LAW AND PUBLIC SAFETY

(a)

DIVISION OF CONSUMER AFFAIRS

STATE BOARD OF MEDICAL EXAMINERS

Surgery, Special Procedures, and Anesthesia Services Performed in an Office Setting

Proposed Amendments: N.J.A.C. 13:35-4A.1 through 4A.12

Proposed New Rule: N.J.A.C. 13:35-4A.19

Proposed Repeal: N.J.A.C. 13:35-4.2

Authorized By: State Board of Medical Examiners, William V. Roeder, Executive Director.

Authority: N.J.S.A. 45:9-2.

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

Proposal Number: PRN 2021-002.

Submit written comments by March 5, 2021, to:

William V. Roeder, Executive Director
State Board of Medical Examiners
PO Box 183
Trenton, New Jersey 08625-0183
or electronically at: http://www.njconsumeraffairs.gov/Proposals/Pages/default.aspx

The agency proposal follows:

Summary

Recent comprehensive studies identify evidence-based approaches to safe provision of abortion care in the United States and demonstrate the need for modernization of New Jersey's regulatory framework. Research also cautions that certain excessive, abortion-specific regulations both are medically unnecessary and harm public health by creating barriers to access to care. Such regulations raise significant constitutional questions. See, for example, *Whole Woman's Health v. Hellerstedt*, 136 *S.Ct*. 2292, 2309 (2016).

In light of these developments, the State Board of Medical Examiners (Board) proposes to repeal N.J.A.C. 13:35-4.2 (Rule 4.2), which regulates abortions, and to amend N.J.A.C. 13:35-4A (Rule 4A) to remove barriers to abortion care that are unrelated to safety and to ensure abortions are regulated like other office-based surgical and special procedures.

Currently in New Jersey, Rule 4.2 restricts where, and by whom, abortion care may be provided. As a general matter, Rule 4.2 provides that after 14 weeks of gestation, abortions are restricted to Department of Health (DOH)-licensed ambulatory care facilities (now referred to as ambulatory surgical centers (ASCs) or hospitals, depending on the methods used to perform the procedure and the gestational age. Rule 4.2 also permits only licensed physicians to perform abortion procedures in New Jersey (the "physician-only" rule). Under Rule 4.2, medication abortion is not considered a "procedure" subject to the physician-only rule.

More specifically, the restrictions under Rule 4.2 are as follows: abortions, other than medication abortions, may be performed by physicians only. From 14 through 18 weeks, dilation and evacuation (D&E) procedures are to be performed only in a hospital or an ASC that has in place a credentialing process to evaluate the physician's training and experience. All other types of abortions are required to be performed in a hospital. From 19 through 20 weeks, D&E procedures may be performed in an ASC, but the ASC must have a written agreement with an ambulance service and the physician must be Board-certified in Obstetrics and Gynecology, with admitting and surgical privileges at a hospital that: 1) can be reached within 20 minutes; and 2) has an operating room, blood bank, and intensive care unit. After 20 weeks, to perform D&E procedures in an ASC, the physician must apply to the Board and demonstrate "superior training and experience," as well as proof of support staff and facilities deemed adequate to accommodate the increased risks. The rule also mandates submission of certain data to the Board.

In December 2018, the Board empaneled a subcommittee to examine its abortion rules in light of advances in the field of abortion care and recent case law. As part of its review process, the subcommittee considered research, reports, and studies relating to current practice and safety of abortion care. For example, in 2018, the National Academies of Sciences, Engineering and Medicine's Committee on Reproductive Health Services (NASEM Committee) undertook a comprehensive review of the state of science on the safety and quality of legal abortion. It reported that the vast majority of abortions in the United States are performed approximately within the first 13 weeks of gestation and that the four most common methods of abortion (medication abortion, aspiration, D&E, and induction) are safe and effective, with very rare serious complications. Nat'l Academies of Sciences, Engineering, and Medicine, *The Safety and Quality of Abortion Care in the United States* (The National Academies Press, 2018) at 10, 26, https://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states.

The Centers for Disease Control and Prevention (CDC) Abortion Surveillance report indicates that approximately 91 percent of abortions performed in the United States in 2016 occurred within 13 weeks of gestation, and 85.4 percent of abortions performed in New Jersey occurred within 13 weeks gestation during the same period. Tara C. Jatlaoui et al., *Abortion Surveillance-United States, 2016*, Morbidity and Mortality Weekly Report, Nov. 29, 2019 at 1, 26, https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6811a1-H.pdf. The literature reviewed by the subcommittee indicated that aspiration abortions are the most common method of first trimester abortions, take only a few minutes to complete and are typically available without anesthesia.

The subcommittee also reviewed recent research from Advancing New Standards in Reproductive Health (ANSIRH), a collaborative research group at the University of California, San Francisco Bixby Center for Global Reproductive Health, which concluded that there are no benefits to patient safety or patient experience from requiring outpatient procedures to be performed in ASCs instead of physician offices, and that these requirements reduce patient access. *State Law Approaches to Facility Regulation of Abortion and Other Office Interventions*, OBS Laws vs TRAP Laws, (ANSIRH, Oakland, C.A.), Feb. 2018, https://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf. Further, the report states that research has failed to find any health benefits to women from requirements that abortions be performed in ASCs as opposed to in office-based settings. *Id.; see also* Sarah C. M. Roberts et al., *Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions*, 319 JAMA 2497 (2018); Nancy F. Berglas et al., *The Effect of Facility Characteristics on Patient Safety, Patient Experience, and Service Availability for Procedures in Non-Hospital-Affiliated Outpatient Settings: A Systematic Review*, 13 PloS one (2018). Indeed, the NASEM Committee also found that most abortions can be provided safely in an office-based setting, and that the need for facility upgrades or equipment mandates are more dependent on the level of sedation utilized, and, therefore, procedures are best regulated via rules of general applicability to health rather than through abortion-specific rules. Nat'l Academies of Sciences, Engineering, and Medicine, *supra*, at 10.

The subcommittee also considered reports and publications recommending that advanced practice clinicians (APCs)-namely, advanced practice nurses (APNs), physician assistants (PAs), certified nurse midwives (CNMs), and certified midwives (CMs)-be permitted to perform certain abortions. For example, the American College of Obstetricians and Gynecologists (ACOG) Committee Opinion on Abortion Education and Training, recommends expansion of "the trained pool of non-obstetrician–gynecologist abortion providers, such as family physicians and advance practice clinicians" through: 1. "integrating first trimester abortion training into family medicine and APC training programs"; and 2. eliminating "restrictions that limit abortion provision to physicians only or obstetrician–gynecologists only." *Abortion Training and Education*, Committee on Health Care for Underserved Women, American Coll. of Obstetricians and Gynecologists, Nov. 2014, at 1, https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2014/11/abortion-training-and-education.pdf. In 2018,

the NASEM Committee concluded that "[b]oth trained physicians ... and APCs ... can provide medication and aspiration abortions safely and effectively." Nat'l Academies of Sciences, Engineering, and Medicine, *supra*, at 14. The American Public Health Association also supports the provision of abortion care by advance practice clinicians. American Public Health Association, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants*, Policy Statement Database (Nov. 1, 2011), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/28/16/00/provision-of-abortion-care-by-advanced-practice-nurses-and-physician-assistants#Anchor%201. The leading and largest study to date examined patient safety data in California after APCs were permitted to provide early aspiration abortions, analyzing 11,487 procedures. It concluded, "[a]bortion complications were clinically equivalent between newly trained NPs [nurse practitioners, equivalent to APNs in New Jersey], CNMs , and Pas, and physicians, supporting the adoption of policies to allow these providers to perform early aspirations to expand access to abortion care." Tracey Weitz et al., *Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under A California Legal Waiver*, 103 Am. J. of Pub. Health 454, 454 (2013). The study results confirm existing evidence from smaller studies that the provision of abortion by nurse practitioners (equivalent to New Jersey's APNs), CNMs, and PAs is safe.

Upon review of current research and evidence-based trends in health care regulation, the Board preliminarily finds that current restrictions in Rule 4.2 are medically unnecessary, do not protect patients' health or safety, and restrict access to abortion care in New Jersey. Similarly, the physician-only rule bars APCs from providing abortion care in contradiction to recent studies and recommendations by leading medical and public health organizations. For these reasons, the Board proposes to repeal Rule 4.2 in its entirety.

Amendments to N.J.A.C. 13:35-4A

The purpose of N.J.A.C. 13:35-4A is to promote the health, safety, and welfare of members of the general population who undergo surgery and special procedures, and receive anesthesia in an office setting. The Board is proposing to update Rule 4A based on evidence of the safety of abortion care and the recognized value in expanding access to care, and in recognition that repeal of Rule 4.2 removes existing restrictions like the mandate that abortions beyond 15 weeks be performed in an ASC or hospital, the physician-only rule, credentialing and emergency transfer agreement requirements, and mandatory reporting of complications. Accordingly, several terms within Rule 4A are being amended to ensure that abortion is regulated similarly to other procedures of comparable complexity and risk, and to ensure sufficient safeguards are applicable to abortions performed in offices.

The Board is proposing to amend N.J.A.C. 13:35-4A.1, which sets forth the purpose of Rule 4A generally, to reflect that references throughout the rule to "minor surgery" are being amended to "minor procedures"; to more accurately reflect that "minor procedures" are low-risk services that do not require compliance with heightened regulatory requirements; to clarify that "special procedures" shall not be interpreted to include "minor procedures"; and to clarify that the purpose of Rule 4A is to ensure that services are offered consistent with the standard of care. By referring to "minor procedures," rather than "minor surgery," the Board intends to clarify that early aspiration abortion, which is identified as a type of "minor procedure" later in the chapter (N.J.A.C. 13:35-4A.3), falls outside the ambit, and does not trigger the requirements, of Rule 4A. Based on its review of recent research and safety data, the Board notes that the risks and complexity of early aspiration abortion are akin to those of procedures that the Board has previously determined do not require or warrant compliance with privileging process requirements, patient selection standards, recovery requirements, discharge protocol requirements, and heightened equipment mandates of Rule 4A.

Further, by referring to "minor procedures" rather than "minor surgery," the Board is ensuring consistency with the position statement issued by ACOG in January 2018. In that statement, ACOG defines "procedure" in the context of obstetrics and gynecology as a "short interventional technique" that includes "[n]on-incisional diagnostic or therapeutic intervention through a natural body cavity or orifice." The American Coll. of Obstetricians and Gynecologists, *Definition of "Procedures" Related to Obstetrics and Gynecology (Jan. 2018)*, https://www.acog.org/en/Clinical%20Information/Policy%20and%20Position%20Statements/Position%20Statements/2018/Definition%20of%20Procedures%20Related%20to%20Obstetrics%20and%20Gynecology. Under this definition, both early aspiration abortions, and later abortions performed by D&E and other non-aspiration methods, are "procedures." However, only the later abortions fall under the current definition of "special procedures" at Rule 4A and require the safeguards the subchapter affords.

The Board is proposing to amend N.J.A.C. 13:35-4A.2, which sets forth the scope of Rule 4A. Specifically, the Board is proposing to amend N.J.A.C. 13:35-4A.2(a) to align it with proposed amendments at N.J.A.C. 13:35-4A.1, such that it refers to "minor procedures" rather than "minor surgery"; and to clarify that the rule is intended to establish the standard of care in a surgical practice. The Board further proposes to amend N.J.A.C. 13:35-4A.2 to clarify that Rule 4A does not apply to the performance of medication abortions, whether they are prescribed by physicians or by APCs. The Board also proposes at N.J.A.C. 13:35-4A.2(a) to delete "and" to replace it with "or" preceding "administer anesthesia services ..." to unambiguously cover offices that administer anesthesia services for procedures that do not qualify as surgery or special procedures.

The Board is proposing to further amend N.J.A.C. 13:35-4A.1 and 4A.2(a), by deleting the word "setting" following "office," allowing for the expansion of the definition of "office" to include, but not be limited to, "licensed ambulatory surgery centers," registered surgical practices, and other sites where surgery and special procedures may be performed.

The Board proposes to add new N.J.A.C. 13:35-4A.2(c) explicitly exempting performance of medication abortions by physicians and APCs from the scope of Rule 4A. This provision replaces a similar exemption at Rule 4.2, which is proposed for repeal. Both the repealed language at Rule 4.2 and the proposed addition at N.J.A.C. 13:35-4A.2(c) make explicit that medication abortions do not fall within the definitions of, and are not covered by, Rule 4A.

The Board proposes to amend various definitions at N.J.A.C. 13:35-4A.3. First, the Board seeks to ensure consistency with ACOG's January 2018 position statement by proposing to amend the definition of "surgery" to delete reference to "curettage" and "extraction of tissue from the uterus," eliminating the implication that abortions beyond the first trimester constitute "surgery"; and to amend the definition of "special procedures" to include such post-first-trimester abortions. Additionally, the Board proposes to amend the definition of "complications" to include "uterine perforation or injury to other organ," so that the duty to report to the Board within seven days and in writing all "incidents, related to surgery, special procedures or anesthesia in an office," pursuant to N.J.A.C. 13:35-4A.5, is triggered when such an injury occurs during an abortion after the first trimester.

Consistent with the amendments described above, the Board proposes to replace the definition of "minor surgery" with "minor procedure," and to add "early aspiration abortion" as an example of such a minor procedure. Further, the Board proposes to define "early aspiration abortion" as "a procedure that terminates a pregnancy in the first trimester of pregnancy (defined as up to 12 completed weeks gestation, as confirmed by the patient, or up to 14 completed weeks as calculated from the last menstrual period and/or by ultrasound) utilizing manual or electric suction to empty the uterus and that does not involve the use of anesthesia services, as defined herein."

The Board proposes to replace the term "conscious sedation" with "moderate sedation" throughout Rule 4A to reflect the terminology currently used by the American Society of Anesthesiologists. This updated term better reflects the continuum of depth of sedation induced during procedures. The definition of the term is not being amended.

For clarification purposes, the Board is proposing to amend the definition of "certified registered nurse anesthetist" (CRNA) by deleting citation to a Board of Nursing licensing rule, which has since been repealed, and by replacing that cross-reference with a plain-language description of the CRNA license.

The Board proposes to define the term "collaborating agreement" to mean a written document entered into by an APC and a practitioner, to

include joint protocols for APNs, delegation agreements for PAs, or clinical guidelines for CNMs and CMs.

The Board proposes to amend N.J.A.C. 13:35-4A.4(b)2, so that the existing requirement for identification of the practitioners in an office who are responsible for ensuring equipment maintenance and sterilization, is expanded to cover practitioners who perform "special procedures," and not just surgery.

The Board proposes to amend N.J.A.C. 13:35-4A.5, which requires reporting to the Board any incidents related to surgery, special procedures, or anesthesia, by adding the word "services" after "anesthesia," to ensure consistency with the defined term "anesthesia services" at Rule 4A. The Board also proposes to update the reference to the statute that ensures confidentiality of these reports from "N.J.S.A. 45:9-19.3" to "N.J.S.A. 45:1-36," reflecting the citation of the currently applicable law (the Health Care Professional Responsibility and Reporting Enhancement Act of 2005).

The Board proposes to amend N.J.A.C. 13:35-4A.6(a), which currently requires practitioners to obtain either hospital privileges or alternative privileges from the Board to perform surgery or special procedures, to recognize privileging by ASCs as well. The Board notes that ASC privileging is governed by DOH and that DOH's rules are comprehensive. For instance, the DOH rule, at N.J.A.C. 8:43A-7.3, requires a Medical Director to participate in "the review of credentials and delineation of privileges of medical staff members, and assign … duties based upon education, training, competencies, and job descriptions." Additionally, N.J.A.C. 8:43A-12.3 requires ASCs to have a board-certified physician director responsible for surgical services, and pursuant to N.J.A.C. 8:43A-12.4(b), an ASC must also have a board-certified physician director of anesthesia services who participates in the credentialing process and delineation of privileges. Consequently, the Board is proposing to add a definition of ASC at N.J.A.C. 13:35-4A.3, and the definition of "privilege" is proposed for amendment to include authorization granted by an ASC licensed by DOH.

The Board is also proposing to add a definition for "surgical practices" to reflect the definition at N.J.S.A. 26:2H-12 and N.J.A.C. 8:43A-1.3, governing health care facilities. While surgical practices are required by P.L. 2017, c. 283, to be licensed by DOH and adhere to the standards at N.J.A.C. 8:43A, P.L. 2017, c. 283, explicitly permits the Board to establish standards of care with respect to the practice of medicine.

N.J.A.C. 13:35-4A.6(c) establishes requirements for pre-procedure counseling and preparation. It specifies that only patients who meet physical health requirements that qualify them for American Society of Anesthesiology (ASA) level I or II classification may undergo surgery or special procedure in an office. Such "physical status classification" is currently defined at N.J.A.C. 13:35-4A.3 as a "description of a patient used in determining if an office surgery or procedure is appropriate." The Board proposes to amend this definition to refer to a "special procedure," rather than a "procedure." Additionally, the Board proposes to make amendments at N.J.A.C. 13:35-4A.6 to conform this provision to other provisions of Rule 4A by referring to "minor procedures," rather than "minor surgeries"; and referring to "moderate sedation," rather than "conscious sedation."

N.J.A.C. 13:35-4A.7 establishes standards for administering or supervising the administration of anesthesia services in an office, pre-anesthesia counseling, patient monitoring, recovery, patient record, and discharge of patients. Consistent with the reasoning above, the Board is proposing to replace all reference to "conscious sedation" with "moderate sedation."

The Board is proposing to amend N.J.A.C. 13:35-4A.8, which sets forth the requirements of performing general anesthesia and personnel authorized to do so. Specifically, for consistency and clarity, at N.J.A.C. 13:35-4A.8(c), which provides that a certified registered nurse anesthetist administering general anesthesia requires a supervising physician to be present, to treat the patient in case of an emergency without concurrent responsibilities to administer anesthesia, or perform surgery, the Board proposes to add the term "special procedures" in addition to the performance of surgery.

The Board also proposes to amend N.J.A.C. 13:35-4A.9, which requires the presence of a supervising physician when a CRNA administers regional anesthesia. Specifically, the Board proposes to add the term "special procedures" at N.J.A.C. 13:35-4A.9(c), so that supervising physicians must be present when these types of procedures are performed.

The Board proposes to amend N.J.A.C. 13:35-4A.10 to replace multiple references to "conscious sedation" with the term "moderate sedation."

The Board proposes to amend N.J.A.C. 13:35-4A.11, which establishes the requirements for the administration of minor conduction blocks and for the personnel authorized to do so, by replacing "certified nurse midwife, an advanced practice nurse or physician's assistant" with "an advanced practice clinician," so that certified midwives, who are included in the definition of advanced practice clinicians at N.J.A.C. 13:35-4A.3, are included as licensees who, with the proper training and experience, may administer minor conduction blocks. Additionally, the board proposes to amend the definition of "minor conduction blocks" at N.J.A.C. 13:35-4A.3 to include "paracervical blocks," a type of local anesthesia frequently used in early aspiration abortion for pain management. The Board also proposes to amend N.J.A.C. 13:35-4A.11(b) to include ASCs, which will allow those who hold privileges at the ASCs to perform retrobulbar blocks.

The Board proposes to amend N.J.A.C. 13:35-4A.12, which establishes alternative privileging procedures by the Board, by adding ASC privileging to all existing references to privileging by hospitals, so that physicians who hold ASC privileges are not required to obtain alternative privileges from the Board.

Proposed new N.J.A.C. 13:35-4A.19 expands access to abortion care by clarifying that amended N.J.A.C. 13:35-4A does not bar physicians from authorizing APCs to perform minor procedures, so long as carrying out such procedures is within the APC's scope of practice and is addressed in the APC's collaborating agreement. Consistent with this new rule, the Board proposes to define "advanced practice clinicians" at N.J.A.C. 13:35-4A.3 to mean a New Jersey-licensed advanced practice nurse, physician assistant, certified nurse midwife, or certified midwife. Additionally, to expand the pool of providers authorized to perform early aspiration abortions, the Board is also proposing to amend the definition of "health care personnel" to include APNs, CNMs, and CMs.

The Board has determined that the comment period for this notice of proposal shall be 60 days; therefore, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is excepted from the rulemaking calendar requirement.

Social Impact

The Board anticipates that the proposed repeal of Rule 4.2 and amendments and new rule at Rule 4A will have a positive impact on the public and on licensed health care practitioners who provide abortion care or may provide abortion care in the future. Abortion is an essential element of reproductive healthcare and "it is critical to the public health interests of the United States that all women have meaningful access to reproductive health services, including abortion." Amici Curiae Brief of Public Health Deans et al. in Support of Petitioners at 3, *Whole Woman's Health v. Hellerstedt*, 136 *S.Ct*. 2292 (2016) (No. 15-274). The proposed repeal of Rule 4.2 will have a positive impact on individuals seeking abortions because it clears the path for expanded access to a broader pool of abortion providers and removes unnecessary barriers to abortion care, while retaining the elements of general health care regulation connected to public safety.

Further, the proposed amendments to Rule 4A will have a positive impact on individuals seeking abortions to the extent that they will have expanded Statewide access to abortions in a manner that complies with safety and health standards. Individuals seeking abortion care will be less likely to have to travel long distances to access abortion care, thus reducing delays in care and the higher costs and increased risks associated thereto. Individuals will also benefit from the ability to receive safe abortion care in less acute settings, recognized to be more cost effective.

The proposed amendments at Rule 4A will have a positive impact on licensed health care practitioners who provide abortion care. Physicians with ASC privileges will have enhanced flexibility to perform abortions because they will not be required to concurrently hold hospital or alternative Board privileges. Similarly, APNs, CNMs, CMs, and PAs who have demonstrated the requisite competencies, to be determined by the applicable regulating boards and committees, will have enhanced

flexibility to perform early aspiration abortions and other minor procedures within their respective scopes of practice.

Economic Impact

The proposed repeal of Rule 4.2 and amendments and new rule at Rule 4A will have an economic impact on individuals seeking abortion care, physicians, and APCs if they are deemed eligible by their regulating boards and committees to perform early aspiration abortions and other minor procedures. Generally, individuals seeking abortion care are likely to incur direct costs related to medical treatment and indirect costs, such as transportation. Because the proposed amendments will expand access to abortion care throughout the State and permit abortion to be performed in office settings, the overall costs of obtaining abortion care are likely to be reduced. For example, a recent study revealed that the average cost of an abortion procedure at an ASC is $750.00 more than in a physician office. Douglas L. Leslie et al., *Healthcare Costs for Abortions Performed in Ambulatory Surgery Centers vs Office-Based Settings*, 222 American J. of Obstetrics & Gynecology 348.e1, 348.e3 (2020). The proposed amendments will also likely reduce the potential for delayed care and higher health risks, which will further reduce the overall probable costs of abortion care to individuals seeking abortions, to insurers who cover such individuals, and to, therefore, to the insured public at large.

Licensees may incur costs related to obtaining ASC privileges and to demonstrating requisite competencies. Physicians without ASC privileges may incur costs related to obtaining ASC privileges in order to perform abortions in an office setting. These costs may be offset by ASC-privileged physicians who will have reduced total costs because they will no longer be required to obtain or hold hospital or alternative Board privileges-which may require collecting information needed to obtain such privileges and incurring associated costs of doing so-to perform abortions in offices. If they are deemed authorized to do so by applicable boards and committees, APCs may incur education costs related to demonstrating certain competencies before they perform early aspiration abortions and other minor procedures within their respective scopes of practice.

The Board anticipates that the proposed repeal, new rule, and amendments will have no direct financial impact on the public, but licensees may pass any costs associated with their education, training, and privileging on to patients as part of the fees they charge for abortion care.

Federal Standards Statement

A Federal standards analysis is not required because the repeal, new rule, and amendments that are proposed are subject to State statutory requirements and are not subject to any Federal requirements.

Jobs Impact

Because the proposed repeal of Rule 4.2 and amendments to Rule 4A remove restrictions that may have prevented individuals who seek abortion care from receiving it in New Jersey, the Board believes that the proposed repeal and amendments may result in increased ability of New Jersey providers to meet demand for services in this State, resulting in the creation of jobs for physicians, APCs, and individuals employed by physicians and APCs. The Board does not believe the repeal of Rule 4.2 and amendments to Rule 4A will result in the loss of any jobs in this State.

Agriculture Industry Impact

The Board does not believe that the proposed amendments, new rule, or repeal will have any impact on the agriculture industry of the State.

Regulatory Flexibility Analysis

Currently, the Board licenses approximately 40,700 physicians, 4,130 physician assistants, 350 certified nurse midwives, 14 certified midwives, and 10,640 advanced practice nurses. If these licensees are considered "small businesses" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., then the following analysis applies.

With regard to physicians, the repeal of N.J.A.C. 13:35-4.2 will remove, rather than impose, regulatory requirements for physicians performing certain abortions, including, but not limited to, requirements to file certifications and other documents with the Board, to maintain contemporaneous and cumulative statistical records, and to obtain alternative privileges from the Board. Pursuant to proposed new N.J.A.C. 13:35-4A, physicians who intend to perform abortions that are not early aspiration abortions in an ambulatory surgery center may have to obtain privileges from the ambulatory surgery center, and will incur associated costs.

With regard to APCs, the proposed revised definition at N.J.A.C. 13:35-4A.3 of "minor procedures" includes early aspiration abortions. "Minor procedures" are not regulated by the proposed rules. Therefore, if APCs are permitted to perform such "minor procedures" by their applicable boards and committees, they will not be covered by N.J.A.C. 13:35-4A and will not need to comply with its regulatory requirements. Additionally, the proposed new rule at N.J.A.C. 13:35-4A.19 clarifies that the proposed rules shall not be interpreted to prohibit APCs from performing minor procedures.

Housing Affordability Impact Analysis

The proposed amendments, new rule, and repeal will have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the proposed amendments, new rule, and repeal would evoke a change in the average costs associated with housing because the proposed amendments, new rule, and repeal concern who may perform abortions and where they may be performed.

Smart Growth Development Impact Analysis

The proposed amendments, new rule, and repeal will have an insignificant impact on smart growth development and there is an extreme unlikelihood that the proposed amendments, new rule, and repeal would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the proposed amendments concern who may perform abortions and where they may be performed.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

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

Full text of the rule proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 13:35-4.2.

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

SUBCHAPTER 4. SURGERY

13:35-4.2 (Reserved)

SUBCHAPTER 4A. SURGERY, SPECIAL PROCEDURES**,** AND ANESTHESIA SERVICES PERFORMED IN AN OFFICE SETTING

13:35-4A.1 Purpose

[These] **The** rules **in this subchapter** are designed to promote the health, safety**,** and welfare of the members of the general public who undergo surgery **or special procedures** (other than minor [surgery] **procedures**)[, special procedures] and receive anesthesia services in an office [setting]**, ensuring that such services are offered in a manner consistent with the standard of care**.

13:35-4A.2 Scope

(a) This subchapter establishes policies and procedures and staffing and equipment requirements for practitioners and physicians who perform surgery **or special procedures** (other than minor [surgery] **procedures**)[, special procedures and] **or** administer anesthesia services in an office [setting] **and represent the standard of care in a surgical practice**.

(b) For **the** purposes of this subchapter, the standards set forth at N.J.A.C. 13:35-4A.6 do not apply to those performing non-invasive special procedures, such as non-invasive radiologic procedures. However, the standards set forth at N.J.A.C. 13:35-4A.7[, including the privileging standards set forth at (a) above,] do apply to the anesthesia services provided in connection with all special procedures, whether invasive or non-invasive.

(c) For the purposes of this subchapter, the established standards shall not be applicable to the performance of medication abortions,

whether as a result of prescriptions issued by physicians or advanced practice clinicians.

13:35-4A.3 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

. . .

"Advanced practice clinician" or "APC" means an advanced practice nurse licensed pursuant to N.J.S.A. 45:11-45, a physician assistant licensed pursuant to N.J.S.A 45:9-27.10, or certified nurse midwives (CNMs) and certified midwives (CMs) licensed pursuant to N.J.S.A. 45:10-1.

"Ambulatory surgery center" means a facility licensed by the New Jersey Department of Health pursuant to N.J.S.A. 26:2H-12 and subject to N.J.A.C. 8:43A.

"Anesthesia services" means administration of any anesthetic agent with the purpose of creating [conscious] **moderate** sedation, regional anesthesia, or general anesthesia. For the purposes of this subchapter, the administration of topical or local anesthesia**,** minor conduction blocks, pain management or pain medication shall not be deemed to be anesthesia services.

. . .

"Anesthetic agent" means any drug or combination of drugs administered with the purpose of creating [conscious] **moderate** sedation, regional anesthesia**,** or general anesthesia.

. . .

"Certified registered nurse anesthetist" (CRNA) means a registered professional nurse who is licensed in this State **as an advanced practice nurse specializing in anesthesia services** and who holds current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA) [and who meets the conditions for practice as a nurse anesthetist as set forth at N.J.A.C. 13:37-13.1].

"Collaborating agreement" means a written document entered into by an APC and a physician, to include joint protocols for APNs, delegation agreements for PAs, or clinical guidelines for CNMs and CMs.

"Complications" means an untoward event occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia services which was performed in an office [setting] including, but not limited to, any of the following events: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, wound infections requiring intravenous antibiotic treatment or hospitalization, **uterine perforation or injury to another organ, or** unintended return to an operating room or hospitalization, death or temporary or permanent loss of function not considered to be a likely or usual outcome of the procedure.

["Conscious sedation" means the administration of a drug or drugs in order to induce that state of consciousness in a patient which allows the patient to tolerate unpleasant medical procedures without losing defensive reflexes, adequate cardio-respiratory function and the ability to respond purposefully to verbal command or to tactile stimulation if verbal response is not possible as, for example, in the case of a small child or deaf person. For the purposes of this subchapter, conscious sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient. Within the context of this subchapter, "conscious sedation" shall be synonymous with the term "sedation/analgesia" as used by the American Society of Anesthesiologists.]

"Early aspiration abortion" means a procedure that terminates a pregnancy in the first trimester of pregnancy (defined as up to 12 completed weeks gestation, as confirmed by the patient, or up to 14 completed weeks as calculated from the last menstrual period and/or by ultrasound) utilizing manual or electric suction to empty the uterus and that does not involve the use of anesthesia services.

. . .

"Health care personnel" means any office staff member who is licensed by a professional or health care occupational licensing board such as [a] **an advanced practice nurse,** professional registered nurse, licensed practical nurse, **certified nurse midwife, certified midwife,** or physician assistant.

. . .

"Minor conduction block" means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, local infiltration or local nerve block), or the block of a nerve by direct pressure or refrigeration. Minor conduction blocks include, but are not limited to, retrobulbar blocks, peribulbar blocks, pudendal blocks, digital blocks, metacarpal blocks**,** [and] ankle blocks**, and paracervical blocks**. "Minor conduction block" does not include regional anesthesia that affects larger areas of the body, such as brachial plexus anesthesia or spinal anesthesia.

"Minor [surgery] **procedure**" means [surgery which] **an intervention that** can safely and comfortably be performed on a patient who has received no more than the maximum manufacturer recommended dose of local or topical anesthesia, without more than minimal pre-operative medication or minimal intra-operative tranquilization and where the likelihood of complications requiring hospitalization is remote. Minor [surgery] **procedure** specifically excludes all procedures performed utilizing anesthesia services as defined in this section. Minor [surgery] **procedure** also specifically excludes procedures which may be performed under local anesthesia, but which involve extensive manipulation or removal of tissue such as liposuction or lipo-injection, breast augmentation or reduction, and removal of breast implants. Minor [surgery] **procedure** includes the excision of moles, warts, cysts, lipomas, skin biopsies, the repair of simple lacerations, or other [surgery] **procedures** limited to the skin and subcutaneous tissue. Additional examples of minor [surgery] **procedures** include closed reduction of a fracture, the incision and drainage of abscesses, certain simple ophthalmologic [surgical] procedures, such as treatment of chalazions and non-invasive ophthalmologic laser procedures performed with topical anesthesia, limited endoscopies such as flexible sigmoidoscopies, anoscopies, proctoscopies, arthrocenteses, thoracenteses**,** [and] paracenteses**, and early aspiration abortions**. Minor [surgery] **procedures** shall not include any procedure identified as "major surgery" within the meaning of N.J.A.C. 13:35-4.1.

"Moderate sedation" means the administration of a drug or drugs in order to induce that state of consciousness in a patient that allows the patient to tolerate unpleasant medical procedures without losing defensive reflexes, adequate cardio-respiratory function, and the ability to respond purposefully to verbal command or to tactile stimulation, if verbal response is not possible as, for example, in the case of a small child or deaf person. Moderate sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization, such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient. Moderate sedation shall be synonymous with the term "sedation/analgesia" as used by the American Society of Anesthesiologists.

. . .

"Office" means a location at which medical, surgical or podiatric services are rendered [and which] **that** contains [only one operating room and which] **no more than one room or suite of rooms in which surgery or special procedures are performed that** is [not] subject to the jurisdiction and licensure requirements of the New Jersey State Department of Health [and Senior Services] **as a licensed ambulatory surgery center**. **"Office" includes, but is not limited to, registered surgical practices and those sites that are not equipped for the performance of surgery, but at which special procedures may be performed.**

. . .

"Physical status classification" means a description of a patient used in determining if an office surgery or **special** procedure is appropriate. The American Society of Anesthesiologists enumerates classifications: I—Normal healthy patient; II—A patient with mild systemic disease; III—A patient with severe systemic disease limiting activity but not incapacitating; IV— A patient with incapacitating systemic disease that is

a constant threat to life; and V—Moribund patients not expected to live 24 hours with or without operation.

. . .

"Privileges" means the authorization granted to a practitioner [or physician] by a hospital licensed in the jurisdiction in which it is located to provide specified services**, or an ambulatory surgery center licensed by the Department of Health** or alternatively by the Board pursuant to N.J.A.C. 13:35-4A.12, such as surgery **or special procedures** or the administration or the supervision of administration of one or more types of anesthetic agents [or procedures].

. . .

"Special procedure" means patient care [which] **that** requires anesthesia services because it involves entering the body with instruments in a potentially painful manner, or requires the patient to be immobile; for a diagnostic or therapeutic procedure. Examples of special procedures include diagnostic or therapeutic endoscopy or bronchoscopy performed utilizing [conscious] **moderate** sedation or general anesthesia; invasive radiologic procedures performed utilizing [conscious] **moderate** sedation, pediatric magnetic resonance imaging performed utilizing [conscious] **moderate** sedation[; or]**,** manipulation under anesthesia [or, extraction of tissue from the uterus utilizing] (MUA)**, or abortions, other than early aspiration abortions**. The term special procedure does not include a procedure which only requires medication to reduce anxiety such as oral benzodiazepine**,** unless the dose given is intended to provide [conscious] **moderate** sedation.

. . .

"Surgery" means a manual or operative procedure, including the use of lasers, performed upon the body for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life**,** or relieving suffering. Surgery includes, but is not limited to: incision [or curettage of] **in** tissue or an organ; suture or other repair of tissue or an organ; a closed or open reduction of a fracture [or extraction of tissue from the uterus].

"Surgical practice" means a structure or suite of rooms that has the following characteristics:

1. Has no more than one room dedicated for use as an operating room that is specifically equipped to perform surgery, and is designed and constructed to accommodate invasive diagnostic and surgical procedures;

2. Has one or more post-anesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged; and is established by a physician professional association surgical practice, or other professional practice form specified by the State Board of Medical Examiners pursuant to N.J.A.C. 13:35-6.1(f) solely for the physician's, association's or other professional entity's private medical practice.

. . .

13:35-4A.4 Policies and procedures requirements

(a) Practitioners who perform surgery [(other than minor surgery)] or special procedures **(other than minor procedures)**, and physicians who administer or supervise the administration or monitoring of anesthesia services in an office shall establish written policies and procedures concerning the following:

1.-10. (No change.)

(b) The written policies and procedures shall also contain the identity of the specific practitioners within the office who are responsible for ensuring that:

1. (No change.)

2. All equipment and instruments utilized in the performance of surgery **or special procedures** are maintained in proper working order and in accordance with such sterilization techniques as are required for safe medical practice;

3.-5. (No change.)

(c)-(d) (No change.)

13:35-4A.5 Duty to report incidents related to surgery, special procedures**,** or anesthesia in an office

Any incident related to surgery, special procedures**,** or the administration of anesthesia **services** within the office [which] **that** results in a patient death, transport of the patient to the hospital for observation or treatment for a period in excess of 24 hours, or a complication [or untoward event as defined in N.J.A.C. 13:35-4A.3], shall be reported to the Executive Director of the Board within seven days, in writing**,** and on such forms as shall be required by the Board. Such reports shall be investigated by the Board and will be deemed confidential pursuant to N.J.S.A. [45:9-19.3] **45:1-36**.

13:35-4A.6 Standards for performing surgery and special procedures in an office; privileges necessary; pre-procedure counseling; patient records; recovery and discharge

(a) A practitioner who performs surgery [(other than minor surgery)] or special procedures **(other than minor procedures)** in an office shall be privileged to perform that surgery or special procedure by a hospital **or an ambulatory surgery center**. If a practitioner is not **so** privileged**,** but wishes to perform surgery or special procedures in an office, the practitioner shall apply to the Board pursuant to N.J.A.C. 13:35-4A.12 to seek Board-approved privileging.

(b) Before any practitioner may perform surgery [(other than minor surgery)] or special procedures **(other than minor procedures)**, the practitioner shall have:

1.-2. (No change.)

(c) A practitioner who performs surgery [(other than minor surgery)] or special procedures **(other than minor procedures)** in an office shall provide pre-procedure counseling and preparation as follows:

1. The practitioner shall appropriately assess, or review a referring physician's assessment of, the physical condition of the patient on whom surgery or a special procedure is to be performed. The practitioner shall refer a patient who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway**,** or neurological problems; substance abusers) to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility for the performance of the surgery or the special procedure. Only patients with an American Society of Anesthesiologists (ASA) physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II**,** or III are appropriate candidates for [conscious] **moderate** sedation.

2. A history and physical examination shall be performed within the 30 days preceding the proposed surgery either by the practitioner performing the surgery or **special** procedure (as appropriate to that practitioner's scope of practice) or by another physician or [physician assistant under the supervision of a physician] **an advanced practice clinician**. Necessary laboratory tests, as guided by the patient's underlying medical condition, shall be conducted within seven days preceding the proposed surgery;

3.-6. (No change.)

(d) A practitioner who performs surgery [(other than minor surgery)] or special procedures **(other than minor procedures)** in an office shall ensure the following during recovery and prior to discharge:

1.-4. (No change.)

(e) A practitioner who performs surgery [(other than minor surgery)] or special procedures **(other than minor procedures)** in an office shall prepare a patient record which shall include the following:

1.-6. (No change.)

(f) No practitioner who performs surgery [(other than minor surgery)] or special procedures **(other than minor procedures)** in an office shall:

1.-2. (No change.)

13:35-4A.7 Standards for administering or supervising the administration of anesthesia services in an office; pre-anesthesia counseling; patient monitoring; recovery; patient record; discharge of patient

(a) (No change.)

(b) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall provide pre-anesthesia counseling and preparation as follows:

1. Any patient to whom anesthesia services are to be provided shall be appropriately screened by the individual administering anesthesia services. Patients who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly

obese patients; patients with severe cardiac, pulmonary, airway**,** or neurological problems; substance abusers) shall be referred to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility. Only patients with an ASA physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II**,** or III are appropriate candidates for [conscious] **moderate** sedation.

2.-9. (No change.)

(c) A physician who administers or supervises the administration or monitoring of any anesthesia services (general anesthesia, regional anesthesia**,** or [conscious] **moderate** sedation) in an office shall ensure that monitoring is provided as follows when clinically feasible for the patient:

1.-5. (No change.)

(d)-(i) (No change.)

13:35-4A.8 Performance of general anesthesia; authorized personnel

(a) (No change.)

(b) The administration and monitoring of general anesthesia shall be provided by an individual who meets the requirements of (a) above and who is at all times present in the anesthetizing location and who is not the practitioner performing the surgery or special procedure. This subsection shall not be construed to preclude the conversion of [conscious] **moderate** sedation to general anesthesia in an emergency to protect the health of the patient, even if there is no physician present who would be qualified to administer and monitor general anesthesia pursuant to (a)1 above.

(c) When the administration and monitoring of general anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency without concurrent responsibilities to administer anesthesia or perform surgery **or special procedures**, other than minor [surgery] **procedures**.

(d) (No change.)

13:35-4A.9 Administration of regional anesthesia; authorized personnel

(a)-(b) (No change.)

(c) When the administration and monitoring of regional anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency, without concurrent responsibilities to administer anesthesia or perform surgery **or special procedures**, other than minor [surgery] **procedures**.

(d) (No change.)

13:35-4A.10 Administration of [conscious] **moderate** sedation; authorized personnel

(a) [Conscious] **Moderate** sedation shall be administered in an office only by the following individuals:

1. A practitioner privileged by a hospital **or** the Board pursuant to N.J.A.C. 13:35-4A.12 to provide [conscious] **moderate** sedation and who, during every consecutive three-year period beginning July 1, 2004, completes at least eight Category I or II hours of continuing medical education in any anesthesia services, including [conscious] **moderate** sedation exclusively, or in anesthesia as it relates to the physician's field of practice, which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association;

2. (No change.)

3. A registered professional nurse or physician assistant, who is trained and has experience in the use and monitoring of anesthetic agents, at the specific direction of a physician qualified under (a)1 above, but only for the purpose of administering through an established intravenous line, a specifically prescribed supplemental dose of [conscious] **moderate** sedation [which] **that** was selected and initially administered by the physician who remains continuously present in the procedure room. "Continuously present in the procedure room" does not require that a practitioner remain in the procedure room in violation of human exposure safety standards regularly employed during radiological procedures.

(b) A patient under [conscious] **moderate** sedation shall be monitored in an office by a physician, CRNA, or a registered professional nurse or physician assistant who has training and experience in the use of monitoring devices, under the supervision of a physician eligible under (a)1 above, to administer [conscious] **moderate** sedation.

(c) The monitoring of a patient under [conscious] **moderate** sedation shall be provided by an individual who meets the requirements of (b) above and who is at all times present and who is not the practitioner who is performing the surgery or special procedure.

(d) When the administration and monitoring of [conscious] **moderate** sedation is being performed by a CRNA, or when the monitoring is being performed by a registered professional nurse or physician assistant, the supervising physician shall be physically present, but may be concurrently responsible for patient care.

(e) An advanced cardiac life support-trained physician, registered nurse**,** or physician assistant shall be present at all times when a patient is receiving or recovering from the administration of [conscious] **moderate** sedation.

13:35-4A.11 Administration of minor conduction blocks; authorized personnel

(a) Minor conduction blocks (with the exception of retrobulbar blocks) shall be administered in an office for surgery or special procedures only by the following individuals:

1.-2. (No change.)

3. [A certified nurse midwife, an] **An** advanced practice [nurse or physician assistant] **clinician** who has training and experience in the administration of minor conduction blocks.

(b) Retrobulbar blocks shall be administered in the office only by a physician privileged by a hospital**, licensed ambulatory surgery center,** or by the Board pursuant to N.J.A.C. 13:35-4A.12.

13:35-4A.12 Alternative privileging procedure

(a) A practitioner who seeks to provide or supervise the administration and monitoring of general or regional anesthesia, as well as [conscious] **moderate** sedation, in an office, but does not hold privileges at a licensed hospital **or ambulatory surgery center** to do so, shall submit**,** to the Board**,** an application for these privileges. To be eligible to apply for these privileges, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1.-3. (No change.)

(b) A practitioner who seeks to administer or supervise the administration and monitoring of only [conscious] **moderate** sedation in an office, but does not currently hold clinical privileges at a licensed hospital **or ambulatory surgery center** to do so, shall submit**,** to the Board**,** an application for this privilege. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1. Demonstration of clinical experience, through an attestation as to the number of procedures for which [conscious] **moderate** sedation was provided by the applicant in the last two years for all age groups within the applicant's practice of patients for which privileges are requested, except age groups as are specifically excluded from the applicant's practice;

2. Any one of the following:

i. (No change.)

ii. Current certification in Critical Care Medicine or Emergency Medicine by a specialty board or certifying entity recognized by the American Board of Medical Specialties (["]ABMS["]) or the American Osteopathic Association (["]AOA["]) or any other certification entity the applicant demonstrates has standards of comparable rigor; or

iii. Satisfactory evidence that the applicant is advanced cardiac life support trained with updated training from a recognized accrediting organization and either:

(1) (No change.)

(2) A course in [conscious] **moderate** sedation offered by a licensed hospital or for continuing medical education credits; and

3. Submission of a list of all patients who have experienced complications relating to the applicant's provision of [conscious] **moderate** sedation in an office setting or licensed ambulatory care facility setting and their resulting outcomes. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log.

(c) A practitioner who seeks to perform surgery (other than minor surgery) or special procedures in an office, but does not hold privileges at a licensed hospital **or ambulatory surgery center** to perform these procedures shall submit**,** to the Board**,** an application for these privileges, including a completed privilege request form appropriate to the privileges requested. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1.-3. (No change.)

(d) A practitioner who seeks to utilize laser surgery techniques in an office, but does not hold privileges at a licensed hospital **or an ambulatory surgery center** to do so, shall submit**,** to the Board**,** an application, which shall include:

1.-2. (No change.)

(e)-(h) (No change.)

13:35-4A.19 Performance of minor procedures by advanced practice clinicians

Nothing in this subchapter shall be construed to preclude practitioners from authorizing advanced practice clinicians to perform minor procedures in the office consistent with their respective scopes of practice and as addressed within their individual collaborating agreements.

TRANSPORTATION

(a)

DIVISION OF HIGHWAY AND TRAFFIC DESIGN

Traffic Regulations and Traffic Control Devices

Proposed Readoption with Amendments: N.J.A.C. 16:27

Authorized By: Diane Gutierrez-Scaccetti, Commissioner, Department of Transportation.

Authority: N.J.S.A. 27:1A-5, 27:1A-6, 27:7-21, 39:4-8, 39:4-31.1, 39:4-120, 39:4-183.27, and 39:4-197; and P.L. 2008, c. 110.

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

Proposal Number: PRN 2021-005.

Submit comments by March 4, 2021, to:

Paul F. Sprewell
Administrative Practice Officer
New Jersey Department of Transportation
PO Box 600
Trenton, New Jersey 08625-0600
Fax: (609) 530-4638
Submit electronically at njdotRules@dot.state.nj.us.

This rulemaking may be viewed or downloaded from the Department's website at http://www.state.nj.us/transportation/about/rules/proposals.shtm.

The agency proposal follows:

Summary

In accordance with N.J.S.A. 52:14B-5.1.c, N.J.A.C. 16:27 was scheduled to expire on January 8, 2021. As the Department of Transportation (Department) has filed this notice prior to that date, pursuant to N.J.S.A. 52:14B-5.1.c(2), the expiration date is extended 180 days to July 7, 2021. N.J.A.C. 16:27 sets forth the Department's procedures concerning the regulation of traffic, particularly as to obtaining approvals for traffic control devices, both existing and new, and the design standards, installation, and inspection of those devices. The Department has reviewed the rules and determined that they are necessary, reasonable, and proper for the purposes for which they were originally promulgated. Amendments are necessary to clarify the procedures for the approval of new and existing traffic control devices and traffic regulations on State highways, update information regarding the standards, and reorganize rule text. The Department is proposing to readopt the rules with amendments as set forth below. Since the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

The current chapter is summarized as follows:

Subchapter 1, Purpose and Scope, provides the purpose and scope of the chapter.

Subchapter 2, Definitions, provides the definitions for the chapter.

Subchapter 3, Standards for Traffic Control Devices, provides the standards.

Subchapter 4 describes the procedures for the approval, design, installation, and inspection of traffic control signals.

Subchapter 5 sets forth the procedure and cost involved with information requests concerning whether a specific traffic control device has received Department approval.

The proposed amendments are as follows:

The heading of Subchapter 1 is proposed for amendment to delete "Traffic Regulations" and replace it with "Purpose and Scope." Proposed new N.J.A.C. 16:27-1.1(c) is added to state that contact information, Commissioner approvals for State highways, information regarding non-State highways, and any required fees, are found at N.J.A.C. 16:27-5.1.

At existing N.J.A.C. 16:27-2.1, there are two definitions of "Impact on a State highway" or "impact to a State highway." In order to eliminate redundancies and clarify the intent, the current definitions are proposed for deletion and a new definition is added with no substantive change.

N.J.A.C. 16:27-3.1(c) is proposed for amendment to update website addresses.

N.J.A.C. 16:27-4.3(a)1 is proposed for amendment to change eight-hour counts to 12-hour counts. This change is being made because, over the years, peak hours have extended beyond eight hours. N.J.A.C. 16:27-4.3(b)2 is proposed for amendment to include other types of vehicles in the traffic mix. These vehicles include bicycles, cars, cars with trailers, and buses. The number of axles per commercial motor vehicle (CMV) is also added. The percentage of each type of vehicle is used to provide accurate information for recommendations to the Commissioner regarding requests for traffic control devices. N.J.A.C. 16:27-4.3(b)3 is proposed for amendment to delete the last sentence and add a requirement for copies of crash reports with appropriate summaries and diagrams. The amendment brings the New Jersey Administrative Code into agreement with the current policy of the Bureau of Traffic Engineering.

Social Impact

The rules proposed for readoption with amendments establish uniform requirements and standards for approval of traffic regulations and traffic control devices on State highways and non-State highways that impact a State highway. The rules also establish the process to approve route restrictions of commercial motor vehicles on non-State highways, to close a non-State highway for more than 48 hours, and to permit the operation of low-speed vehicles on certain State highways. The rules continue to ensure that traffic regulations are reviewed and approved in a consistent manner and that traffic control devices are installed at locations on, or impacting, the State highway, where a demonstrable need for safety and the expedition of traffic exists. The continued use of uniform design standards for traffic control devices further enhances traffic safety and improves traffic expedition as motorists and pedestrians can follow readily recognizable and understandable traffic control devices throughout the State.

Economic Impact

An authority seeking approval of a traffic regulation or traffic control device will incur engineering costs to conduct traffic analyses, prepare a certification report and as-built plans, and conduct inspections. These costs will vary depending upon the scope of work and whether this work is done by in-house staff or outside consultants. The costs of acquisition, installation, and maintenance of traffic control devices are borne by the authority, except for the cost of maintenance of traffic control devices under authority jurisdiction, but maintained by the Department.

The Department does not impose a fee on authorities to review and investigate requests to establish or modify traffic regulations and traffic control devices, limit the use of commercial motor vehicles on non-State highways, close a non-State highway for a duration lasting more than 48 hours, or to operate low-speed vehicles on State highways. The $25.00 fee