

HEALTH AND SENIOR SERVICES

SENIOR SERVICES AND HEALTH SYSTEMS BRANCH

HEALTH FACILITIES EVALUATION AND LICENSING DIVISION

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Hospital Licensing Standards

Readoption with Amendments: N.J.A.C. 8:43G

Proposed: August 16, 2010 at 42 N.J.R. 1774(a).

Adopted: \_\_\_\_\_, 2011 by \_\_\_\_\_,

Poonam Alaigh, MD, MSHCPM, FACP, Commissioner, Department of Health  
and Senior Services (with the approval of the Health Care Administration Board).

Filed: \_\_\_\_\_, 2011 as R.2011 d. \_\_\_\_\_, **with substantive and technical  
changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-  
6.3).

Authority: N.J.S.A. 26:2H-79, 80 and 81 and 26:2H-12.

Effective Date: \_\_\_\_\_, 2011, Readoption;  
\_\_\_\_\_, 2011, Amendments.

Expiration Date: \_\_\_\_\_, 2016.

**Summary** of Hearing Officer's Recommendations and Agency Response:

The public comment period for the notice of proposal was originally scheduled to close on October 15, 2010. "Based upon sufficient public interest specifically as it relates to N.J.A.C. 8:43G-6, which establishes standards for hospital anesthesia services," the Department determined to convene a public hearing and to extend the comment period to November 15, 2010. 42 N.J.R. 2561(a) (November 1, 2010).

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *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.

The Department convened a public hearing on November 8, 2010. Walter C. Kowalski, Legal Specialist, Office of Legal and Regulatory Compliance, served as hearing officer. 33 persons provided comments at the hearing. The hearing officer took no position on the rulemaking except to recommend that the agency review and respond to the comments in the context of reviewing and responding to the written comments submitted on the proposal.

The record of the public hearing is available for review by contacting Ms Stark, Office of Legal and Regulatory Compliance, Office of the Commissioner, New Jersey Department of Health and Senior Services, PO Box 360, Trenton, NJ 08625-0360.

**Prefatory note to Summary of Public Comments and Agency Responses:**

Due to the number of comments received on the proposed amendments at N.J.A.C. 8:43G-6, this Summary of Public Comments and Agency Responses is arranged in two sections. The first part provides a Summary of Public Comments and Agency Responses bearing on all of the proposed readoption with amendments except for the proposed amendments at N.J.A.C. 8:43G-6. The second part provides a Summary of Public Comments and Agency Responses bearing on the proposed amendments at N.J.A.C. 8:43G-6. Persons commenting at the public hearing described above testified exclusively with respect to the proposed amendments at N.J.A.C. 8:43G-6. Therefore, the Department identifies those commenters and responds to their testimony in part two of Summary of Public Comments and Agency Responses. The Department identifies twice those persons commenting on matters relevant to both parts.

**Summary of Public Comments and Agency Responses (Part One):**

The Department received comments on the proposed readoption with amendments (exclusive of comments on proposed amendments at N.J.A.C. 8:43G-6, which are addressed in Part Two) from the following individuals:

1. Catherine A. Ainora, FACHE, Senior Vice President, System Development/Planning, Saint Barnabas Health Care System, West Orange, NJ
2. Ms. Joan Alsop, Englewood, New Jersey;
3. John A. Carlson, Jr., M.D., Chair, Department of Obstetrics and Gynecology, St. Peter's University Hospital, New Brunswick, NJ
4. Carol Concepcion, RN, Belleville, NJ
5. Michael Jernigan, Radiology Technologist, Ringwood, NJ
6. Elfrieda V. Johnson, RN, Newark, NJ
7. Amy Kaminski, R.D., Region 1 Co-Chair, New Jersey Dietetic Association, Trenton, NJ
8. William J. Lowe, III, M.D., Director, Division of Obstetrics and Gynecology, Saint Peter's University Hospital, New Brunswick, NJ
9. Corinne Orlando, Director, Government Relations, American Heart Association/American Stroke Association
10. Patricia Peterson, Registered Respiratory Therapist, Ramsey, NJ
11. Anne Rohe, RN, Nutley, NJ
12. Johanna Shaheed, RN, Newark, NJ
13. Joan Smith, RN, Wayne, New Jersey;

14. Deanna Sperling, MAS, RN, CAN, BC, President, One New Jersey:  
Organization of Nurse Executives, Princeton, NJ

15. Virginia C. Treacy, RN, Executive Director, Jersey Nurses Economic  
Security Organization (JNESO)—the Professional Health Care Union, District Council 1,  
International Union of Operating Engineers, AFL-CIO, New Brunswick, New Jersey;

16. Ann Twomey, President, Bernie Gerard, Vice-President, Barbara Rosen,  
Secretary-Treasurer, Stephanie Orrico, Executive Committee, Health Professionals and  
Allied Employees, Emerson, NJ. This commenter’s comment was accompanied by  
hand-written comments containing personal stories of their efforts to provide care in  
“understaffed” situations, and supportive of the comments of commenter 16, particularly  
with respect to the enhanced of nurse-to-patient ratios:

(Illegible)

(Illegible), RN

(Illegible), East Windsor, NJ

(Illegible), RN, Somerset, NJ

Anonymous

Anonymous, Glassboro, NJ

Ana C. Acosta, RN, Englewood, NJ

Marita Ams, RN

Christina Ba, Mahwah, NJ

Sabrina Brown-Oliver, Neptune, NJ

Ruthann Callaghan, RN, Erial, NJ

Teresa M. Clark, RN, Browns Mills, NJ  
Cicilio Claudis  
Sonia Cole, RN, Piscataway, NJ  
Charlotte Crowe, Lyndhurst, NJ  
Karen Ann Daly, RN, Barnegat, NJ  
L. Dan, RN  
Elmer Daniels, RN, West Orange, NJ  
Lillian A. Degracia, North Bergen, NJ  
Diane Deluca, Jackson, NJ  
Joanne Dudsak, Wood Ridge, NJ  
Kathleen Eamone, Flemington, NJ  
Lucia Ejio, RN, Burlington, NJ  
Kate Luscombe Elliott, RN, Manasquan, NJ  
Rudy S. Espiritis Belleville, NJ  
Leonida Esposito, RN, Belleville, NJ  
Beverly J. Fey, RN, Neptune, NJ  
Jamie M. Fitzgerald, RN, Glassboro, NJ  
Beverly J. Frey, RN, Neptune, NJ  
Julie George, RN, Manahawkin, NJ  
Lorie A. Halter, RN, Alloway, NJ  
M. F. He, Manasquan, NJ  
S. He, Jackson, NJ

Rita Hrcsko, RN, Neptune, NJ  
Rona Johnson, LCSW NJ  
Mary Kelly, Maplewood, NJ  
Laura Kokes, Wayne, NJ  
MaryEllen Levine, RN, Stanhope, NJ  
Myrna Libaigne, Jersey City, NJ  
Sylvia Lopez RN, Ridgefield, NJ  
Mae Ma, Jersey City, NJ  
Mary Mack, RN, Bayonne, NJ  
Christina Madden, Woodstown, NJ  
Mae C. Man, Cranford, NJ  
Beth A. Manganaro, RN, Monroeville, NJ  
Tracy A. McAllister, RN, Bridgeton, NJ  
Anna McCausland, RN, Gibbsboro, NJ  
Cynthia McDougall, Maplewood, NJ  
Isabella Michaels, Hewitt, NJ  
Sheryl Mount, RN, Mount Holly, NJ  
Latorpe Myers, RN, Westampton, NJ  
Elizabeth Myod, COR  
Christine L. Neilli RN, Egg Harbor Township, NJ  
Judy O, Bayville, NJ  
Karen Ortiz

Paul P, Ocean Grove, NJ  
Debbie Pacitti, RN, Pittsgrove, NJ  
Jeffrey Perk, RN, Paterson, NJ  
Cheryl E. Portee, RN, Hamilton, NJ  
Ophelia Rasih, Jersey City, NJ  
Jo Resici, Burlington, NJ  
Nanette Rivera  
Denise Rivera, RN  
Renee Rizzo, RN  
Joanne Sa, Pittsgrove,  
Kathleen F. Schaippa, RN, Boonton Twp, NJ  
Janus A. Scharff, RN, Collingswood, NJ  
Patti Scharff, RN, Collingswood, NJ  
Geraldine Sim, Prospect Park, NJ  
Claudia Storicks, RN, Pemberton, NJ  
Louane Thone, RN, Moorestown, NJ  
Mae B. Tiogson  
Lolita Torrino, RN, Belleville, NJ  
Jill Tralka, RN, Belmar, NJ  
Linda Tsiaklis, Bayonne, NJ  
Michele Veilletti, Bayonne, NJ  
Annie Webb, RN, Newark, NJ

Dianne Wechisser, Bayonne, NJ

Nancy Weinstein, RN, Bayonne, NJ

Kathy Whalen, RN, Barnegat, NJ

Debbera White, RN, Marlton, NJ

W. White, LPN, Linden, NJ

Joan Ziteman, Keyport, NJ

17. Jacqueline Valera, RN, Jersey City, NJ

18. Debra L. Wentz, Ph.D., Chief Executive Officer, New Jersey Association of Mental Health and Addiction Agencies, Mercerville, NJ

19. 19. Rebecca B. Wolf, Director of Corporate Planning, Meridian Health, Neptune, NJ

20. Each of the following submitted letters containing identical comments:

Kathleen Stilling Burkhart, RN, MSN, APN, Adult/Geriatric Nurse

Practitioner, New Jersey Representative, American Academy of Nurse Practitioners, Edison, NJ

Theresa M. Campo, DNP, APN, NP-C, CEN, Ocean View, NJ

Valerie T. Cotter, DrNP, APN, C, FAANP, Haddonfield, NJ

Erin M. Glospie, RN, BSN, PCCN, Vice President, Communications, Region 4, New Jersey State Nurses Association, Hamilton, NJ

Tara N. Heagele, RN, BSN, PCCN, EMT-Basic, Member-at-Large Mercer County, Region 4, New Jersey State Nurses Association, Hamilton, NJ



Kristine M. Olson, RN, MS, APN, Lambertville, NJ

Nancy L. Risser, MN, APN, Adult Nurse Practitioner, Basking Ridge, NJ

Lauro Lucio Rocha, APN, Livingston, NJ

Carolyn T. Torre, RN, MA, APN, Director, Regulatory Affairs, New Jersey  
State Nurses Association, Trenton, NJ

Ann Tritak, RN, BSN, MA, EdD, Dean and Professor of Nursing, School of  
Nursing, Saint Peter's College, Jersey City, NJ

Lois Weissman, MS, APN, C, Washington Township, NJ;

21. Meschell Mansor, APN-C, Nurse Practitioner Professional Resources,  
Turnersville, NJ

22. Kenneth I. Mirsky, M.D., Westfield, NJ

The numbers in parentheses after each comment below identify the respective commenters listed above.

### **General comments**

1. COMMENT: A commenter inquires, as to the proposed amendments at N.J.A.C. 8:43G, whether there will be “another proposal after the comments have been received”; when the proposed amendments would take effect; whether the Department needs to add language regarding local health department inspections “as well as ‘accrediting body recognized by Medicare and Medicaid Services’”; whether there “will be fees for inspections, if they are not inspecting”; and how would additional time for pre- and post-admission medical histories and physicals impact patient health in regard to timely and appropriate nutrition intervention. (7)

RESPONSE: Pursuant to the Administrative Practice Act and the Rules for Agency Rulemaking, proposed amendments generally take effect and become operative upon the date of publication of a notice of adoption thereof in the New Jersey Register, unless the promulgating entity establishes a later operative date. The Department is not establishing a delayed operative date for the proposed amendments at N.J.A.C. 8:43G.

Except as the Department describes below, in response to comments raising substantive issues for consideration as to the development of future rulemaking, there would be no other proposal prior to the adoption of the proposed amendments.

Biennial inspection fees are necessary to support the Department's licensure activities and the portion of its surveillance activities (particularly complaint investigations, functional reviews, and waiver analyses) for which the Department collects no fees. N.J.S.A. 26:2H-12b prohibits the establishment of inspection fees and complaint surveys. The initial licensure and licensure renewal processes require far more than periodic inspections, often requiring Department staff to review compliance with hospital performance measures and reporting requirements prior to license reissuance. These licensing activities are necessary to assure that all hospitals subject to this chapter provide quality health care. Therefore, biennial inspection fees remain necessary.

The Department does not anticipate that the proposed amendments at N.J.A.C. 8:43G would have any impact on nutritional intervention.

The Department will make no change on adoption in response to the comment.

## **N.J.A.C. 8:43G-1**

2. COMMENT: A commenter suggests that the Department accompany the proposed inclusion, at N.J.A.C. 8:43G-1.1, of “psychiatric hospitals” within the scope and purpose of the chapter with the requirement that all psychiatric hospitals submit and release Uniform Billing discharge data in accordance with N.J.A.C. 8:31B. The commenter states that this would provide public knowledge that would be useful for such things as community needs assessment, utilization patterns and performance measurements, and that the absence of this information has hindered healthcare institutions and advocates to determine Statewide and regional information necessary to plan appropriately and encourage proper allocation of psychiatric inpatient resources and services. (1)

RESPONSE: As the Department indicates in the proposal Summary, the proposed amendment at N.J.A.C. 8:43G-1.1, adding “psychiatric hospitals” to the list of facilities to which the chapter would apply, is for consistency with existing provisions elsewhere in the chapter that establish standards applicable to psychiatric hospitals. The chapter, which has always applied to licensed psychiatric hospitals, would continue to contain a definition of the term, “psychiatric hospital,” and a subchapter devoted to psychiatric services. N.J.A.C. 8:31B establishes standards for hospital financial reporting. Thus, the change the commenter suggests would exceed the scope of the proposed rulemaking. Therefore, the Department will make no change on adoption in response to the comment.

3. COMMENT: A commenter states that the proposed addition of “psychiatric hospitals” to the list of hospitals subject to the chapter “is a much needed and appreciated effort for consistency throughout New Jersey’s hospital system.” (18)

RESPONSE: The Department acknowledges the commenter’s support of the proposed amendment.

4. COMMENT: A commenter requests that the Department use the same definition of a hospital “campus” that the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services (CMS) uses at 42 CFR §413.65(2), as follows:

“‘Campus’ means the physical area immediately adjacent to the provider’s main buildings other areas and structures that *are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual basis, by the CMS regional office, to be part of the provider’s campus* [(emphasis added by commenter)].”

The commenter asserts that this change would enable departments and/or services on a hospital campus to fall under a hospital’s existing license, avoid separate State licensure fees and processes or the Medicaid moratorium, and establish in rule form the broader scope of the concept of “campus” that the Department “has historically in licensure practice used.”

The commenter states that the suggested definition would permit the Department to treat, for licensure purposes, structures across the street from, and at other locations not connected by bricks and mortar to, the main hospital building, as part of the

provider's campus. The commenter states that New Jersey's urban density, aging facilities, and lack of expansive space hamper the ability of hospitals to address service requirements in a manner that is cost effective or facilitates patient access. The commenter asserts that N.J.A.C. 8:43G-2.11(b) implicitly appears to accept this more expansive view, and suggests that the Department change existing N.J.A.C. 8:43G-2.11(c) to incorporate the phrase that appears in italics below:

“All off-site ambulatory care service facilities *located off the hospital campus* (including mobile units) must be licensed to operate by the Department. A hospital may seek licensure and classification of off-site ambulatory care service facilities as either “free-standing’ or “hospital-based” facilities.

The commenter states that the Department currently does not license certain satellite services, such as mammography centers, low level imaging (ultrasound, nuclear imaging, basic radiography, DEXA scans) and physical and occupational therapy centers. The commenter requests “a *de facto* recognition that these non-licensure category services operate under the authority of the hospital acute care license.” (1)

RESPONSE: The Department has not encountered difficulties with its current hospital off-site licensing policies and considers the existing process, set forth at N.J.A.C. 8:43G-2.11(c), to be sufficiently expansive to provide licensing opportunities for the broad array and configuration of off-site hospital departments and services that the Department has evaluated to date. Moreover, explicit licensure by the Department that

clearly identifies these off-site services as being hospital-operated provides hospitals positive reimbursement outcomes in their dealings with third-party payers.

The Department declines to change N.J.A.C. 8:43G-2.11(c) as the commenter suggests. The definition of “campus” that the commenter urges the Department to use appears to be inappropriate as a New Jersey hospital licensure standard. First, it appears that the suggested definition would require CMS, rather than the Department, to determine the licensure status of a health care service. Second, the commenter does not provide a rationale for the suggested identification of “buildings within 250 yards” to be an appropriate standard, particularly in New Jersey, which has some regions that are extremely densely built-out and others that are more rural with spread-out development. Finally, the phrase, “and any other areas determined on an individual basis,” provides a vague and nonspecific standard that identifies no factors that one could deliberate in evaluating “other areas ... on an individual basis,” and be confident of obtaining consistent and fair results. In contrast, the existing criteria at N.J.A.C. 8:43G-2.11(c) are fair to licensees and susceptible to implementation in a consistent manner.

The Department declines to recognize “*de facto*” that the services the commenter characterizes as “select satellite services” are not subject to licensure. N.J.A.C. 8:43G establishes standards for health care services that are subject to licensure. The Department declines to make a blanket pronouncement in the manner the commenter suggests, that is, without identifying specific services not subject to licensure. To do so would be in dereliction of the Department’s general responsibility to oversee patient safety in the delivery of healthcare services in the State.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

**N.J.A.C. 8:43G-1.2, 2.2 and 2.5**

5. COMMENT: Existing N.J.A.C. 8:43G-1.2, 2.2 and 2.5 require submission of a licensure application form in which a facility officer certifies by signature that the facility meets applicable standards. A commenter requests that the Department consider making the existing form sufficient for attestation purposes in addition to serving as the means of making this certification. The commenter suggests that the Department consider changing the form to accommodate attestation, thereby reducing additional paperwork. The commenter also suggests that the Department consider amending the written attestation language to allow for signature by “a duly authorized officer” of the facility rather than only by the “chief executive officer” because many facilities operate under the leadership of professionals holding titles such as “administrator” and “executive director,” rather than “chief executive officer.” (1)

RESPONSE: The Department agrees to consider the commenter’s suggestions with respect to the licensing application form with a view toward the development of rulemaking to change the form and the associated rule text as appropriate to implement the commenter’s suggestions. In doing so, the Department will consult with stakeholders in the regulated community to achieve an acceptable consensus with respect to specific substantive and technical changes. Subject to the foregoing, the Department will make no change on adoption in response to the comments.

**N.J.A.C. 8:43G-2.4**

6. COMMENT: A commenter requests that the Department add the phrase, “and provide written notice of any deficiencies found that require a written plan of correction,” at N.J.A.C. 8:43G-2.4. (1)

RESPONSE: The existing survey process permits survey personnel to provide survey team findings to a facility during an exit interview at the conclusion of a survey. During that interview, the survey team indicates that its findings are subject to supervisory review prior to the Department’s issuance of an official written notice of licensing deficiencies to a facility. Supervisory review of survey team findings is a prerequisite to the Department’s issuance of official deficiency determinations. The change the commenter suggests would require all supervisors who participate in survey reviews and deficiency determinations to be present, review survey findings, and make determinations of a final nature at the immediately upon the conclusion of each survey. This would be neither a practicable nor an efficient use of the Department’s resources. Based on the foregoing, the Department will make no change on adoption in response to the comment.

**N.J.A.C. 8:43G-1.2, 2.2 through 2.5 and 17.1**

7. COMMENT: A commenter opposes the proposed elimination of biennial inspections, stating that private accreditation entities, although highly regarded, are “paid for [their] services by the facilities” and, therefore, not the best entities “to protect



New Jersey hospital patients that is the responsibility of the State.” The commenter asserts that there is a “lack of any specific language for establishing acuity patterns or minimum staffing ratios in the [private accreditation] standards” and that the proposed amendments “are fundamentally different and much weaker than the current standards set by N.J.A.C. 8:43G[-]17.1 and [contradict] the intent of the underlying legislation.”

The commenter states that it has testified before the New Jersey Senate Health Committee on the “lack of appropriate oversight and enforcement that has frustrated front line care providers and put tremendous pressure on patient safety. The numerous complaints made by [the commenter’s] members to the [Department] citing violations of the existing standards are met with repeated assertions that they lack jurisdiction to enforce facilities’ self determined acuity systems.” The commenter asserts that when the Department responds to complaints and determines the need for a plan of correction, “there is a complete lack of transparency. Plans of correction that were previously posted on the [Department’s] website are now only publicly disclosed through an OPRA process, and then only when a plan of correction has been submitted to the hospital and approved by [the Department]. There is no open posting or process in place to hold the facility accountable to the plan. Stymied nurses and other providers with no evidence of progress can repeatedly make the same complaints about the same facility year after year.” The commenter states that the elimination of biennial inspections without monitoring or tracking complaints would be “an abdication of regulatory authority” resulting in “a system designed to sacrifice patient safety.”

As evidence that, because of the economic climate, “all hospitals have an economic incentive to reduce staffing,” the commenter cites to a January 2010 report of the New Jersey Hospital Association, which, the commenter asserts, indicates that 43 percent of New Jersey hospitals laid-off employees and an additional 48 percent eliminated unfilled positions. The commenter states, “other economic constraints enforced additional cuts that resulted in fewer Registered Nurses and other essential staff who take care of an ever increasing patient load while hospitals deal with an increasing number of patients without reimbursement.”

The commenter objects to the renewal of “inadequate staffing ratios,” stating, “failing to address the obvious and well-documented need for improved and therefore safer staffing ratios for nurses, respiratory and radiology technicians as well as many other disciplines defies belief and continues to endanger patients in New Jersey.” (15)

A commenter expresses “grave concern” over the proposed amendments, particularly the elimination of biennial inspections, as not holding facilities accountable for their lack of adequate staffing. (12)

8. COMMENT: Commenters express both support of the proposed readoption with amendments of N.J.A.C. 8:43G, and concern that the Department is missing an opportunity “to improve and safeguard both patient care and [the] monitoring of quality of care in ... hospitals during the readoption period.” A commenter states that the health care system has been “battered by constraints posed by the managed care industry; by the introduction of for-profit systems; by reduced and more restrictive [Federal and State] support and reimbursement; by misplaced priorities and unhealthy

competition among ... hospitals; and by ... a seriously weakened economy with rising numbers of uninsured families.” As a result, the commenter states, emergency rooms are crowded with long waits, sicker patients in medical/surgical units, and the exertion of strong financial pressure to reduce patient length of stay. The commenter states, “patients who are in need of more nursing care are receiving less care in shorter periods of time; hospitals are competing for ‘paying patients’ at the risk of closing less profitable, but equally needed services; and, in fact, hospitals are closing or being sold as a result of financial vulnerabilities.”

The commenter cites to a study, comparing nurse-to-patient staffing levels and patient mortality among the states of California, New Jersey and Pennsylvania, which found higher surgical patient mortality in both New Jersey and Pennsylvania due to higher patient workloads for nurses in these states. The commenter states, “there are numerous other studies that link patient outcomes, costly readmission and complication rates, nursing ‘burnout’ and patient satisfaction to nursing staff ratios.” The commenter, while acknowledging the poor economic climate and the financial fragility of hospitals, states that the healthcare workers the commenter represents have witnessed the costs of unsafe staffing, including costs due to medical errors and patient complications, re-admissions and nursing turnover. The commenter identifies the following “five overarching problems” with N.J.A.C. 8:43G-17: the rules have not kept up with changing patient needs, higher acuity levels and technology; do not specify staffing numbers for medical/surgical and emergency departments; do not require “real-time” corrections of inadequate staffing; do not involve front-line caregivers in staffing need assessment or

contingency planning; and do not have the enforcement capacity needed to ensure patient safety at all times. The commenter acknowledges that the chapter establishes specific ratios for critical care areas, but considers these specific ratios have not kept pace with patient acuity and need improvement.

The commenter asks the Department to require hospitals to: “Establish joint staffing committees comprised of front-line nurses and health professionals to assess and develop safe staffing guidelines for all units; Develop methods to revise and maintain safe nurse staffing levels; Formulate contingency plans for addressing periods of increased census; Require proper orientation before floating RNs from unit to unit; [and] Provide adequate ancillary and support services for patient care.” The commenter recommends, given the proposed amendments eliminating biennial inspection, that the Department strengthen provisions related to complaint investigations by providing access to complete information on complaint investigations to staff, the collective bargaining agent, and/or the patient filing the complaint. The commenter believes that complainants should be able to: accompany the inspector wherever possible; receive timely reports on the outcome of the inspection prior to the filing of corrective action plans; receive copies of the corrective action plans and follow-up Department actions; and comment on Department actions. Finally, the commenter requests that the Department establish a working group comprised of stakeholders to examine changes that would improve staffing ratios in existing specialty areas and develop ratios for medical/surgical and emergency departments. (4, 16)

9. COMMENT: Commenters who are healthcare professionals describe their various experiences with short staffing that had adverse effects on patient care. Examples of adverse effects that the commenters describe include delayed treatment, medication errors or medication delays, and inattention leading to unnecessary injury. Commenters express concern for the absence of adequate nurse-to-patient staffing reflective of patient acuity. Commenters claim that hospital management have failed to respond appropriate to their complaints regarding insufficient staffing levels and/or expertise given patient acuity. A commenter states that short staffing forms have been sent to the Department, but that the commenter has “yet to see a positive outcome from these well-documented complaints.” (6, 10 through 13, 17)

10. COMMENT: A commenter expresses concern over insufficient hospital nursing and support staff and expresses support for an amendment to improve nurse-to-patient “staffing levels on all units of” hospitals. (2)

RESPONSE TO COMMENTS 7 through 10: As the Department states in the proposal Summary, the proposed amendments eliminating biennial inspections would enable the Facility Survey Program to concentrate its efforts on complaint investigations at licensed health care facilities, focused hospital surveys following a complaint investigation and monitoring surveys in licensed health care facilities that declare financial difficulties or have strike activity, and that this would make the most efficient use of the Facility Survey program’s limited resources and hasten responses to complaints, including those complaints regarding staffing issues. Thus, the proposed

amendments would address the issues the commenters raise as requiring the Department's corrective efforts.

The Department has authority to enforce a facility's self-directed acuity system. The Department lacks jurisdiction to determine which acuity system is appropriate for used by each facility. Many legitimate acuity systems have been proven reasonable for hospital use.

The Department reiterates the following statement from the proposal Social Impact, "Establishing rules that set minimum standards in the operation of acute care hospitals is necessary to protect public health and safety. Facilities must employ qualified patient care staff who possess specified skill levels to provide the services that patients under their care require. Hospitals must ensure continuity and coordination of health care services and keep accurate records of patient care provided. Officers and administrators of licensed acute care hospitals must appropriately direct and support acute care hospital services and provide oversight of the quality of care.... The rules proposed for readoption would continue to fulfill this need and ensure a high level of quality care, leading to improved health, safety, and overall wellness of patients receiving acute care hospital services."

Existing N.J.A.C. 8:43G proposed for readoption establishes minimum nurse-to-patient staffing ratios for a wide range of inpatient hospital units. However, general medical/surgical units pose a technical challenge to establishing appropriate minimum staffing ratios, due to the extreme variability among the illness, injury, and/or disease acuity level and attendant nursing care needs of patients admitted to those types of

units. Hence, the existing rules require hospitals to use patient acuity as one factor in developing their staffing levels each day. There is no nationally recognized standard for assessing acuity and converting that to a staffing ratio. Existing N.J.A.C. 8:43G-17A implements a statute that requires hospitals to post nurse-to-patient staffing information on a daily basis in all general hospitals, instead of requiring minimum staffing ratios. The fact that the statute does not direct the Department to prescribe specific staffing ratios suggests indicates a continued lack of consensus on this issue. Therefore, it would be inappropriate for the Department, and the Department declines, to establish by rule an across-the-board minimum staffing ratio.

The Department acknowledges the importance of maintaining appropriate staffing levels to assure quality health care services. The rules proposed for readoption would continue to require minimum staffing ratios for such critical areas as cardiac surgery intensive and intermediate care, N.J.A.C. 8:43G-7.5; critical care, N.J.A.C. 8:43G-9.7; intermediate care, N.J.A.C. 8:43G-9.20; normal care newborn nursery, N.J.A.C. 8:43G-19.6; intermediate care nursery, N.J.A.C. 8:43G-19.17; intensive care nursery, N.J.A.C. 8:43G-19.18; pediatric intensive care, N.J.A.C. 8:43G-22.16; and psychiatric services, N.J.A.C. 8:43G-26.5. In virtually all cases, however, these critical care services are to adjust nurse staffing based on patient acuity levels because, while the rules listed above provide minimum standards, ultimately, service directors must exercise clinical judgment with respect to staffing levels to ensure patient safety.

A commenter is incorrect in stating that in the past the Department has posted facilities' plans of correction on the Department's website. In the past, the Department

has posted notices of enforcement actions on its website, and it plans to do so in the future. As the commenter acknowledges, much of the information relating to facility deficiencies and plans of correction are available to the public upon submission of requests for government records.

The existing rules proposed for readoption already require hospitals to establish joint staffing committees, develop methods to maintain safe nursing staffing levels, formulate contingency plans, provide proper orientation for floating nurses and provide adequate ancillary care are already established in the licensing rules. Rather than prescribe strict ratios without regard to the particular situation of each hospital, the rules proposed for readoption require each hospital to achieve patient safety through its establishment of staffing levels and contingency plans, while at the same time allowing each hospital to determine and establish those levels and plans within the context of its particular organizational structure and clinical circumstances.

As stated above, the elimination of biennial inspections will enable the Department to expand its licensing oversight by providing more timely complaint investigations, including those involving nurse staffing and staff posting requirements. However, unlike routine facility inspections in which Department surveyors can share potential deficiencies with the facility at the completion of a visit, complaint investigations often contain confidential patient information that Department surveyors cannot share with either facility staff or “collective bargaining agents” during the investigative process.



With respect to some commenters' request that the Department establish a stakeholder working group to consider the development of rulemaking to improve staffing ratios in existing specialty areas, and develop ratios for medical/surgical and emergency departments, the Department has consistently sought the advice and expertise of stakeholders in every major evaluation of its licensing standards and will continue to do so in the future.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

#### **N.J.A.C. 8:43G-2**

11. COMMENT: A commenter supports the proposed amendments at N.J.A.C. 8:43G-2, stating that they "will lead to reducing unnecessary inspections, which will enable providers to focus more thoroughly on delivering care." (18)

RESPONSE: The Department acknowledges the commenter's support of the proposed amendments at N.J.A.C. 8:43G-2.

#### **N.J.A.C. 8:43G-2.2**

12. COMMENT: A commenter opposes "the proposed amendment at N.J.A.C. 8:43G-2.2(g)1 to establish that the biennial facility inspection fee is in addition to the annual licensure fee for that year." The commenter states, "when hospitals throughout the [State] struggle to survive one of the nation's worst economic downturns

and the continued budget crisis in New Jersey, [the commenter opposes] any additional fees for the hospital to absorb.” (14)

RESPONSE: The commenter appears to perceive incorrectly the biennial inspection fee at N.J.A.C. 8:43G-2.2(g)1 as a new fee being added for the first time in this rulemaking. N.J.S.A. 26:2H-12b(1) establishes, and, at the same time, limits, the Department’s authority to impose annual licensing and biennial inspection fees on health care facilities, while also prohibiting any other form of inspection fee. The proposed amendment at N.J.A.C. 8:43G-2.2(g) would inform hospitals (1) that the existing biennial inspection fee would continue and (2) how the Department will collect it for both new and renewal licensing activities. As the proposal Summary states, the proposed amendment at existing N.J.A.C. 8:43G-2.2(g) would “establish the purpose of the biennial facility inspection fee and that the fee would be assessed every other year at licensure renewal instead of being assessed in the year a facility is inspected.” The proposed amendment would not change the amount of the existing biennial inspection fee.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

#### **N.J.A.C. 8:43G-4.1**

13. COMMENT: Commenters express support of the proposed amendment at N.J.A.C. 8:43G-4.1(a)23 addressing visitation rights of patients’ civil union and domestic partners. (20)

RESPONSE: The Department acknowledges the commenters' support of the proposed amendment.

**N.J.A.C. 8:43G-5.2**

14. COMMENT: With respect to proposed N.J.A.C. 8:43G-2.4(3) [*sic*, *probably means 2.4(e)*] and N.J.A.C. 8:43G-2.5(f)1, a commenter requests "clarification about site visits only to investigate complaints, to ensure this is not interpreted as a contradiction to N.J.A.C. 8:43G-2. (18)

RESPONSE: The Department believes clarification about site visits to be unnecessary. N.J.A.C. 8:43G-2.4(e) as proposed for amendment would reserve the Department's right, in the interest of patient safety, to "make survey visits to a hospital at any time." While site visits may be to investigate complaints, the Department's authority to conduct site visits extends beyond complaint investigations.

Proposed new N.J.A.C. 8:43G-2.5(f)1 would establish that the Department might conduct a hospital survey in the event a hospital has not had a timely on-site inspection by the certifying or accrediting body and an inspection is not scheduled within 30 days of the hospital license expiration. The proposed amendment would ensure that there is not a prolonged period between on-site hospital inspections.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

**N.J.A.C. 8:43G-5.2**

15. COMMENT: A commenter expresses support of the proposed amendment at N.J.A.C. 8:43G-5.2 requiring hospitals to prohibit smoking therein. (18)

RESPONSE: The Department acknowledges the commenter's support of the proposed amendments.

#### **N.J.A.C. 8:43G-7 and 7A**

16. COMMENT: A commenter expresses support of the Statewide stroke registry and the proposed amendments at N.J.A.C. 8:43G-7A, and states its belief that the registry will become a valuable tool in improving the treatment of stroke in New Jersey. The commenter expresses interest in working with the Department in a future effort to update N.J.A.C. 8:43G-7 governing cardiac services. (9)

RESPONSE: The Department acknowledges the commenter's support of the Statewide stroke registry and the proposed amendments and acknowledges the commenter's interest in participating in stakeholder and constituent working groups the Department may convene in future to evaluate and update N.J.A.C. 8:43G-7.

#### **N.J.A.C. 8:43G-7A.2**

Commenters request that the Department include advanced practice nurses (APNs) within the proposed new definition of the term "hospitalists" at N.J.A.C. 8:43G-7A.2. The commenters state, "APNs are both [State] and nationally certified as acute care, family, and adult nurse practitioners work increasingly in stroke care and those

providers, like their physician colleagues, have special competence in caring for stroke patients, qualifying them to be an integral member of the acute stroke team.” (20, 30)

RESPONSE: As the Department has frequently stated in previous rulemaking actions affecting N.J.A.C. 8:43G-7A, and in response to previous comments, above, adding the designation, “stroke center,” to a facility’s license carries with it the responsibility to provide personnel who have higher levels of training and expertise in stroke care than that provided in hospitals that have not achieved licensure designation as stroke centers. In developing the clinical components of N.J.A.C. 8:43G-7A that the Stroke Center Act does not specifically prescribe in detail, the Department convened, and consulted with, a Stroke Advisory Panel, comprised of New Jersey clinical experts in stroke diagnosis and treatment. The existing rules establishing requirements for stroke teams reflect the recommendations of the Stroke Advisory Panel. Therefore, the Department will make no change on adoption in response to the comment, but will share the comment with the Department’s Stroke Advisory Panel.

#### **N.J.A.C. 8:43G-7A.2 and 7A.4**

17. COMMENT: A commenter suggests that the Department add the word, “either” within the definitions of “hospitalist” and “stroke team” for both comprehensive and primary stroke centers to indicate the Board Certification/Eligibility in any of the categories listed as opposed to all sub-specialties. (1)

RESPONSE: As the Department has frequently stated in previous rulemaking actions affecting N.J.A.C. 8:43G-7A, and in response to previous comments, above,

adding the designation, “stroke center,” to a facility’s license carries with it the responsibility to provide personnel who have higher levels of training and expertise in stroke care than that provided in hospitals that have not achieved licensure designation as stroke centers. In developing the clinical components of N.J.A.C. 8:43G-7A that the Stroke Center Act does not specifically prescribe in detail, the Department convened, and consulted with, a Stroke Advisory Panel, comprised of New Jersey clinical experts in stroke diagnosis and treatment. The existing rules establishing requirements for stroke teams reflect the recommendations of the Stroke Advisory Panel. Therefore, the Department will make no change on adoption in response to the comment, but will share the comment with the Department’s Stroke Advisory Panel.

#### **N.J.A.C. 8:43G-7A.4**

18. COMMENT: A commenter expresses support of the proposed amendment at N.J.A.C. 8:43G-7A.4(b), adding hospitalists to the list of professionals who are authorized to serve on an acute stroke team and adding critical care, family medicine, general internal medicine, general surgery and anesthesiology to the list of specializations in which a team member must hold board certification or board eligibility to serve on a team. The commenter views the proposed amendments as representing a movement towards parity between licensure requirements for physicians to work in emergency rooms and licensure requirements for emergency physicians to serve on acute stroke teams. (19)

RESPONSE: The Department acknowledges the commenter's support of the proposed amendment.

### **N.J.A.C. 8:43G-7A.7**

19. COMMENT: With respect to the time within which stroke team physicians would need to satisfy the mandatory eight hours of training in the area of cerebrovascular disease pursuant to N.J.A.C. 8:43G-7A.7(c), a commenter urges the Department to change the requirement from “yearly” to “every two years,” in consideration of the extensive continuing education requirements that emergency room physicians are already required to meet to maintain their credentialing. (19)

RESPONSE: As the Department has frequently stated in previous rulemaking actions affecting N.J.A.C. 8:43G-7A, and in response to previous comments, above, adding the designation, “stroke center,” to a facility’s license carries with it the responsibility to provide personnel who have higher levels of training and expertise in stroke care than that provided in hospitals that have not achieved licensure designation as stroke centers. In developing the clinical components of N.J.A.C. 8:43G-7A that the Stroke Center Act does not specifically prescribe in detail, the Department convened, and consulted with, a Stroke Advisory Panel, comprised of New Jersey clinical experts in stroke diagnosis and treatment. The existing rules establishing requirements for stroke teams reflect the recommendations of the Stroke Advisory Panel. Therefore, the Department will make no change on adoption in response to the comment, but will share the comment with the Department’s Stroke Advisory Panel.

### **N.J.A.C. 8:43G-12.7**



20. COMMENT: A commenter states that N.J.A.C. 8:43G-12.7(j) establishes an important requirement that must be supported by sufficient funding to ensure adequate qualified staff to comply with the required timeframes. The commenter inquires whether this section would apply to psychiatric emergency patients, and, if so, the commenter recommends that the Department add the following as an exception: “The patient is awaiting placement at an appropriate short-term care facility where such a bed is currently unavailable.” (18)

RESPONSE: N.J.A.C. 8:43G-12.7(j) requires a hospital to either transfer an emergency patient to an appropriate inpatient facility or discharge the patient to home, no later than 12 hours after initial treatment or stabilization. The subsection applies to all patients, including psychiatric patients. The existing exceptions to this requirement include placing the patient under clinical observation, which would apply in the situation presented in the exception language that the commenter suggests.

The Department acknowledges a general need to update and expand the psychiatric service licensing requirements set forth in the chapter and is actively working with the Division of Mental Health Services in the Department of Human Services to develop rulemaking to address the implied concerns that the commenter expresses.

The Department acknowledges that funding of psychiatric inpatient services, and health care services in general, continues to be a significant problem throughout the health care system. However, the Department proposes no amendments to this section in this rulemaking. Therefore, readoption of N.J.A.C. 8:43G-12.7(j) would impose no additional compliance costs and would maintain existing funding burdens.

Subject to the foregoing, the Department will make no change on adoption in response to the comment.

**N.J.A.C. 8:43G-19.11**

21. COMMENT: Commenters questioned the appropriateness of the requirement at N.J.A.C. 8:43G-19.11(d) that a patient begin electronic fetal heart monitoring and undergo a vaginal examination by a physician with obstetric privileges, a certified midwife, or an advanced practice nurse in accordance with hospital bylaws, within one hour of administration of oxytocics. Both commenters recommend the removal of this requirement in the interest of patient safety because of the increased risk of infection and to more closely reflect modern obstetrical care. A commenter stated that the need for an additional vaginal exam prior to the initiation of pitocin, for example, could lead to delays in the administration of pitocin if an acceptable licensed professional is unavailable, and that the existing requirement is a problem at teaching institutions with resident physicians, since residents “are learning to care for patients and will do examinations to monitor the progress of labor. However, if it is decided that pitocin will be administered, then the attending of record needs to repeat the examination.” (3, 8)

RESPONSE: As the Department has indicated in responses to previous comments, above, licensing rules are minimum standards. Ultimately, professionals must exercise clinical judgment in the interest of ensuring patient safety. N.J.A.C. 8:43G-2.8 establishes a process by which facilities can apply for waivers to remedy the

problem the commenters describe. In an emergency, when there is a clinical necessity to divert from licensing requirements, clinicians should follow best practices and document the clinical necessity of doing so in the medical record to avoid licensing deficiency. N.J.A.C. 8:43G-19.11(d) requires a vaginal exam and the initiation of electronic fetal monitoring. The deletion of the requirement as requested by the commenters would be substantive as to require additional public notice and comment, and therefore would be an inappropriate change to make on adoption. Given the clinical nature of this comment and the absence of any other comment regarding this requirement, the Department will include this subsection in its review with stakeholders and clinicians for consideration of the development of rulemaking on the issue.

Subject to the foregoing, the Department will make no change on adoption in response to the comments.

22. COMMENT: Commenters expressed support of the proposed amendment at N.J.A.C. 8:43G-20.2 addressing the detection and control of mycobacterium tuberculosis. (20)

RESPONSE: The Department acknowledges the commenters' support of the proposed amendment.

### **Economic Impact**

23. COMMENT: A commenter states that the Economic Impact provides "another example of the need for sufficient funding for hospitals to meet expenses incurred in complying with these rules."

RESPONSE: The Department agrees that funding of health care services is an important component in the delivery of quality health care services. The Economic Impact addresses the ways the rules proposed for readoption and the proposed amendments provide facilities flexibility to conserve resources and to reduce duplication, overlap and fragmentation of services while ensuring that patient receive necessary services and quality care. The Department will make no change on adoption in response to the comment.

24. COMMENT: A commenter states, “The [Department] should ensure truth and transparency to the public so that only people who have medical degrees could use the term ‘doctor’ in clinical health-care settings. Identifying name tags should boldly identify the nature of one’s degree. The public expect that in a health care situation, anyone who introduces herself or himself as a doctor does in fact have a medical degree, and not a doctor does in fact have a medical degree, and not a doctorate in an allied health field.” (84)

RESPONSE: The commenter’s request, that the Department require persons holding a degree with the title, “doctor,” within it to wear nametags in “clinical health-care settings” upon interaction with the public, exceeds the scope of the proposed rulemaking. The Department will make no change on adoption in response to the comment, but will refer the comment for review by stakeholders for consideration of the development of rulemaking on the issue in the context of the standards applicable to all licensed healthcare facilities at N.J.A.C. 8:43E.

## Summary of Public Comments and Agency Responses (Part Two):

The Department received comments on the proposed readoption with amendments of N.J.A.C. 8:43G-6 from the following individuals:

1. Aileen Armstrong, M.D., Morristown, NJ
2. Patrick A. Armstrong, M.D., Morristown, NJ
3. David Avella, M.D., Cherry Hill, NJ
4. John V. Azzariti, Jr., M.D., Saddle River, NJ
5. Manal Basilious, M.D., Raafat Beshara, M.D., Anthony Co, M.D., Susan Dashow, D.O., Cung Dinh, M.D., Emad Ghabious, M.D., Michael Gordon, M.D., President, Prashant Kulkarni, M.D., Stan Li, M.D., Marina Markos, M.D., Israel Sanchez, M.D., Andrew Spiteri, M.D., Boris Spodik, D.O., Benjamin Suaco, M.D., and Annette Zwick, M.D., Hamilton Anesthesia Associates, PC, Hamilton, NJ
6. Mordechai Bermann, M.D., Associate Professor of Anesthesiology, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, and Chair, Department of Anesthesia, Southern Ocean County Hospital, Manahawkin, NJ
7. Peter Bockmeyer, RN, BSN, SRNA, Brooklyn, NY
8. Noah J. Borris, SRNA, Staten Island, NY
9. James G. Bravyak, D.O., Marlton, NJ
10. Patricia M. Browne, M.D., Shamong, NJ, Past President, New Jersey State Society of Anesthesiologists, Clinical Associate Professor,

University of Pennsylvania, and Medical Director, Surgery Center,  
Voorhees Division, Children's Hospital of Philadelphia, Voorhees,  
NJ

11. Elizabeth S. Bussard, M.D., Ringoes, NJ
12. Natividad M. Caguicla-Cruz, M.D., Boonton, NJ
13. Bonnie M. Carcione, CRNA, APN, Trenton, NJ
14. Paul J. Carniol, M.D., President, New Jersey Chapter, American College  
of Surgeons, Morristown, NJ
15. Christina W. Chin, M.D., Warren, NJ
16. Oliver Choo, M.D., New Brunswick, NJ
17. Darleen Chyu, MSN, APN-C, Adult Health Nurse Practitioner
18. Darrick Chyu, M.D., Anesthesiology Resident, University of Medicine and  
Dentistry of New Jersey, New Brunswick, NJ
19. Richard J. Claps, M.D., President, Morris County Medical Society,  
Morristown, NJ
20. Dale L. Cohen, M.D., Summit, NJ
21. Alan M. Crosta, Jr., M.D., Randolph, NJ
22. Mary Cullen-Drill, DNP, APN-C, Psychiatry, Upper Montclair, NJ
23. Deirdre Ryan Davis, CRNA, APN/Anesthesia, Forked River, NJ
24. Ruth Davis, RN, MSN, APN, Brick, NJ
25. Linda M. DeLamar, APN, CRNA, MSN, MS, MAJ, USAFR, Retired, Mount  
Laurel, NJ

26. Howard W. Denenberg, M.D., East Brunswick, NJ
27. Robert A. De Simone, M.D., Morris Anesthesia Group, Parsippany, NJ
28. Joseph DeStefano, M.D., Chair, New Jersey Section, The American Congress of Obstetricians and Gynecologists, Parsippany, NJ
29. Jim Dieterle, Senior State Director, Sy Larson, State President, and Patrica Kelmar, AARP New Jersey, Princeton, NJ
30. Ms Linda Dietz, Chester, NJ
31. Jim Doran, APN/CRNA, MS, Chief Nurse Anesthetist, Department of Anesthesiology, New Jersey Medical School, University of Medicine and Dentistry of New Jersey, Newark, NJ
32. JoAnn Dower, Vice President, Surgical Services, Virtua Health, Marlton, NJ
33. Lawrence Downs, Esq., General Counsel, and Clark Martin, Medical Society of New Jersey, Lawrenceville, NJ
34. Glenn Dragon, M.D., Chair, Department of Anesthesiology, Underwood Memorial Hospital, Woodbury, NJ
35. Edward Eaton, M.D., and Chad Itzkovich, M.D., Synergy Anesthesia, Morris Plains, NJ
36. Stanislav Erenburg, SRNA, Brooklyn, NY
37. Michael Flashburg, M.D., Medical Director, Cranmer Ambulatory Surgicenter, Monmouth Medical Center, Long Branch, NJ
38. David A. Garfunkel, M.D., Closter, NJ

39. Bernie Gerard, Jr., Vice President, Health Professionals and Allied Employees, AFT, AFL-CIO, Emerson, NJ
40. Judy R. Gerardis, M.D., President, New Jersey Obstetrical and Gynecological Society, Parsippany, NJ
41. Chris Giberson, RN, MSN, CRNA, APN/Anesthesia, Somerdale, NJ
42. Steven Ginsberg, M.D., Bridgewater, NJ
43. Barry Gleimer, D.O., President, Orthopaedic Surgeons of New Jersey, Trenton, NJ
44. Michael E. Goldberg, M.D., Department of Anesthesiology, Director of the Operating Room, Cooper University Hospital, Professor of Anesthesiology, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, Camden, NJ
45. Clare Golden, CRNA, DNP, Newton, NJ
46. Michael S. Gordon, M.D., Chair, Department of Anesthesia, Robert Wood Johnson University Hospital at Hamilton, Hamilton Anesthesia Associates, PC, Hamilton, NJ
47. William J. Greeley, M.D., M.B.A., Professor and Chair, Anesthesiologist-in-Chief, Department of Anesthesiology and Critical Care Medicine, The Children's Hospital of Philadelphia, Philadelphia, PA
48. Joy Grimes, RN, BSN, CCRN-CSC, Jersey City, NJ
49. Davida Grossman, M.D., West Jersey Anesthesia Associates, Cherry Hill, NJ



50. Robert Y. Gumnit, M.D., Cherry Hill, NJ
51. Jianhua Guo, M.D., PhD, Clinical Assistant Professor of Anesthesiology, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, and Staff Anesthesiologist, Southern Ocean County Hospital, Manahawkin, NJ
52. Xiaoyang Guo, Livingston, NJ
53. Jonathan D. Halevy, M.D., Cherry Hill, NJ
54. Alexander A. Hannenberg, M.D., President, American Society of Anesthesiologists, Washington, DC
55. George J. Hebert, MA, RN, Executive Director, New Jersey Board of Nursing, Division of Consumer Affairs, New Jersey Office of the Attorney General, Trenton, NJ
56. Linda Higger, APN-C, CRNA, Basking Ridge, NJ
57. Rick Higger, President, Valiance Partners, Inc, Bernardsville, NJ
58. Maggie M. Ho, D.O., Parsippany, NJ
59. Christine W. Hunter, M.D., Associate Professor and Chair, Department of Anesthesia, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, New Brunswick, NJ
60. Richard Iannacone, D.O., Ho-Ho-Kus, NJ
61. Theresa Impedulgia, M.D., President, Vascular Society of New Jersey, Trenton, NJ
62. Jonathan D. Jaffe, D.O., Blackwood, NJ

63. Dory Jewelewicz, M.D., MPH, Morris Anesthesia, Parsippany, NJ
64. Paul Jordan, M.D., President, State Board of Medical Examiners, Division  
of Consumer Affairs, New Jersey Office of the Attorney General,  
Trenton, NJ
65. Frances E. Kasarda, M.D., Medford, NJ
66. Yasmeen Khan, M.D., The Valley Hospital, Ridgewood, NJ
67. John Jude Klein, D.O., East Hanover, NJ
68. Frank J. Knoll, M.D., Cherry Hill, NJ
69. David Konigsberg, M.D., President, Bergen County Medical Society, River  
Edge, NJ, and Trustee, Medical Society of New Jersey, Princeton,  
NJ
70. Patrick Konitzer, M.D., Vineland, NJ
71. Jonatha Kraidin, M.D., Associate Professor of Anesthesia, Chief, Section  
of Thoracic Anesthesia, Robert Wood Johnson Medical School,  
University of Medicine and Dentistry of New Jersey
72. James Ku, M.D., Hillsborough, NJ
73. Michael Landolfi, D.O., President, The New Jersey Academy of  
Ophthalmology, Trenton, NJ
74. Kenneth C. Liao, M.D., MBA, Morris Anesthesiology Group, PA,  
Morristown, NJ
75. James B. Loftus, M.D., Harvey Cedars, NJ
76. Antonio Luciano, APN/Anesthesia, Manalapan, NJ

77. Jonathan Lustgarten, M.D., President, New Jersey Neurological Society,  
West Long Branch, NJ
78. Jeffrey R. Lynch, M.D., Medford, NJ
79. Jeffrey B. Magnes, M.D., Short Hills, NJ
80. Meshell Mansor, APN-C, Nurse Practitioner Professional Resources,  
Turnersville, NJ
81. Harout Mekhjian, M.D., Paterson, NJ
82. Howard Mendel, M.D., Staff Anesthesiologist, Virtua Memorial Hospital,  
Mount Holly, NJ
83. Audrey Meyers, President and CEO, The Valley Hospital, Ridgewood, NJ
84. Kenneth I. Mirsky, M.D., Westfield, NJ
85. T. Deborah Montemurno, M.D., Bergen Anesthesia Group, Wyckoff, NJ
86. Roger Moore, M.D., Chair Emeritus, Department of Anesthesiology,  
Deborah Heart and Lung Center, Past President, New Jersey State  
Society of Anesthesiologists, Past President, Society of  
Cardiovascular Anesthesiologists, and Immediate Past President,  
American Society of Anesthesiologists, Browns Mills, NJ
87. Kathleen Morgan, M.D., Woolwich Township, NJ
88. Ervin Moss, M.D., individually and in his capacity as Executive Medical  
Director, New Jersey State Society of Anesthesiologists,  
Parsippany, NJ
89. Peter Nagy, M.D., Ridgewood, NJ

90. Khan Nguyen, M.D., Holmdel, NJ
91. Thomas Nicholas, M.D., Interim Chair, Department of Anesthesia, Jersey Shore University Medical Center, Neptune, NJ
92. George Olechowski, M.D., Randolph, NJ
93. A. Sahani Panjwani, M.D., Princeton, NJ
94. Enrique Pantin, M.D., Associate Professor of Anesthesiology, Division of Cardiac Anesthesia, Head Section of Pediatric Anesthesia, Head Section of Intraoperative Echocardiography, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, New Brunswick, NJ
95. James Petrowski, CRNA, Sewell, NJ
96. Igor Pikus, M.D., Morris Anesthesia Group, Parsippany, NJ
97. Leon Pirak, M.D., Chairman, Department of Anesthesiology, Trinitas Regional Medical Center, Elizabeth, NJ, and Clinical Assistant Professor of Medicine, Seton Hall University, South Orange, NJ
98. Rex Ponnudurai, M.D., President, New Jersey State Society of Anesthesiologists, Roseland, NJ
99. Helen A. Raleigh, PhD, Suffern, NY
100. Cynthia M. Reichman, M.D., Moorestown, NJ
101. Grace M. Reilly, RN, MSN, APN, Brick, NJ
102. Marisabel Reyes, SRNA, RN, Brooklyn, NY

103. Stephen G. Rice, M.D., PhD, MPH, FAAP, President, New Jersey Chapter, American Academy of Pediatrics, Hamilton, NJ
104. Michael J. Richardson, M.D., Medical Director, Internal, Quality, and Government Relations, Vice-Chief, Obstetrical Anesthesia, Saint Peter's University Hospital, New Brunswick, NJ
105. Angela Richman, APN/Anesthesia, Clayton, NJ
106. Joel Rock, D.O., MBA, Chair, Department of Anesthesia, JFK Medical Center, James Street Anesthesia Associates, Edison, NJ
107. Héctor Rodriguez, M.D., The Valley Hospital, Ridgewood, NJ
108. Melissa Rubin, MS, APN, Chair, Scholarship and Awards Committee, Forum of Nurses in Advanced Practice, New Jersey State Nurses Association, Monroe, NJ
109. Alma L. Saravia, Esq., Flaster Greenberg, Cherry Hill, NJ, on behalf of the New Jersey Association of Nurse Anesthetists, Mount Laurel, NJ
110. Nancy Schultz, CRNA, MS, Sparta, NJ
111. Bertram H. Shapiro, M.D., Retired, Livingston, NJ
112. Matthew Shatz, M.D., Towaco, NJ
113. Horngfu Shiau, M.D., Montville, NJ
114. Ronald A. Shore, D.O., Wyckoff, NJ
115. Leslie Shrem, M.D., Mendham, NJ
116. Louis Siciliano, M.D., Cedar Run, NJ

117. Monique Simmons-Romano, MSN, APN-C, Developmental Disabilities  
Health Alliance, Inc., Hamilton, NJ
118. Gary Smotrich, M.D., FACS, President, New Jersey Society of Plastic  
Surgeons, Trenton, NJ
119. Karen M. Sobrepena, CRNA, Brigantine, NJ
120. Al Solina, M.D., Professor and Vice Chair, Chief, Division of Cardiac  
Anesthesia, Robert Wood Johnson Medical School, University of  
Medicine and Dentistry of New Jersey, New Brunswick, NJ
121. Deanna Sperling, MAS, RN, CNA, BC, President, Organization of Nurse  
Executives, Princeton, NJ
122. Nancy E. Staats, M.D., Colts Neck, NJ
123. Dan Stabile, M.D., Freehold, NJ
124. Bruce Tang, M.D., PhD, Towaco, NJ
125. Celeste Telfeyan, D.O., Englewood Cliffs, NJ
126. Jay M. Tandler, M.D., Livingston, NJ
127. Sharon Thompson, SRNA, Newark, NJ
128. Mitchell Tobin, Senior Director, State Government Affairs, American  
Association of Nurse Anesthetists, Park Ridge, IL
129. Michael Umanoff, M.D., Director of Pain Medicine, St. Joseph's Hospital  
and Medical Center, Paterson, NJ
130. Peter Vaclavik, M.D., Chief of Pediatric Anesthesiology, Jersey Shore  
University Medical Center, Neptune, NJ

131. Ioan B. Voca, M.D., Caldwell, NJ
132. Zev Wachtel, M.D., New Jersey Anesthesia Group, P.A., Lyndhurst, NJ
133. Craig Wagner, D.O., Haddonfield, NJ
134. Daniel D. Wambold, M.D., Franklin Lakes, NJ
135. Changzheng Wang, M.D., Morris Anesthesia Group, Parsippany, NJ
136. Ms Betty Wilson, Burlington, NJ
137. The Honorable Barbara W. Wright, RN, PhD, FAAN, Health Policy  
Consultant, Cranbury, NJ
138. Mei Lene Wu, BSN, RNC, M.D.
139. Zhaomin Yang, M.D., Department of Anesthesiology, Jersey Shore  
University Medical Center, Neptune, NJ
140. Sulin Yao, M.D., Linwood, NJ
141. Altan Yenicay, M.D., New York, NY
142. Jill S. Young, D.O., Chair and CEO, Morris Anesthesia Group, Parsippany,  
NJ
143. Andrew Zembrzuski, M.D., Sparta, NJ
144. Henry Zhou, M.D., PhD, Saddle River, NJ
145. Jie Zhou, M.D., Morris Anesthesia Group, Parsippany, NJ
146. Each of the following submitted letters containing identical comments:  
  
Sajad Bilgrami, D.O., Medford, NJ  
  
Davida Grossman, M.D., Cherry Hill, NJ  
  
Todd Hermann, M.D., Mount Laurel, NJ

Heng Jiang, M.D., Mount Laurel, NJ

Frances Kasarda, M.D., Medford, NJ

Stacy Lewin, M.D., Cherry Hill, NJ

Brian McIntyre, D.O., Medford, NJ

Bruce Miller, M.D., Medford, NJ

Enrico Pace, M.D., Voorhees, NJ

Andre M. Pierre, M.D., Sicklerville, NJ

Donna Pisera, M.D., Marlton, NJ

147. Each of the following submitted letters containing identical comments:

Matthew Berberich, M.D., Neptune, NJ

Stephanie Berberich, PharmD, RPh, Neptune, NJ

Christina Breen, PharmD, RPh, Doylestown, PA

Ms Arlene Toth, Little Falls, NJ

Ms Leonora Toth, Denville, NJ

Mr. Steve Toth, Denville, NJ

Mr. Steven Sam Toth, DMD, Brigantine, NJ

148. Each of the following submitted letters containing identical comments:

Craig Feder, M.D., The Anesthesia Pain Treatment Center, Hamilton  
Township, NJ

Gary Loren, M.D., The Anesthesia Pain Treatment Center, Hamilton  
Township, NJ

149. Each of the following submitted letters containing identical comments:



Shaul Cohen, M.D., Professor, Department of Anesthesia, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, New Brunswick, NJ

John T. Denny, M.D., Associate Professor, Department of Anesthesia, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, New Brunswick, NJ

Maria Negron-Gonzalez, M.D., Assistant Professor, Department of Anesthesia, Robert Wood Johnson Medical School, University of Medicine and Dentistry of New Jersey, New Brunswick, NJ

150. Each of the following submitted letters containing identical comments:

Hak Cha, M.D., Princeton Junction, NJ

Nicholas Chiu, M.D., Princeton, NJ

John Coccaro, M.D., Forked River, NJ

Stephen D'Angelo, M.D., Toms River, NJ

Charles Farrell, M.D., Wall, NJ

Sang Kim, M.D., Toms River, NJ

Morris Ligorski, M.D., Toms River, NJ

Renny Lin, M.D., Toms River, NJ

Frank Mara, M.D., President, American Association of Anesthesiologist Specialists, Toms River, NJ

Dong Park, M.D., Toms River, NJ

Yung Park, M.D., Toms River, NJ

Vu Pham, M.D., Manasquan, NJ

Mark Silverstein, M.D., Toms River, NJ

Hasmukh Tank, M.D., Freehold, NJ

Eric Villafane, M.D., Red Bank, NJ

Yanina Zabrodina, M.D., Brielle, NJ

151. Each of the following submitted letters containing identical comments:

Ann Higgins, M.D., Columbia Pain Management, Union, NJ

Julia Iwamasa, M.D., Columbia Pain Management, Union, NJ

Alex Klashtorny, M.D., Columbia Pain Management, Union, NJ

Gregory Lawler, D.O., Columbia Pain Management, Union, NJ

Ross Peet, M.D., Columbia Pain Management, Union, NJ

Thomas P. Ragukonis, M.D., Bergen Pain Management, Paramus, NJ

Thomas P. Ragukonis, M.D., Columbia Anesthesia Associates, Paramus,  
NJ

Thomas P. Ragukonis, M.D., Endoscopic Anesthesia, L.L.C., Paramus,  
NJ

Thomas P. Ragukonis, M.D., Essex Anesthesia, L.L.C., Paramus, NJ

Thomas P. Ragukonis, M.D., MSTR Practice Management, Paramus, NJ

Jodi Reiss, M.D., Columbia Pain Management, Union, NJ

Mark R. Schoenfeld, M.D., Columbia Anesthesia Associates, Paramus, NJ

Mark R. Schoenfeld, M.D., Endoscopic Anesthesia, L.L.C., Paramus, NJ

Stefan Trnovsky, M.D., Columbia Pain Management, Union, NJ

Yourie Yim, M.D., Columbia Pain Management, Union, NJ

152. Each of the following submitted letters containing identical comments:

Mr. Richard Doran, Toms River, NJ

Mr. Frank X. Kraft, Bridgewater, NJ

153. Each of the following submitted letters containing identical comments:

Frank Acchione, MS, APN/Anesthesia, Marlton, NJ

Sharon Baker Witzel, CRNA, APN, MSN, North Caldwell, NJ

Kareem Bosede, APN/Anesthesia, Hillsdale, NJ

Thuy T. Dao, CRNA, Princeton Junction, NJ

Jessica Deiter, BS, MS, CRNA, Lumberton, NJ

Bruce DeLarso, CRNA, APN, Marlton, NJ

Edward J denBraven, CRNA, Voorhees, NJ

Dan Denesevich, APN, Egg Harbor Township, NJ

Robert deVente, CRNA, Barnegat, NJ

Ogelue Ezeife-Ugorji, CRNA, MSN, APN, Berlin, NJ

Donna Fisher, APN, CRNA, Sewell, NJ

Timothy Guito, CRNA, Mount Laurel, NJ

Jenna Hegge, CRNA, MSN, APN, Mullica Hill, NJ

Linda Higger, APN-C, CRNA, Basking Ridge, NJ

Alice M. Jurski, CRNA, MSN, Assistant Program Director, Nurse

Anesthesia Program, Our Lady of Lourdes Medical Center,

Camden, NJ

Herman Lenthe, CRNA, Somerdale, NJ

Grigoriy Levin, CRNA, MS, ARNP, Cherry Hill, NJ

Margaret A. Liddy, APN/Anesthesia, Monroe Township, NJ

Patricia Manderbaugh, CRNA, APN, MS, Haddonfield, NJ

Cynthai C. Mason, APN/Anesthesia, Northfield, NJ

Dennis J. McFadden, CRNA, Glenside, PA

Kenneth M. McHale, APN, CRNA, Beachwood, NJ

Michael P. McMillen, CRNA, Maple Glen, PA

Karen D. Meisberger, APN/Anesthesia, Robbinsville, NJ

Corbin Mills, APN, CRNA, CFNP, Philadelphia, PA

Mark Molinari, CRNA, Mullica Hill, NJ

Rosauro Monasterial, CRNA, Mount Royal, NJ

Edward L. Morrison, APN, CRNA, Monroeville, NJ

Catherine Morse, APN, CRNA, EdD, MSN, Program Director, Nurse  
Anesthesia Program, Our Lady of Lourdes Medical Center,  
Camden, NJ

Gregory J. Myslinski, CRNA, APN, MSN, Mullica Hill, NJ

Patricia L. Norton, APN, CRNA, Petersburg, NJ

Blanche Parent, CRNA, APN, Pilesgrove, NJ

Carole Quiroz, CRNA, Montclair, NJ

Margaret Rathbun, APN, CRNA, Long Valley, NJ

Jennifer Ridgeway, APN/Anesthesia, Westville, NJ

Eddie Russell, APN-C/Anesthesia, Mount Laurel, NJ

Barbara Keegan Shackford, APN/Anesthesia, CRNA, Harrington Park, NJ

Matthew Scott Sheedy, CRNA, APN, Medford, NJ

Michael L. Soule, APN, CRNA, Colts Neck, NJ

Sanford Stark, PhD, APN/Anesthesia, Woodbury, NJ

Jacqueline VanGelderren, CRNA, Holmdel, NJ

Michael W. Walls, APN/Anesthesia, Northfield, NJ

154. Each of the following submitted letters containing identical comments:

Theresa M. Campo, DNP, APN, NP-C, CEN, Ocean View, NJ

Valerie T. Cotter, DrNP, APN, C, FAANP, Haddonfield, NJ

Kathleen Stilling Burkhart, RN, MSN, APN, Adult/Geriatric Nurse

Practitioner, New Jersey Representative, American Academy of  
Nurse Practitioners, Edison, NJ

Erin M. Glospie, RN, BSN, PCCN, Vice President, Communications,

Region 4, New Jersey State Nurses Association, Hamilton, NJ

Tara N. Heagele, RN, BSN, PCCN, EMT-Basic, Member-at-Large Mercer

County, Region 4, New Jersey State Nurses Association, Hamilton,  
NJ

Kristine M. Olson, RN, MS, APN, Lambertville, NJ

Nancy L. Risser, MN, APN, Adult Nurse Practitioner, Basking Ridge, NJ

Lauro Lucio Rocha, APN, Livingston, NJ

Kathleen Russell-Babin, MSN, RN, NEA-BC, ACNS-BC, Millstone  
Township, NJ

Carolyn T. Torre, RN, MA, APN, Director, Regulatory Affairs, New Jersey  
State Nurses Association, Trenton, NJ

Ann Tritak, RN, BSN, MA, EdD, Dean and Professor of Nursing, School of  
Nursing, Saint Peter's College, Jersey City, NJ

Lois Weissman, MS, APN, C, Washington Township, NJ

155. Each of the following submitted letters containing identical comments:

Frances Adamo, RN, SRNA, Oxford, PA

Eunice Aguda, RN, SRNA Wayne, NJ

Laura L. Ardizzone, DNP, CRNA, Director, Clinical Education, Nurse  
Anesthesia Program, School of Nursing, Columbia University, New  
York, NY

Natalya Baketova, RN, SRNA, Brooklyn, NY

Bruno Beja-Umukoro, RN, SRNA, Irvington, NJ

Jessica Benetatos, RN, SRNA, Long Island City, NY

Peter Bockmeyer, RN, SRNA, Brooklyn, NY

Noah Borris, RN, SRNA, Staten Island, NY

Nancy Burnett, BSN, RN, SRNA, Brooklyn, NY

Jason R. Calomadre, RN, SRNA, New York, NY

Mary Caputo, RN, SRNA, Staten Island, NY

Daniel Chang, RN, SRNA, Bayside, NY

Dora Jean Charles, RN, SRNA, Spring Field Gardens, NY

Sandra Choi, RN, SRNA, Amityville, NY

Lauren Costabile-Lopez, RN, SRNA, Yonkers, NY

Suzanne Cottle, RN, CCRN, SRNA, Ramsey, NJ

Caroline B. Cruz, RN, SRNA, Paramus, NJ

Lauren Cuccia, RN, SRNA, Staten Island, NY

Jillian Cullinane, RN, SRNA, West New York, NJ

Timothy Daly, RN, SRNA, Franklin Square, NY

Sara A. Danziger, RN, SRNA, Passaic, NJ

Barbara Delbago, RN, SRNA, Ozone Park, NY

William M. Enlow, DNP, CRNA, Assistant Program Director, Program in  
Nurse Anesthesia, School of Nursing, Columbia University, New  
York, NY

Gabriel Elias, RN, SRNA, New York, NY

Stanislav Erenburg, RN, SRNA, Brooklyn, NY

Eileen Y. Evanina, MS, CRNA, Director, Program in Nurse Anesthesia,  
School of Nursing, Columbia University, New York, NY

Michael Finkenbine, RN, SRNA, New York, NY

Jhenelle Forbes, RN, SRNA, Clifton, NJ

Girlyn Garcia, RN, SRNA, Jersey City, NJ

Pamela Glennon, RN, CCRN, SRNA, Staten Island, NY

Margaret Gorman, RN, SRNA, Staten Island, NY

Crystal A. Grant, RN, SRNA, Newark, NJ

Sara Greeley, RN, SRNA, Brooklyn, NY

Myrlinda Grimes, RN, SRNA, Jersey City, NJ

Xiaoling Griswold, RN, SRNA, Scarsdale, NJ

Matthew Ingles, RN, SRNA, Wheatley, NY

Megan Johnston, RN, SRNA, Cherry Hill, NJ

Meagen Judge, RN, SRNA, Fair Lawn, NJ

Clare Keaveney, RN, SRNA, West Nyack, NY

Shannon Kelly, RN, CCRN, SRNA, Sewell, NJ

Hinda Kozlovsky, RN, SRNA, Bronx, NY

Kathleen Logan, RN, CCRN, SRNA, New York, NY

Brian Lui, RN, SRNA, Brooklyn, NY

Pauline Maietta, RN, SRNA, New York, NY

Maureen P. McCartney, RN, SRNA Neptune City, NJ

Emma O'Connor, RN, SRNA, Lodi, NJ

Maria Parchesky, RN, SRNA, Larchmont, NY

Jubilee Po, RN, SRNA, Syosset, NY

Jineen Redden-Huff, RN, SRNA, BSN, BC, CCRN, Newark, DE

Carrie Reinhart, RN, SRNA, BSN, MS, Wernersville, PA

Marisabel Reyes, RN, SRNA, Brooklyn, NY

Kara Roberts, RN, SRNA, Basking Ridge, NJ

Martina Robinson, RN, SRNA, Englewood, NJ



Luis B. Rodriguez, RN, SRNA, Jackson, NJ  
Rebecca Rogan, RN, SRNA, Iselin, NJ  
Keshia Romelus, RN, SRNA, Rosedale, NY  
Jacqueline P. Root, RN, SRNA, Conshohocken, PA  
Veronica Sanchez, RN, BSN, BA, SRNA, Drexel Hill, PA  
Kristi J. Scacco, RN, SRNA, Brick, NJ  
William Schwalm, RN, SRNA, Ringwood, NJ  
Genny Shmushkevich, RN, SRNA, Staten Island, NY  
Manjju A. Thadathil, RN, SRNA, Westwood, NJ  
Peturah Thompson, RN, SRNA, Mount Vernon, NY  
Sharon Thompson, RN, SRNA, Valley Stream, NY  
Jason Tolton, RN, SRNA, Wilmington, DE  
Jennifer M. Venafra, RN, SRNA, Doylestown, PA  
Jean P. Vieira, RN, SRNA, Wayne, NJ  
Angela Vires, RN, SRNA, Ocean, NJ  
Rheana Watts, RN, SRNA, Narberth, PA  
Thomas Zimmerman, RN, SRNA, East Windsor, NJ

156. The Honorable Joseph F. Vitale, Senator, New Jersey Senate,  
Woodbridge, NJ
157. James Armstrong, M.D., Chief of Anesthesia, Our Lady of Lourdes  
Medical Center and Medical Director, Our Lady of Lourdes School  
of Nurse Anesthesia, NJ

158. Leah Baron, M.D., Chief, Department of Anesthesia, Virtua Memorial Hospital, Mount Holly, NJ
159. Pat Barnett, RN, Esq., CEO, New Jersey State Nurses Association
160. Tracy Caftlenal, APN/anesthesia, NJ
161. Rosemary Cappelli, RN, USAFR—Retired, NJ
162. Linda M. DeMar, APN/anesthesia, Mount Laurel, NJ
163. Maryann Donohue, RN, President, New Jersey State Nurses Association
164. Felix Fianko, M.D., Jersey Shore Medical Center, NJ
165. Jamie Eisenberg, APN/anesthesia, President, New Jersey Association of Nurse Anesthetists, Mount Laurel, NJ
166. Praveen Gollapudi, M.D., NJ
167. Peter Golzweig, M.D., NJ
168. Douglas Jaffee, RN, M.D., New Jersey State Society of Anesthesiologists
169. Russell Lynn, APN/anesthesia, Associate Program Director, University of Pennsylvania Nurse Anesthesia Program, NJ
170. Howard Mandell, M.D., Virtua Memorial Hospital, Mount Holly, NJ
171. Durgesh Mankikar, M.D., Past President, New Jersey State Society of Anesthesiologists, NJ
172. Bob Mirynowski, APN/anesthesia, Board Member, New Jersey Association of Nurse Anesthetists, Mount Laurel, NJ
173. Mark Nemiroff, M.D., NJ

174. Robert Sharon, APN/anesthesia, President-elect, New Jersey Association of Nurse Anesthetists, Mount Laurel, NJ

175. Catherine A. Ainora, FACHE, Senior Vice President, System Development/Planning, Saint Barnabas Health Care System, West Orange, NJ

The numbers in parentheses after each comment identify the respective commenters listed above.

**Deletion of references to CRNAs and addition of references to APNs/anesthesia**

1. COMMENT: A commenter “recognizes the important role that APNs play in the healthcare delivery system,” while asserting that, “expanding the scope of practice to include the administration of all types of anesthesia while at the same time ... eliminating the requirement that supervising physicians be present ... may place patients at risk.” The commenter “encourages the Department to reconsider its position and proceed with caution with respect to imposing comprehensive changes to the standards that govern the supervision and staff qualifications of persons administering anesthesia.” (83)

2. COMMENT: Commenters oppose the proposed amendments at N.J.A.C. 8:43G-6 eliminating references to physician supervision of CRNAs and adding references to APNs/anesthesia subject to joint protocols, and assert the following:

The elimination of physician supervision would be detrimental and would compromise patient care and pose a threat to patient safety.

The New Jersey Supreme Court has determined that the practice of anesthesia constitutes the practice of medicine.

In contrast to APNs/anesthesia, anesthesiologists: undergo more education; have greater technical skills, clinical expertise, and medical training that prepares them to think critically and make medical judgments, particularly in life-threatening situations; and are required during their training to handle high-risk patients, participate in fellowships, and have exposure to caring for the sickest of patients requiring close supervision and multiple interventions.

The educational and examination requirements of APNs/anesthesia are far less demanding in duration and complexity as compared to anesthesiologists.

Anesthesiologists have subspecialty certification in several areas, such as nephrology, neurology, pulmonology, cardiology, critical care medicine, obstetrics, and pediatrics, whereas APNs/anesthesia do not.

Supervision by an anesthesiologist better protects patients when complications occur. The medical judgment of an anesthesiologist is crucial during all stages of anesthesia procedures but is lifesaving at critical junctions.

Patient surveys show that patients want physicians to provide them with anesthesia, and not nurses.

Studies that find no difference in outcomes between anesthesiologists and APNs/anesthesia are fundamentally flawed and scientifically unreliable.

States that have eliminated the physician supervision requirement are in rural areas where anesthesiologists are unavailable. New Jersey has no rural underserved hospitals.

36 states preclude independent practice for APNs/anesthesia, including the neighboring states of Pennsylvania, Delaware, and New York. Some patients may elect to obtain care in these other states if the Department were to adopt the proposed amendments.

“Granting equal privileges to doctors and nurses will discourage young people from taking rigorous medical training ... necessary for ... patients’ safety.”

Federal Medicare reimbursement rules require physician supervision of CRNAs, and pay the same for the services of anesthesiologists as for the services of CRNAs, thus providing the State no cost savings by acknowledging APNs/anesthesia as independent practitioners.

The anesthesia care team approach, rather than the administration of anesthesia by unsupervised APNs/anesthesia, is the safest affordable means of providing anesthesia services to patients.

Peer-reviewed studies demonstrate that involving anesthesiologists or other anesthesia physicians in operations improves patient outcomes.

Changing the title of “CRNAs” to “APNs/anesthesia” does not change their skills, capabilities or need for physician supervision in hospital operating rooms.

(While not all of the following commenters made all of the points listed above, the significant overlap among them makes it impracticable to isolate and attribute individual

comments to individual commenters: 1 through 7, 9 through 12, 14 through 21, 26 through 28, 34 and 35, 37 and 38, 40, 42 through 44, 46 and 47, 49 through 54, 58 through 63, 65 through 75, 77 through 79, 81 and 82, 84 through 87, 89 through 94, 96 through 98, 100, 104, 106 and 107, 111 through 116, 118, 120, 122 through 126, 129 through 135, 138 through 151, 157 and 158. 164, 166 through 168, 170 and 171, 173)

3. COMMENT: A commenter opposes “the removal of physician supervision of” CRNAs as being “counter to the goal to provide the best quality of care while ensuring patient safety,” that anesthesiologists are essential to meeting this goal, and that physician supervision is “a critical resource for quality patient care within surgical services.” The commenter states, “the critical times are the induction of anesthesia or the initiation of a regional anesthesia procedure and then during reversal of the anesthesia” and that physicians as supervisors during this time are essential for safe outcomes because of their education and experience. (32)

4. COMMENT: A commenter requests that the Department “retain the supervision requirement,” and asserts that the proposed amendments “would not be in the best interests of” the people of New Jersey and would contravene the opinion of the Supreme Court of New Jersey, “which held in 2005 that the ‘administration of anesthesia is, in fact, the practice of medicine.’” The commenter states, “Supervision represents a higher standard of care and is consistent with the role of nurse anesthetists ....” The commenter states that authorizing a “nurse anesthetist, now defined as an ‘APN/anesthesia’ ... to practice in collaboration with an anesthesiologist, rather than under [anesthesiologist] supervision, would severely jeopardize patient

safety” because during the administration of anesthesia, “a patient’s condition can adversely change within seconds.” The commenter describes the differences in training between anesthesiologists and nurse anesthetists as making “the necessity of retaining the physician supervision requirement for patient safety reasons ... evident.” The commenter describes the physician supervision requirement as “imperative,” because, “As the population ages, anesthesia providers will need to be qualified in treating highest risk patients with complex medical illnesses.”

The commenter states, “Since the inception of Medicare [and] Medicaid in 1965, [Federal] law has required supervision of nurse anesthetists by a physician (anesthesiologist or operating surgeon).” (54)

RESPONSE TO COMMENTS 1 THROUGH 4: The commenters’ factual and legal assertions appear to object to the action of the New Jersey Board of Nursing (“BON”) eliminating references to physician supervision of CRNAs and establishing standards for APNs/anesthesia subject to joint protocols. The commenters’ concerns are matters for consideration by the professional licensing boards of the Division of Consumer Affairs of the Department of Law and Public Safety in determining the appropriate authorized scopes of practice of the professionals they respectively license and/or certify. Thus, the commenters concerns exceed the scope of the proposed rulemaking.

The BON and the State Board of Medical Examiners (“BME”) of the Professional Boards Section of the Division of Consumer Affairs within the Department of Law and Public Safety, rather than the Department, hold jurisdiction to establish the minimum

training and experiential requirements, and the authorized scopes of practice, of the professionals they respectively license and/or certify. The proposed amendments reflect an effort to make the hospital licensing rules consistent with the rules of the BON and the BME. The Department has neither the intention nor the authority to expand or narrow the authorized scope of practice of professionals under the jurisdiction of those boards.

It appears that the commenters fail to take into consideration the proposed amendments at N.J.A.C. 8:43G-6.2. N.J.A.C. 8:43G-6.2(a), as proposed for amendment, would require hospital policies and procedures for anesthesia services to be “reviewed at least annually, and revised as needed to ensure the safety of patients during the administration and conduct of, and emergence from, anesthesia.” Moreover, proposed new N.J.A.C. 8:43G-6.2(b) would require an anesthesia department to be “[administered] under the overall supervision of a qualified physician director; and [operated] in accordance with applicable laws governing the scope of practice of professionals performing anesthesia services within the anesthesia department.”

The Department's authority to regulate certain health care services and health care facilities originates in the Health Care Facility Planning Act (Act), as set forth at N.J.S.A. 26:2H. Pursuant to the Act, the Department promulgated the Hospital Licensing Rules at N.J.A.C. 8:43G to set minimum standards for hospital operations. Specifically, under the administrative rules at N.J.A.C. 8:43G-5, 6 and 16, hospitals must ensure the safe and effective administration of anesthesia services through their policies, procedures and by-laws.



In responding to the petition for rulemaking, the Department was obliged to consider how its licensing rules related to the changes in the BON rules governing APN practice. The resulting determination was that the rules at N.J.A.C. 8:43G-6 improperly referenced CRNAs after the BON eliminated the title of CRNA.

Existing Federal regulations governing hospital operations under CMS Conditions of Participation, particularly at 42 CFR § 482.52, require the supervision of “non-physician providers” of anesthesia services. The proposed amendments would have no impact on the applicability of that requirement.

One of the Department's primary responsibilities is oversight of patient safety in hospitals. Anesthesia services are one of the more complex procedures provided in hospital settings. Towards that end, the proposed amendments at N.J.A.C. 8:43G-6 would ensure patient safety without duplicating Federal standards. Pursuant to N.J.A.C. 8:43G-5, hospitals demonstrate compliance with State licensing standards in this regard through the governing body's oversight of hospital operations and in its communication with the hospital's Medical Staff Organization (MSO).

Specifically, the MSO's credentialing and privileging activities pursuant to N.J.A.C. 8:43G-16 are central to the conferring of hospital privileges, which would include the provision of anesthesia services by APNs/anesthesia. During this process, a committee within the MSO reviews information supporting the sufficiency of an applicant's education, training, experience, and clinical competency relative to the requested privileges and makes recommendations to the hospital's governing body. In this way, the hospital assures that all patient care provided at the facility is performed

under a grant of privileges from the governing body to practitioners working within the scope of those privileges. In this system of checks and balances, the hospital ensures that only qualified practitioners may provide health care services at the hospital, as delineated by the individual privileges it grants.

The proposed amendments at N.J.A.C. 8:43G-6 are consistent with its authority to regulate health care facilities as they correctly establish a standard for safe and effective anesthesia services under existing mechanisms of hospital operations, while streamlining the regulatory process, consistent with the Common Sense Principles concerning regulatory burdens outlined in Executive Order 2 and objectives set forth by Governor's Red Tape Review Group in Executive Order 3 .

While New Jersey statutes are silent on the manner and extent of anesthesia services in hospital settings, the BON commented on the matter in its 2008 APN rule adoption redesignating CRNAs as APNs/anesthesia, asserting that those rules would not prohibit physician supervision requirements imposed by other regulatory bodies. The BON therein stated that its adoption of those rules, “does not negate or cast doubt on the appropriateness of requirements imposed by other entities on the individuals and facilities they regulate.” 40 N.J.R. 3729, 3731 at Response to Comment 17 (June 16, 2008). See also 40 N.J.R. at 3733 at Response to Comment 36, wherein the BON stated, “The Board’s rules cannot alter the regulatory requirements imposed by [other] entities on individuals and facilities that they regulate and do not call into question the appropriateness of those requirements”; and Response to Comment 37, wherein the

Board stated, “To the extent that questions ... arise, or practice issues ... engender confusion, the [BON] will reach out the [BME] to coordinate.”

42 CFR § 482.52 requires physician supervision of “non-physician professionals” providing anesthesia services in hospitals unless the Governor of the State elects to opt out of this requirement under the conditions set forth in the regulation. The Department, as the agent for the Federal government, is responsible to monitor hospital compliance with this condition of participation in the Federal Medicare program. N.J.A.C. 8:43E-2.1. Thus, the proposed amendments at N.J.A.C. 8:43G-6 neither exceed nor conflict with Federal standards, and do not prohibit hospitals from complying with Federal laws and regulations related to scope of practice and licensing. In fact, the Department facilitates compliance through its survey and oversight activities.

Thus, the proposed amendments accomplish the Department’s mandate to establish standards for hospital operations consistent with State law, while not overlapping Federal requirements governing the supervision of “non-physician professionals” providing anesthesia services in hospital settings.

In their assertion that the administration of anesthesia is the practice of medicine, the commenters appear to rely on the opinion of the New Jersey Supreme Court in *New Jersey Association of Nurse Anesthetists, Inc. v. New Jersey State Board of Medical Examiners*, 183 N.J. 605 (2005), which affirmed the decision of the New Jersey Superior Court, Appellate Division, in the same matter at 372 N.J. Super. 554 (App. Div. 2004). In that case, the professional organization that represents APNs/anesthesia challenged rules of the BME that require physician supervision of certified registered

nurse anesthetists during the performance of anesthesia in physicians' offices. These opinions do not appear to be dispositive of the Department's determination to remove references to physician supervision of CRNAs from the hospital licensing rules, and to acknowledge the BON's establishment of the APN/anesthesia title and the associated joint protocol practice standards.

Both the Supreme Court and the Appellate Division, in their opinions, were careful to narrow the applicability of their holdings to the specific rule under challenge, that is, a rule requiring physician supervision of CRNAs in physicians' offices. See 372 *N.J. Super.* at 563, and see 183 *N.J.* at 608, note 1, wherein the Supreme Court specifically notes that the rules under challenge were "not applicable in hospitals or ambulatory care settings." See also 183 *N.J.* at 611.

Both courts agreed, moreover, that a regulation establishing whether or not to require supervision was an effort to regulate a profession (a function the courts found under the facts of that case to rest within the jurisdiction of the BME), stating, "the point remains that the BME is not regulating the nursing profession, but rather the physician who offer anesthesia in an office setting." 183 *N.J.* at 611, quoting 372 *N.J. Super.* at 566. This suggests that it would be inappropriate for the Department to engage in rulemaking regulating the scope of practice of a professional under the jurisdiction of one of the professional boards in a rule addressing facility licensure.

In short, the opinion in *New Jersey Association of Nurse Anesthetists, Inc. v. New Jersey State Board of Medical Examiners* does not address the issues the proposed amendments to N.J.A.C. 8:43G-6 raise.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

5. COMMENT: A commenter objects to proposed amendments at N.J.A.C. 8:6, and recommends that the Department “‘carve out’ the practice of anesthesia by non-physician providers so that they will continue to practice with physician supervision, not by looser collaborative practice agreements,” because “during anesthesia, as opposed to other specialties, medical evaluations, decisions and physical actions may need to be taken within seconds or minutes to prevent serious complications.” (84)

6. COMMENT: A commenter describes the regulatory history of the hospital licensing rules and the role of the New Jersey State Society of Anesthesiologists” (NJSSA) in their development over the years. The commenter opposes the proposed amendments removing references to physician supervision without the Department having consulted with the NJSSA.

The commenter quotes from a February 2009 letter from the Director of the Division of Consumer Affairs in which the then-Director states, “The Division is not aware of any movement to amend statutes or regulations to remove the supervision requirements. While the [BON] has recently adopted regulations that allow the certification of advanced practice nurses specializing in anesthesia, the regulations in no way remove supervision requirements imposed by other state entities. The [BON] very clearly articulated this position in its notice of adoption at 40 N.J.R. 3729(a): [The Director’s letter thereupon quotes from the Response of the BON to Comment 17 in the cited notice of adoption].” (86)

RESPONSE TO COMMENTS 5 AND 6: The commenter is incorrect in asserting that the Department failed to consult with the New Jersey State Society of Anesthesiologists in the development of the proposed amendments addressing physician supervision of APNs/anesthesia. More than one Commissioner and other Department representatives have met and consulted with NJSSA representatives over the years with respect to the relationship between, and respective roles of, anesthesiologists and APNs/anesthesia in licensed healthcare facilities, as this issue is not newly controversial. The Department has been aware of the position of the NJSSA with respect to these matters. The Department's willingness to obtain the benefit of the opinions and experiences of different constituents when it is developing rulemaking does not necessitate that the Department conduct that rulemaking in a manner that reflects agreement with those opinions, particularly when State law requires the Department to reach a different result.

The Department of Health and Senior Services is a coequal department of State government with the Department of Law and Public Safety. Therefore, absent a statute or court decision to the contrary, the extant rules of each Department have full force and effect. The rules of the Department of Health and Senior Services in effect as of the issuance of the Director's letter require physician supervision of CRNAs. Thus, the Director's letter was accurate when issued and continues to be accurate.

The proposed amendments reflect an effort by the Department to defer to the authority of the BON and the BME to determine the scopes of practice of the professions over which they respectively have jurisdiction. In view of the 2008

amendments to the rules of the BON, and upon the request of the petitioner for rulemaking, the Department was obliged to reevaluate its existing rules. Upon the conclusion of that review, the Department determined that its existing hospital licensing rules were no longer appropriate in that they improperly impose requirements for CRNAs in conflict with the BON's elimination of that title, and fail to reflect the BON's articulation of the practice of APNs/anesthesia pursuant to a joint protocol.

The Department defers to the BME and the BON in its interpretation of its enabling statute, and declines to maintain existing or establish new facility licensure rules that would contravene applicable law and/or undermine or contravene the expertise of the BME or the BON in their respective exercise of authority to determine the scope of practice of the professionals under its jurisdiction. Therefore, the Department is obliged to remove references to physician supervision of the title, "CRNA," and is without authority to "carve out" the practice of APNs/anesthesia. The Department instead defers to the BON and the BME to establish the training and experiential requirements necessary to obtain licensure and/or certification from those boards, and to articulate the required content of joint protocols to address the commenters' concerns with respect to patient safety. This is consistent with the Department's rulemaking approach with respect to professionals licensed by the professional boards in the Department's other rules at Title 8.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

7. COMMENT: A commenter that “opposes the removal of physician supervision,” quotes from the “Guidelines for the Pediatric Perioperative Anesthesia Environment” (“Guidelines”), developed and published by the Anesthesiology Section of the American Academy of Pediatrics (citations omitted), as requiring “Anesthesia care for pediatric patients [to] be provided or supervised by anesthesiologists with clinical privileges” and requiring anesthesiologists “providing or directly supervising the anesthesia care of patients ... at increased anesthesia risk” to be “graduates of an accredited pediatric anesthesiology fellowship training program or its equivalent or have documented demonstrated historical and continuous competence in the care of such patients.” The commenter states, “Providing safe and effective anesthesia care to children presents unique challenges, [encourages] delivery of care only by highly qualified individuals to this vulnerable population,” and requests the “[State] to work toward ensuring the safety and quality of all pediatric health care delivered and to provide avenues for access to health care for all children.” The commenter believes “that specific policies and guidelines regarding necessary competencies for the administration of pediatric anesthesia and sedation are essential to provide effective and safe care to children in the State.” (103)

RESPONSE: The Department has always acted, and cooperated in the efforts of other State agencies, to ensure pediatric patients’ access to safe and quality healthcare.

The Department does not take issue with the Guidelines from which the commenter quotes. Those Guidelines may guide the practice of pediatric anesthesia by



pediatric anesthesiologists who elect to adhere to them, subject to applicable standards of the BME, and other anesthesiologist accrediting and credentialing authorities.

That the Guidelines require supervision of the performance of pediatric anesthesia, when it lawfully occurs, to be by an anesthesiologist with specified training does not conflict with the proposed amendments eliminating references to CRNAs and acknowledging the authority of APNs/anesthesia to practice pursuant to a joint protocol.

Moreover, proposed new N.J.A.C. 8:43G-6.2(b) would require qualified physician directors to undertake the overall supervision of hospital anesthesia departments. Hospitals that elect to adhere to the Guidelines can determine to appoint anesthesiologists who meet the eligibility criteria specified therein in the position of director of their anesthesia departments.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

### **Joint protocol requirements with respect to physician availability and presence**

8. COMMENT: The BME comments, “Although the prefatory language reflects that the Department ... consulted with the BME, the comments here reflect the BME’s concern with regard to [N.J.A.C. 8:43G-6 as proposed for readoption with amendment]. While the BME is aware that the regulatory changes adopted by the [BON] at N.J.A.C. 13:37-7.5, by which [CRNAs] have been recognized as [APNs/anesthesia], it also notes that the BON, in its response to public comments, made clear that the reclassification of CRNAs as APNs did not alter physician

obligations under N.J.A.C. 13:35-4A.1 et seq. (See 40 N.J.R. 3731 to 3740). The proposed amendments to N.J.A.C. 8:43G-[6.3(e)3] make clear that the joint protocol between an APN and a collaborating anesthesiologist 'would need to include sections governing the availability of an anesthesiologist to consult with the APN/anesthesia on-site, on call or by electronic means.' The deletion of the supervision requirement, if replaced with a meaningful standard in the joint protocol, may be appropriate in the hospital setting. The BME [is concerned] that availability of a collaborating anesthesiologist 'on call or by electronic means' is unlikely to provide the requisite safety net that the BME has felt necessary in the office setting. However described, whether as 'supervision' or through a defined joint protocol requiring anesthesiologist presence, the BME continues to be of the view that the ongoing availability of a knowledgeable, trained physician — an anesthesiologist for general and regional anesthesia or a privileged physician for conscious sedation — is an essential requirement to assure patient safety, in all settings.

N.J.A.C. 13:35-6.6 and N.J.A.C. 13:37-6.3 establish for physicians and APNs, respectively, the issues that must be addressed in a ... joint protocol, including, but not limited to, the identification of the means by which the advanced practice nurse and collaborating physician can be in direct communication, as well as a description of arrangements which will assure that the collaborating physician or peer coverage is accessible and available. While the [proposed] amendments to N.J.A.C. 8:43G[-6] provide that [APNs/anesthesia] need not be 'supervised,' as the BME interprets the language, it envisions that the joint protocol with a collaborating anesthesiologist must

address the availability of the collaborating anesthesiologist (N.J.A.C. 8:43G-6.3(e)3). [The BME reads] the requirement that the protocol address the ‘*presence* of an anesthesiologist during induction, emergence and critical change in status’ [emphasis in original comment] to reflect that the anesthesiologist must be on-site and immediately available, as is presently required under the BME [rules]. However, to the extent that the [Department] intends to countenance oversight during these critical phases through electronic means, the [existing] BME [rule] would be in conflict and, in the view of the BME, not in the public interest. [The existing] BME rule requires the physician to be ‘physically present and available to immediately diagnose and treat the patient in an emergency, without concurrent responsibilities to administer anesthesia or perform surgery, other than minor surgery.

Although [the BME presumes] that the language at N.J.A.C. 8:43G-6.3(e)3 will require the same availability that the BME requires by its rules applicable to the office setting, if that is not the intent of the [Department, the BME is] concerned that this standard is inadequate, particularly if it is extended to other health care settings. A clarification would be helpful. [The BME notes] that similar language appears in [the proposed amendments at] N.J.A.C. 8:43G-6.3(h)3 [and] (j)3 with respect to conscious sedation and minor regional blocks, [with respect to which, existing BME rules] would not mandate anesthesiologist presence.” (64)

RESPONSE: Just as the Department intends the proposed amendments at N.J.A.C. 8:43G-6 to defer to the authority of the BON to regulate the practices of the professionals under its jurisdiction, the Department likewise intends the proposed

amendments to defer to the comparable jurisdiction vested in BME. The commenter accurately notes the concurrent applicability of the rule the BME promulgated at N.J.A.C. 13:35-6.6, the “Standards for joint protocols between advanced practice nurses and collaborating physicians.” The Department inadvertently omitted to provide a cross-reference to this rule at N.J.A.C. 8:43G-6.3 to accompany the cross-references to the joint protocol rule of the BON, that is, N.J.A.C. 13:37-6.3. The Department agrees that the BME rule would apply to collaborating physicians in their execution of and compliance with joint protocols, regardless of whether N.J.A.C. 8:43G-6.3 were to cross-refer to it.

The commenter is correct with respect to its understanding of the Department’s intention related to anesthesia services in a hospital setting with respect to the concepts of the availability and presence of collaborating anesthesiologists. The commenter correctly understands N.J.A.C. 8:43G-6.3(e)3, (h)3 and (j)3 as proposed for amendment, to establish that a joint protocol between an APN/anesthesia and a collaborating anesthesiologist is to require that the anesthesiologist be available to consult electronically during the perioperative period and to be present during induction, emergency and critical change in status. The Department defers to the BME and the BON as part of these respective agencies’ exercise of jurisdiction to establish the minimum requirements of a joint protocol between the professionals they respectively license.

9. COMMENT: A commenter writes “in opposition to” the proposed amendments at N.J.A.C. 8:43G-6 because they would “remove physician supervision of

nurse anesthetists ... and require a joint protocol with APN—anesthetists to address how and when a physician will be available. [The proposed amendments] do not require a physician to be present during the administration of anesthesia. That matter is deferred to the joint protocol.

The [proposed amendments raise] patient safety concerns because [they are] unclear as to whether [an] anesthesiologist will be required to be present and what role, if any the physician will have. [This] has the potential to put patients in New Jersey at greater risk of complications. If there is a medical problem during anesthesia[,] it is safest to have both an anesthesiologist present in addition to the nurse anesthetist to deal with the problems, rather than only the nurse anesthetist. In order to optimize this safety[,] this ratio should not exceed two nurse anesthetists per supervising anesthesiologist.

[The commenter's] one and only concern remains patient safety. [The commenter recognizes] the training and skill of nurse anesthetists but in the interest of increased patient safety [believes] there should be this supervision.” (14)

10. COMMENT: A commenter states, “The sterile environment of operating rooms and many procedure rooms purposely restricts access to facilitate maintenance of the sterile environment. This, of necessity, inhibits the ready availability of in-house physicians ... should [an emergency related to the patient’s anesthesia] arise ... when every moment is critical [because] time does not permit medical personnel outside of the operating room to STOP, change into scrubs and other surgical attire, and then access the specific room where the [emergency] is occurring. [This] would leave the

patient without the support of an experienced anesthesiologist for immediate intervention and corrective action. The alternative is that anesthesiologists, not having the time to scrub and change into appropriate attire, may risk contaminating the operating room and creating a situation that may lead to patient infections.” For these reasons, the commenter urges the Department “to retain the existing requirements for anesthesiologist supervision of anesthesia services and not to [adopt the proposed amendments].” (32)

11. COMMENT: With respect to the proposed amendments at N.J.A.C. 8:43G-6.3(e)3, (h)3 and (j)3, a commenter states that the Department “should specifically and authoritatively set forth requirements of physician presence and supervision during the administration of anesthesia. Leaving the terms of physician presence and supervision to the terms of collaborative agreements invites inconsistency in patient care standards from hospital to hospital, even within hospitals. [The proposed amendment at N.J.A.C. 8:43G-6.3(e)3] could be read to leave to the collaborators the option of agreeing to no presence or supervision by an anesthesiologist. [Patient] care works best in a team approach with both physicians and nurse working together in the interests of the patient.... However, patient safety and good practice must be the primary focus.” (33)

12. COMMENT: A commenter states that the proposed amendments at N.J.A.C. 8:43G-6.3 would “establish too loose a requirement and thus [jeopardize] patient safety.” (84)

RESPONSE TO COMMENTS 9 THROUGH 12: As stated above in response to a previous comment, these comments relating to the “presence” of an anesthesiologist during the performance of anesthesia suggest that the proposed amendments at N.J.A.C. 8:43G-6.3(e)3, (h)3 and (j)3, describing the required content of a joint protocol, are subject to misinterpretation. Therefore, in response to the commenters’ requests for clarification, the Department will make a change on adoption to delete the phrase, “address sections governing,” and to add in its stead, the term, “require,” and to reorganize these subsections to improve readability by breaking some of the clauses into paragraphs and subparagraphs.

The Department is satisfied that this change on adoption would resolve the commenters’ apparent misinterpretation of and objection to the proposed amendment, as reflected in their comments, above. At the same time, the change would accurately reflect the Department’s intended meaning.

This change on adoption would ensure that the rule is understood to mean that a joint protocol governing anesthesia services would require an anesthesiologist to be present during induction of and emergence from anesthesia, and during critical changes in status.

The Department declines to prescribe a ratio, as one commenter requests, by which for anesthesiologists are to “supervise” APNs/anesthesia. N.J.A.C. 8:43G-6.2(b), requiring anesthesiologist supervision of anesthesia departments, would provide a mechanism for resolution of “ratio” issues.

Except as described above and in response to previous comments, the Department will make no change on adoption in response to the comments.

**Comments supportive of removing references to physician supervision of CRNAs and addition of references to APN/anesthesia**

13. COMMENT: The BON states, “The New Jersey Board of Nursing ... voted to support the proposed amendments to the Hospital Licensing Standards, deleting the supervisory requirement for Advanced Practice Nurses with a Specialty in Anesthesia. This change in language reflects an awareness of and respect for the requirement of a joint protocol with a collaborating physician for all Advanced Practice Nurses who prescribe medications and devices.” (55)

14. COMMENT: Commenters support the proposed amendment at N.J.A.C. 8:43G-6.1 establishing a definition of the term, “advanced practice nurse specializing in anesthesia” or “APN/anesthesia,” and deleting the existing definition of and references to the term, “certified registered nurse anesthetist” or “CRNA,” as being consistent with rules of the [BON]. The commenters assert that the “joint protocol has been working for over 4,000 nurse practitioners in the State, resulting in cost-effective, quality health care to the people of New Jersey” and that APNs/anesthesia would “continue to deliver the highest quality anesthesia care to the people of New Jersey.” (154)

15. COMMENT: Commenters indicate their support of the proposed amendments at N.J.A.C. 8:43G-6. (22, 24, 76)

16. COMMENT: Commenters indicate their support of the proposed amendments at N.J.A.C. 8:43G-6 and assert that the proposed amendments would



“offer a solution for cutting healthcare cost, while continuing to provide excellence in anesthesia care.” (31, 152, 155) A commenter asserts that the proposed amendments do not mean that APNs/anesthesia “would replace anesthesiologists [because] there is plenty of work available for both” and that the proposed amendments “would provide facilities with more flexibility [but] would not mandate that any individual facility change its mix of anesthesia professionals.” (56)

17. COMMENT: A commenter expresses support of the proposed amendments, and states, “Evidence has not shown that outcomes are of greater quality care as the result of supervision of APNs/Anesthesia by Anesthesiologists. There appears to be no evidence to support such a practice or public policy. [It is necessary] to continue to reduce the barriers to [the] practice [of APNs/anesthesia], and costs for care, when quality is not compromised.” (137)

18. COMMENT: Commenters indicate their support of the proposed amendments at N.J.A.C. 8:43G-6, and provide citations to research articles and studies that, the commenters assert, indicate that APNs/anesthesia “provide as high quality of care as do physicians in anesthesia, as well as care management in primary care, chronic care management, and pain management,” and that “the quality of care provided by APNs/anesthesia is at the same high level as the care provided by anesthesiologists.” The commenters assert that the existing rules, “without the proposed changes are a significant cost driver, raising a barrier to affordable care,” and cite to a research article that, the commenters assert, indicates “that the cost of healthcare is increased ... when APNs/anesthesia are supervised by any physician

compared to when APNs/anesthesia independently provide that care or when anesthesiologists directly administer ... anesthesia....” Commenters state, “there are no data to support” requiring APNs/anesthesia to be subject to physician supervision. Commenters indicate support the proposed amendments at N.J.A.C. 8:43G-6 as being “supported by recent literature related to anesthesia delivery.” Commenters assert that the existing rules, requiring physician supervision of APNs/anesthesia, improperly limit and conflict with the scope of practice of APNs/anesthesia as established by the American Nurses Association and the BON. Commenters support the joint protocol requirement for collaboration rather than supervision, and assert that “hospitals [have] the best perspective on the dynamics of their institution [and] should have the right to decide whether anesthesiologist supervision is required for safe and cost-effective health care.” (While not all of the following commenters made all of the points listed above, the significant overlap among them makes it impracticable to isolate and attribute individual comments to individual commenters: 23, 25, 29, 39, 41, 48, 56, 57, 102, 105, 108, 110, 121, 117, 119, 127, 153, 154, 158 through 163, 165, 169, 172, 174)

19. COMMENT: A commenter asserts that the New Jersey “APN Practice Act dictates collaboration with [physicians], not supervision. Currently CRNAs are singled out as the only APN group in New Jersey ... supervised by physicians.... Collaboration between anesthesiologists and CRNAs is reality in clinical practice. Supervision allows for unnecessary additional billing at the cost of the [State] and the consumer.” (7)

20. COMMENT: A commenter indicates support of the proposed amendments at N.J.A.C. 8:43G-6, and notes that APNs/anesthesia are trained to

practice “in all settings” and for all types of patients, including “pediatrics, geriatrics[,] critically ill and traumatized patients,” and notes that many “have been deployed and cared for our soldiers overseas in combat situations, without physician supervision.” The commenter notes that in New Jersey the “true working relationship [between APNs/anesthesia and anesthesiologists] has been one of collaboration not of supervision” and that the “supervision language has been a hindrance ... requiring [waiting for] the presence of an anesthesiologist to enter [operating rooms] before [the] conduct [of] certain anesthetics.” (25)

21. COMMENT: A commenter indicates support of the proposed amendments at N.J.A.C. 8:43G-6, stating that APNs/anesthesia “are licensed by [their] national board and the [BON] to provide all aspects of anesthesia, including induction and emergence[,] do so in [operating rooms] across the [State] and [Country] on a daily basis, with a track record of safety [and] are often the sole anesthesia providers physically present with ... patients, responsible for their lives, safety, and comfort. [The Department should] recognize [the] legal right of [APNs/anesthesia] to practice autonomously.” (36)

22. COMMENT: A commenter indicates support of the proposed amendments at N.J.A.C. 8:43G-6, stating, “The attributes that contribute to safe anesthesia care, [that is,] vigilance, meticulous habits, careful attention to detail and basic intelligence are not exclusive to any set of providers. The level of anesthesiologist involvement in any case should be dictated by the complexity of the case and

determined by the two collaborating professionals, not arbitrarily and blindly mandated by regulation.” (45)

23. COMMENT: A commenter comments in the form of a brief, with appendices, in support of the proposed amendments, in which the commenter asserts the following points:

No other state in the nation mandates anesthesiologist supervision of APNs/anesthesia.

The BON certifies certified registered nurse anesthetists as APNs/anesthesia.

Advanced practice nurses do not practice under physician supervision.

A joint protocol for prescribing or ordering medication does not contemplate physician supervision.

New empirical studies confirm that there is no difference in outcomes as among APNs/anesthesia and anesthesiologists.

The shortage of nurses that exists in New Jersey intensifies the need for APNs/anesthesia.

Assertions by the New Jersey State Society of Anesthesiologists lack legal and factual support.

The proposed amendments comport with the Administrative Procedure Act’s rulemaking requirements.

The adoption of the proposed amendments is consistent with Governor Christie’s efforts to eliminate unnecessary “red tape.” (109)

24. COMMENT: A commenter comments in the form of a brief, with appendices, in support of the proposed amendments in which the commenter asserts the following points:

New Jersey is the only state in the country that requires APNs/anesthesia to be supervised by anesthesiologists, and the Department has never produced evidence justifying this requirement.

The Department's rules should be consistent with State law, and the proposed amendments would be consistent with the Nurse Practice Act and the BON rules.

Requiring anesthesiologist supervision of APNs/anesthesia is unnecessary. The evidence is overwhelming that patient outcome is the same regardless of whether the anesthesia provider is an APN/anesthesia or an anesthesiologist. The national professional association for APNs/anesthesia defines the scope of practice of the profession as not requiring anesthesiologist supervision.

New Jerseyans have not benefited from the anesthesiologist supervision requirement as it is not cost-effective and inasmuch as research studies have found no significant differences in rates of anesthesia complications or mortality between APNs/anesthesia and anesthesiologists or among anesthesia delivery models for anesthesia that involve one or the other or both of these types of professionals.

The largest voluntary hospital accrediting agency in the United States has explicitly stated that its standards do not require hospitals to use the services of anesthesiologists in any capacity. (128)

25. COMMENT: Commenters support the proposed amendments at N.J.A.C. 8:43G-6. Based on personal experiences with APNs/anesthesia as a patient and as a family member of other patients, a commenter states, “the requirement for supervision of APNs/anesthesia ... will ultimately jeopardize [this profession].” (30) Commenters assert that the proposed amendments would reduce medical costs. (30, 57)

26. COMMENT: Commenters express support of the proposed amendments at N.J.A.C. 8:43G-6, and describe the training of APNs/anesthesia, noting the “extremely competitive” admissions standards for, and the “grueling” training provided in, APN/anesthesia programs and that training an APN/anesthesia costs “just one sixth of what it costs to train a physician anesthesiologist.” (76, 102)

27. COMMENT: Commenters express support of the proposed amendments at N.J.A.C. 8:43G-6, and assert that the proposed amendments “would reflect current practice, not change it,” and therefore, concerns over the term “supervision” are a matter of semantics.” (101, 110, 119)

28. COMMENT: A commenter expresses support of the proposed amendments at N.J.A.C. 8:43G-6, and asserts that APNs/anesthesia “provide most of the direct anesthesia care in the United States .... The commenter asserts that the proposed amendments would result in care at the same level of safety, lower costs to patients, and reduce health care insurance costs. (95)

29. COMMENT: A commenter states, “Like so many Americans, I am alarmed by escalating medical costs and a health care system that seems stagnant when almost everyone agrees that changes are needed. The task of changing such a

huge and entrenched system is daunting to be sure, but a good strategy, it seems, would be to start with small changes. Many small changes can eventuate in a large impact. [The proposed amendments at N.J.A.C. 8:43G-6 are] an opportunity to implement on such change. [Enabling APNs/anesthesia] to provide anesthesia for standard procedures, independently of anesthesiologists, would substantially reduce surgical costs. In practice, many of these well-trained [APNs/anesthesia] are already providing these services, but the legal requirement of a physician's signature significantly increases cost. As a [sextagenarian] grandmother ..., I ... expect to need more medical care in the future, than [I have] needed up until now.... I urge you to allow hospitals to determine the most effective and efficient ways of providing quality anesthesia for ... patients, while taking measures to safely reduce cost." (99)

30. COMMENT: A commenter states, "I am a senior citizen.... With the growing senior population and its increased need for medical care, the availability of care from appropriately trained professionals is a concern. [The proposed amendments at N.J.A.C. 8:43G-6 are] a major step forward toward assuring that every patient in New Jersey will receive the anesthesia services and care they need when they need it. ... Your foresight and leadership will benefit New Jersey's patients." (136)

RESPONSE TO COMMENTS 13 THROUGH 30: The Department acknowledges the commenters' support of the proposed amendments.

The BON and the BME, rather than the Department, hold jurisdiction to establish the authorized scopes of practice of the professionals they respectively license and/or certify, and the factual and legal assertions the commenters assert are within their

purview. Therefore, the commenters may wish to address those assertions to those Boards for consideration.

The proposed amendments reflect an effort to make the hospital licensing rules consistent with the rules of the BON and the BME as to the authorized scope of practice of the professionals under their respective jurisdictions. In proposing amendments to N.J.A.C. 8:43G-6, the Department neither intends, nor claims to hold the authority, to expand or narrow the authorized scope of practice of professionals under those Boards' respective jurisdictions.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

31. COMMENT: Senator Vitale commends the Commissioner and staff of the Department of Health and Senior Services for their work to negotiate the proposed hospital licensing standards, and states that the proposed amendments would appropriately modify the standards for hospital anesthesia services by clarifying that APNs/anesthesia would practice within the full scope of their licensing act.

The commenter states, "As a primary sponsor of the law that enhanced the scope of practice for all advanced practice nurses, let me be clear that the spirit and intent of the law was to make sure that all advanced practice nurses, no matter their specialty, have the autonomy to practice as professionals who are required to have joint protocol with collaborating with a physician for prescribing purposes only. Advanced practice nurses do not function under the supervision of physicians in New Jersey. It is both necessary and appropriate for the proposed [amendments] updating hospital



licensing standards to accurately reflect the spirit and intent of New Jersey's law defining the scope and practice of all advanced practice nurses, including those that specialize in anesthesia.

Joint protocols ensure that advanced practice nurses and physicians with whom they collaborate discuss how they will work well together. They ensure that both parties have the opportunity and flexibility to determine the level of consultation they must follow when initiating or refilling a drug or device, including those used in the discipline of anesthesia.

I want to make it absolutely clear that the joint protocol does not mean one party supervises another. It is a plan of how a team of health professionals determines together how to safely and effectively serve patients.

Effective care teams lead to better patient outcomes and important decision use of resources. The Institute of Medicine recommends that states eliminate barriers keeping nurses from practicing to the full extent of their professional education. This includes eliminating barriers that keep advanced practice nurses from practicing independently.

The Board of Directors of the AARP agrees by releasing the following statement in March of 2010: 'Current state nurse practicing acts and accompanying rules should be interpreted and/or amended where necessary to allow advanced practice nurses to fully and independently practice as defined by their education and certification.'

As many of you know, it's been my [goal] that health care in New Jersey and its health care system become accessible to everyone who lives here. As that happens,

as the health care system becomes more accessible to more New Jersey residents, the need to collaborate care among multiple providers will become even more and more important.

Developing all functioning teams will be critical to meeting the future needs of patients. These teams must make the best use of each member's education, skill and expertise to achieve optimum patient outcome and to ensure resources are used efficiently. Quite honestly, we will fail in our accessibility goal without the very best use of every member of the health care team....

The New Jersey Legislature has taken steps to ensure that nurses are able to practice in accordance with their professional training and education, however, system-wide changes are still needed to capture the full economic value of nurses.

Modifying of the hospital licensing standards and removing any supervision of the physician for the delivery of anesthesia in hospitals is one such needed change and [the commenter applauds] the Department. New Jersey's progress to recognize the competency of advanced practice nurses by expanding their scope of practice has had a positive impact on patient care and patient outcomes.

These policies do not diminish the role of physicians in delivering health care. Instead, they foster collaborative working relationships rather than hierarchy. They replace the silos of health care with interdisciplinary teams. As a result of this improved communication from health care disciplines, New Jersey residents will [realize improvements in] our current quality of care and better health outcomes. (156)

**RESPONSE:** The Department acknowledges the commenter's expression of

legislative intent and the commenter's support of the proposed amendments.

32. COMMENT: A commenter "urges the ... Department ... to include [APNs/anesthesia] in the list of 'providers' in the Definitions [at N.J.A.C.] 8:43-G1 [(sic)]. The current list which notes 'physician, dentist, or podiatrist' would help to increase consumers' access to anesthetic services by including 'APN/anesthesia.'" (29)

RESPONSE: The Department is unable to locate the definition to which the commenter refers and is uncertain as to the commenter's meaning. A representative of the Department contacted the commenter to obtain clarification of the comment but received no response. Therefore, the Department will make no change on adoption in response to the comment.

**Comments addressing requirement that an anesthesiologist, rather than any physician, has to be party to joint protocol**

33. COMMENT: Commenters object to the proposed amendments at N.J.A.C. 8:43G-6.3 requiring the physician entering into a joint practice agreement with an APN/anesthesia for the provision of anesthesia services to be an anesthesiologist. A commenter asserts that existing law does not require an an APN/anesthesia to enter into a joint collaboration protocol agreement with an anesthesiologist (as opposed to a physician of any specialization), that anesthesiologists "are resistant to signing these protocols," and that APNs/anesthesia should continue to be authorized to enter into joint protocols with other types of physicians. (101)

A commenter requests that APNs/anesthesia “have the same type of joint protocol that other advanced practice registered nurses have with physicians. The joint protocol is congruent with the language of the [BON] regarding APNs’ authority to order or prescribe medication. Therefore, the APNs/anesthesia would share the same level of practice as the [State’s] other advanced practice registered nurses: nurse practitioners and clinical nurse specialists.” (29)

Commenters assert that the proposed amendments exceed the requirements of the BON and the joint protocol standards in requiring that the parties to the required joint protocol would be an APN/anesthesia and an anesthesiologist as collaborating physician, as opposed to a physician of any specialty. (154)

34. COMMENT: A commenter supports the proposed amendment requiring the collaborating physician to be an anesthesiologist. (109)

RESPONSE TO COMMENTS 33 and 34: Comment 33 correctly describes the rules of the BON with respect to the required parties to a joint collaboration protocol agreement, as the Department understands those rules. Comment 34 correctly represents that the proposed amendment at N.J.A.C. 8:43G-6.2, requiring the physician party to a joint protocol agreement with an APN/anesthesia for the provision of anesthesia services in a hospital to be an anesthesiologist, reflects the intention of the Department and the professional association that represents APNs/anesthesia (by its representative, Commenter 109 in the list of Commenters).

As described more fully above in response to previous comments, the rules of the BON “cannot alter the requirements that another board imposes on its own licensees.” 40 N.J.R. at 3733 at response to Comment 37.

The Department has encouraged, and continues to encourage, representatives of anesthesiologists and APNs/anesthesia to meet with the BON and the BME to collectively resolve issues that impede their implementation of the collaboration that both sides expressly support.

**Comments addressing impact of amendments of student nurse anesthetists  
clinical training**

35. COMMENT: A commenter asserts that the rules should not require “a greater level of supervision for physician residents than nurse anesthetists.” The commenter states that the proposed amendments would “require a physician resident or dental resident who administers or monitors general or regional anesthesia to be supervised by an anesthesiologist, but this would no longer apply to nurse anesthetists. Likewise, a physician resident or dental resident administers conscious sedation under the supervision of a privileged physician who is immediately available, but nurse anesthetists would collaborate with an anesthesiologist pursuant to a joint protocol. The physician resident has already completed medical school [and] gained experience in multiple medical specialties. [This training enables physicians] to recognize complications **that** may arise. The mandatory level of supervision of the lesser[-]trained nurse anesthetist must be no less than that of the physician or dental resident.” (54)

36. COMMENT: A commenter asserts that the repeal of the title, “student nurse anesthetist” is appropriate, and “will not present any issues regarding the continued ability of students in New Jersey’s two graduate nurse anesthesia programs to continue their training in the State’s hospitals.” (109)

37. COMMENT: Commenters note, “student nurse anesthetists are eliminated from the list of those who can administer anesthesia under the supervision of a physician credentialed in anesthesia” and request that the Department make accommodation for them. (154)

38. COMMENT: Commenters are “concerned ... that graduate students enrolled in accredited programs in nurse anesthesia are not specifically named in [the proposed amendments] as anesthesia care providers along with anesthesiology and dental residents.” (155)

39. COMMENT: A commenter states, “The Hospital Licensing Standards are silent regarding the education of Advanced Practice Nurses in master’s level anesthesia programs. The [BON requests that the Department amend N.J.A.C. 8:43G to] reflect that education of students in master’s level Advanced Practice Nurse Anesthesia programs will continue to be permitted with support and clinical oversight by clinicians deemed appropriate by the anesthesia program faculty.” (55)

RESPONSE TO COMMENTS 35 THROUGH 39: In proposing to amend existing N.J.A.C. 8:43G-6.3 to delete the term, “student nurse anesthetist,” from the list of professionals authorized to administer and monitor anesthesia under the supervision of an anesthesiologist, the Department does not intend to exclude “student nurse

anesthetists” from participation in hospital-based clinical training or to otherwise alter a master’s level APN/anesthesia program. As stated in response to previous comments, the proposed amendment reflects the Department’s effort to harmonize the hospital licensing rules with the rules of the BON.

The Department agrees with the assertion of Commenter 109 in Comment 39 that the proposed amendment would continue to permit and would not impede the operation of graduate APN/anesthesia programs in New Jersey hospitals. The Department believes that standards for all clinical education programs conducted in licensed health care facilities should be set forth in hospital policies and procedures and is considering the uniform treatment of this issue in a future rulemaking under Chapter 43E of Title 8 governing “General Licensure Procedures and Standards Applicable to All Licensed Facilities.”

Based on the foregoing, the Department will make no change on adoption in response to the comments.

#### **Other comments on Subchapter 6**

40. COMMENT: The commenter states that the existing definition of “deep sedation” at N.J.A.C. 8:43G-6.1, proposed for deletion, “mirrors the definition used by [a voluntary hospital accrediting agency] and [the American Society of Anesthesiologists]. The commenter opposes the proposed amendment, stating, “sedation is a continuum [and] it is not always possible to predict how an individual patient will respond. [Practitioners] intending to produce a given level of sedation should be able to rescue a patient whose level of sedation becomes deeper than initially intended. [Deep] sedation

is a term that is commonly used by accrediting organizations, government agencies, and the medical community.” The commenter recommends retaining the definition due to “its widespread use and patient safety.” (54)

RESPONSE: The proposed amendments, deleting references to the term, “deep sedation,” from throughout N.J.A.C. 8:43G-6 as proposed for readoption with amendments, would bring the chapter into consistency with the rules of the BME at N.J.A.C. 13:35 and the BON, which do not use or refer to the term, “deep sedation.” The Department will monitor the impact of the deletion of this term and will consider its reinstatement if the deletion were to create confusion in, or other difficulty to, the regulated community.

Subject to the foregoing, the Department will make no change on adoption in response to the comment.

41. COMMENT: With respect to proposed N.J.A.C. 8:43G-6.2, a commenter states that indicators are a more effective safety measure than annual review of policies and procedures. (175)

RESPONSE: N.J.A.C. 8:43G-6.2 would require anesthesia services to be administered based on policies and procedures that are reviewed at least annually, and revised more frequently as needed. As these are minimum licensing standards, hospitals are encouraged to explore whatever measures, such as “indicators,” that they may find effective in providing safe anesthesia services for their patient populations and to incorporate those measures in their policies and procedures.

The Department will make no change on adoption in response to the comment.



## Federal Standards Analysis

Federal regulations govern the operation of acute care hospitals, as set forth in 42 CFR Ch. IV, Refs & Annos. The Centers for Medicare and Medicaid Services of the Department of Health and Human Services, established in its Conditions of Participation for Hospitals, Subchapter G: Standards and Certification, codified at 42 CFR Part 482, the standards hospitals must follow to participate in the Federal programs. These Conditions of Participation serve as a survey mechanism for selected hospitals participating as providers in the Medicare and Medicaid Programs. Some of the Conditions of Participation are not comprehensive and have not been updated recently. Accordingly, there are rules contained within N.J.A.C. 8:43G that exceed Federal standards. For example, Subchapter 5 and Subchapter 12, relating to “Hospital Administration and General Hospital-Wide Policies” and “Emergency Department and Trauma Services,” respectively, contain requirements that exceed Federal requirements.

N.J.A.C. 8:43G-5.2(c) requires acute care hospitals to treat all patients regardless of their ability to pay. This requirement is consistent with N.J.S.A. 26:2H-18.64, which provides in pertinent part that, “no hospital shall deny any admission or appropriate service to a patient on the basis of that patient’s ability to pay or source of payment.” No Federal standards contain such a requirement.

Subchapter 12, Emergency Department and Trauma Services would exceed 42 CFR § 482.55, pertaining to emergency services, only to the extent that the rules

elaborate on Federal standards that require “appropriate” staffing levels and training without providing additional guidance or suitable licensure criteria. Specifically, 42 CFR § 482.55 requires that “the hospital must meet the emergency needs in accordance with acceptable standards of practice,” and 42 CFR § 482.55(b)2 requires that, “there must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.” In contrast, N.J.A.C. 8:43G-12 establishes specific “acceptable standards of practice,” and identifies unambiguously identifies “adequate medical and nursing personnel qualified in emergency care” in an enforceable standard. The Department has found it essential in order to maintain effective licensing requirements, which assure the delivery of quality services and which, thereby, protect the public safety to set these minimum standards.

**Full text** of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:43G.

**Full text** of the proposed amendments follow (additions to proposal appear in boldface with asterisks **\*thus\***; deletions from proposal appear in brackets with asterisks **\*[thus]\***):

8:43G-6.3 Anesthesia staff: qualifications for administering anesthesia

(a)-(d) (No change from proposal.)

(e) General or major regional anesthesia shall be administered and monitored only by the following:

1. – 2. (No change from proposal.)

3. An APN/anesthesia, in accordance with a joint protocol established in accordance with N.J.A.C. 13:37-6.3, Standards for joint protocols between advanced practice nurses and collaborating anesthesiologists, which joint protocol shall **\*[address sections governing the]\*** **\*require:**

**i. The\*** availability of an anesthesiologist to consult with the APN/anesthesia on site, on-call or by electronic means\*;\* and **\*[the]\***

**\*ii. The\*** presence of an anesthesiologist during induction, emergence and critical change in status; or

4. (No change from proposal.)

(f)-(g) (No change from proposal.)

(h) Anesthetic agents used for conscious sedation shall be administered only by the following:

1. – 2. (No change from proposal.)

3. An APN/anesthesia, in accordance with a joint protocol established in accordance with N.J.A.C. 13:37-6.3, Standards for joint protocols between advanced practice nurses and collaborating anesthesiologists, which joint protocol shall \*[address sections governing the]\* **require:**

**i. The\*** availability of an anesthesiologist to consult with the APN/anesthesia on site, on-call or by electronic means\*;\* and \*[the]\*

**\*ii. The\*** presence of an anesthesiologist during induction, emergence and critical change in status.

(i) (No change from proposal.)

(j) Minor regional blocks shall be administered by the following:

1. – 2. (No change from proposal.)

3. An APN/anesthesia, in accordance with a joint protocol established in accordance with N.J.A.C. 13:37-6.3, Standards for joint protocols between advanced practice nurses and collaborating anesthesiologists, which joint protocol shall \*[address sections governing the]\* **require:**

**i. The\*** availability of an anesthesiologist to consult with the APN/anesthesia on site, on-call or by electronic means\*;\* and \*[the]\*

**\*ii. The\*** presence of an anesthesiologist during induction, emergence and critical change in status; or

(k)-(l) (No change from proposal.)

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