient's initial receipt of dialysis treatment in an outpatient setting.

Accordingly, and for the reasons listed above, the Department proposes to amend N.J.A.C. 8:43G-30:6(a) to delete paragraph 1 at N.J.A.C. 8:43G-30.6(a) and to recodify the remaining text at N.J.A.C. 8:43G-30.6(a).

The Department is providing a 60-day comment period for this rulemaking.

Therefore, the notice of proposal is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The proposed amendment would have a positive social impact on New Jersey dialysis patients because changing the rule would remove an unnecessary barrier to prompt dialysis care. The proposed amendment would have a positive social impact by safeguarding the health of New Jerseyans while enhancing the healthcare experience of renal dialysis patients in New Jersey hospitals.

Economic Impact

The proposed amendment would have no economic impact on the public. The proposed amendment would enable hospitals to deploy their personnel and economic resources more efficiently to address other patient care needs.

Federal Standards Statement

The proposed amendment is not subject to any Federal standard or requirement and the Department does not propose the amendment under the authority of, or to implement, comply with, or participate in, any program established under Federal law or under a State statute that incorporates or refers to Federal law, standards, or requirements. Therefore, a Federal standards analysis is not required.

Jobs Impact

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

Agriculture Industry Impact

The proposed amendment would not have an impact on the agriculture industry in New Jersey.

Regulatory Flexibility Statement

The proposed amendment would apply to hospitals, none of which are small businesses within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16, et seq. Therefore, a regulatory flexibility analysis is not required.

Housing Affordability Impact Analysis

The proposed amendment would have no impact on affordable housing in New Jersey and would not evoke a change in the average costs associated with housing,

because the proposed amendment would address hospital personnel utilization and would have no bearing on housing prices or costs.

Smart Growth Development Impact Analysis

The proposed amendment would not have an impact on the achievement of smart growth, and would not 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 proposed amendment would address hospital personnel utilization and would have no bearing on development or housing production.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the proposed amendment follows (additions indicated in boldface, **thus**; deletions indicated in brackets, [thus]):

CHAPTER 43G. HOSPITAL LICENSING STANDARDS
SUBCHAPTER 30. RENAL DIALYSIS

8:43G-30.6 Staffing requirements for inpatient dialysis services

- (a) A nephrologist shall be present prior to the initiation of [the following:
 - 1. A patient's first inpatient dialysis treatment;
 - i. Chronic dialysis patients who are dialytically stable and who have been admitted to the hospital for conditions unrelated to their end stage renal disease shall be exempt from (a)1 above; and

- 2. Emergency dialysis to a patient with a life-threatening situation, as determined by medical staff[.
 - i. In the], **in which** case [of emergency dialysis], the nephrologist shall be present during the dialysis and until the patient is deemed stable.

(b)–(d) (No change.)