

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

IOWA MEDICAL SOCIETY,
Petitioner,

and

IOWA OSTEOPATHIC MEDICAL
ASSOCIATION

Intervenor.

v.

IOWA DEPARTMENT OF PUBLIC
HEALTH
AND IOWA BOARD OF NURSING,

Respondents,

IOWA ASSOCIATION OF NURSE
ANESTHETISTS,

Intervenor,

and

IOWA NURSES ASSOCIATION,
Intervenor

Consolidated Case No. CV 8252

**FINDINGS OF FACT,
CONCLUSIONS OF LAW AND
RULING**

IOWA SOCIETY OF
ANESTHESIOLOGISTS,

Petitioner,

and

IOWA OSTEOPATHIC MEDICAL
ASSOCIATION

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Petitioners' and Respondents' Motions for Summary Judgment came before the Court for oral argument on September 9, 2011. Having considered the State's certified record of agency action, along with the parties' briefs, documents and arguments, the Court finds that none of the material facts at issue in this matter are in dispute. Therefore, the Court enters summary judgment in favor of Petitioners. This Court's ruling should not surprise any participant. These issues have been argued repeatedly before the Court.

This case was filed on June 21, 2010. On November 23, 2010, this Court entered a Stay Order, considering, *inter alia*, the likelihood of Plaintiff's success on the merits. As this Court has repeatedly voiced, this case is not about restricting access to medical services or about the competency of any particular health practitioner to perform procedures relating to the subject matter. This case involves legal issues, not factual issues. The Court has repeatedly outlined the legal issues. The Court's record now consists of sixteen (16) volumes of documents.

Because Petitioners' Proposed Findings of Facts and Conclusions of Law tracks with the Court's prior rulings and current law and state of the case, this Court has relied upon that document in drafting this Order, after independent consideration of all arguments and submissions.

I. FINDINGS OF FACT

1. On June 2, 2009, the Iowa Board of Nursing (IBN) adopted a noticed rule identified as ARC 7888B, which it codified within Iowa Administrative Code § 655-7.2. The rule authorizes Advanced Registered Nurse Practitioners (ARNPs) to provide "direct supervision" of fluoroscopy pursuant to the definition of "direct supervision" set forth IAC 641-42.1(2). (IAC §655-7.2).

2. In adopting ARC 7888B, IBN contends that it had authority to do so under Iowa Code §152.1(6)(d).

3. On March 10, 2010, the Iowa Department of Public Health (IDPH) adopted a noticed rule identified as ARC 8659B, which it codified within Iowa Administrative Code § 641-41.1(5)(n). IDPH's rule authorizes ARNPs to provide direct supervision of radiologic technologists and radiologic students in the performance of fluoroscopy for purposes of localization to obtain images for diagnostic or therapeutic purposes pursuant to IDPH's rule. (IAC § 641-41.1(5)(n)).

4. Fluoroscopy involves real-time medical imaging technology that employs a beam of radiation to project a real-time visual image of the body onto a monitor screen. During a fluoroscopy procedure, a continuous ionizing radiation beam is passed through the body. The image is then transmitted to a monitor so that the medical provider can view the body part and its motion in detail. (Respondents' Answer, ¶¶ 10-11).

5. Respondents admit in their Answer that patients undergoing fluoroscopic procedures can be exposed to as much radiation as between 250 to 3,500 chest x-rays. (Respondents' Answer, ¶12).

6. Respondents admit in their Answer that as with all radiation procedures, health risks associated with fluoroscopy include an increased life risk of cancer due to overexposure to radiation for both the patient and the medical personnel involved. (Respondents' Answer, ¶13).

7. Respondents admit in their Answer that, due to the ability to deliver high radiation doses, performance and supervision of fluoroscopy requires elevated safety and training to ensure maintenance of patient radiation exposures to levels that are as low as reasonably achievable for the patient. (Respondents' Answer, ¶13).

8. Pursuant to Iowa Administrative Code § 641-42.1(2), "supervision" for purposes of these rules, means responsibility for and control of quality, radiation safety and protection, and technical aspects of the application of ionizing radiation to human beings for diagnostic or

therapeutic purposes. Direct supervision is physically observing and critiquing the actual procedure and giving immediate assistance if required. (IAC 641-42.1(2)).

9. IDPH enacted its rule without establishing or approving a curriculum or minimum training standards including continuing education requirements, examinations and disciplinary procedures with respect to ARNPs' supervision of fluoroscopy as the term is defined within these rules. (IDPH Meeting Minutes, 3/10/10).

10. The Iowa Board of Medicine submitted its written opposition to IDPH and IBN regarding these rules on December 12, 2007, June 1, 2009, and December 3, 2009, respectively. (IBN Agency Record 896, 106-07; IDPH Agency Record 580).

11. The American College of Radiology (ACR), a professional organization representing 34,000 members practicing within the radiology field, submitted its written opposition to IDPH and IBN regarding these rules noting a complete lack of educational standards for ARNPs to engage in the practice within its objections. (IBN Agency Record 261; IDPH Agency Record 223-24).

12. The following additional medical and allied health professional groups (among others) registered their opposition to the rules during the respective public comment periods:

- Iowa Medical Society (IMS)
- Iowa Society of Anesthesiologists (ISA)
- Iowa Association of Osteopathic Medicine (IBN Agency Record 264)
- Iowa Radiological Society (IDPH Agency Record 12-13).
- Society of Interventional Radiology (IDPH Agency Record 226 – 29; 532-34).
- American Society of Radiologic Technologists (IBN Agency Record 105; IDPH Agency Record 504)
- Polk County Medical Society (IBN Agency Record 104)
- University of Iowa Dept. of Radiology Chairperson (IDPH Agency Record 210-11).

13. According to an IBN survey of its 1,459 ARNP licensees, a total of forty-three ARNPs purported to use fluoroscopy in some way in their practice prior to enactment of the rules in

question. Of this amount, thirty-three ARNPs stated their use had been for less than five years. From this number, only 3 ARNPs not of the Certified Registered Nurse Anesthetist (CRNA) classification reported using fluoroscopy in some way. IBN did not provide the survey results to IDPH prior to IDPH's enactment of its rule.

14. IANA admitted during the rulemaking process that the IBN survey included responses from 223 of its 302 members (nearly 80%) which showed only 29 CRNAs utilizing fluoroscopy in some way in only sixteen of Iowa's 118 hospitals across the state. (IBN Agency Record 871-72).

15. IANA admitted during the rulemaking process that training CRNAs receive during their schooling at the University of Iowa nurse anesthesia program is insufficient to make CRNAs competent to utilize fluoroscopy in practice. (IBN Agency Record 75).

16. On June 21, 2010, Petitioner Iowa Society of Anesthesiologists (ISA) filed a petition for judicial review of agency action pursuant to Chapter 17A of the Iowa Code. Petitioner Iowa Medical Society (IMS) filed a similar petition on June 21, 2010. Due to common issues of law and fact, the Court consolidated these matters on August 11, 2010.

17. The Iowa Nurses Association (INA), Iowa Association of Nurse Anesthetists (IANA) and the Iowa Osteopathic Medical Association (IOMA) each filed motions to intervene in this matter, which the Court subsequently granted.

18. Upon Petitioners' joint motion, the Court entered an order staying the enforcement and effect of these rules on November 23, 2010, based in part on the Court's finding of the likelihood of Petitioners' success on the merits of the case.

19. Petitioners subsequently filed their separate motions for summary judgment. Respondents and IANA filed cross-motions for summary judgment. Both Petitioners and

Respondents agree that, regardless of any factual findings/issues, summary judgment regarding this matter is appropriate one way or the other.

20. INA seeks to introduce factual questions to preclude summary judgment in this matter through its briefings and oral arguments. To the extent the Court believes any factual disputes exist in this matter, the Court specifically finds that none of these disputes are material or relevant to the Court's limited inquiry with respect to these rules.

II. CONCLUSIONS OF LAW

A. Standard for granting Summary Judgment.

21. Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories and admissions on file, together with any affidavits, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Iowa R. Civ. Pro. 1.981(3) (2010), Wright v. Am. Cyanmid Co., 599 N.W.2d 66, 670 (Iowa 1999).

22. If the conflict in the record consists only of the legal consequences flowing from undisputed facts, entry of summary judgment is proper. Farm Bureau Mut. Ins. Co. v. Milne, 424 N.W.2d 422, 423 (Iowa 1988). If a motion for summary judgment has been properly supported by relevant portions of the record and/or affidavits, the resisting party "must set forth specific facts showing there is a genuine issue for trial." Iowa R. Civ. Pro. 1.981(5). The purpose of summary judgment is to enable a party to obtain judgment promptly without an expensive trial where there is no fact issue to try. Bates v. Allied Mut. Ins. Co., 467 N.W.2d 255, 257-58 (Iowa 1998).

23. In this matter, the original parties, Petitioners Iowa Medical Society and the Iowa Society of Anesthesiologists, as well as the Respondents, Iowa Board of Nursing and the Iowa

Department of Public Health, have each filed motions for summary judgment and are seemingly in agreement that this matter should be decided on the record made before the agencies. While the Iowa Nurses Association has sought to introduce additional evidence outside of the record, it is apparent that this matter is most appropriately resolved as a matter of law through this means.

B. Law Applicable to all matters.

24. This action is brought under Chapter 17A of the Iowa Code. Pursuant to Iowa Code § 17A.19, the Court may reverse or grant other appropriate relief from an agency action, including declaratory relief, if the agency action is beyond the authority delegated to it by any provision of law, or is in violation of any provision of the law.

25. An agency may enact rules that are in conformance with the agency's authority and in conformance with the law. *See Iowa Power & Light Co. v. Iowa State Commerce Comm.*, 410 N.W.2d 236, 239 (Iowa 1987); *see* Iowa Code § 17A.19. Although agencies are entrusted with general grants of rulemaking, that general grant of rulemaking authority does not, in and of itself, give an agency interpretive powers over the statute it administers. *Doe v. Iowa Dept. of Human Servs.*, 786 N.W.2d 853, 858 (Iowa 2010). The limitation on an agency's rulemaking authority is why Iowa Code § 17A.19(10) exists.

26. Any rule adopted by an agency must be within the scope of powers delegated to it by statute. *Iowa Power & Light Co. v. Iowa State Commerce Comm.*, 410 N.W.2d at 239. If a rule such as those rules adopted by the IBN and IDPH exceed the agency's statutory authority, those rules are invalid. *See Wallace v. Iowa State Bd. of Educ.*, 770 N.W.2d at 344; *See also Motor Club of Iowa v. Dept. of Tran.*, 251 N.W.2d 510, 517-18 (Iowa 1977).

27. What is at issue in this case is a matter of statutory construction. The IBN and IDPH advance the argument that their rules were enacted according to their enabling statutes and the

will of the legislature. IMS and ISA assert that this is not the case and that the actions of both agencies are outside their statutory authority, and the action of each is erroneous as a matter of law. While other parties have attempted to introduce evidence outside the record and have advanced arguments concerning past and current practices and need analysis, that is not the issue before the court at this time.

C. Action of the Iowa Board of Nursing

28. The Iowa Legislature, in defining the practice of nursing, specifically limited that practice when it said the “practice of nursing” means the practice of a registered nurse or a licensed practical nurse. It does not mean any of the following: (a) The practice of medicine and surgery and the practice of osteopathic medicine and surgery, as defined in Chapter 148, ...except practices which are recognized by the medical and nursing professions and approved by the Board and properly performed by a registered nurse. (Iowa Code § 152.1(5)(a)).

29. The IBN may expand the scope of practice for registered nurses pursuant to Iowa Code section 152.1(6)(d). (Iowa Code § 152.1(6)(d)).

30. Registered nurses may perform additional acts or nursing specialties which require education and training under conditions which are recognized by the medical and nursing professions and are approved by the board as being proper to be performed by a registered nurse. (Iowa Code § 152.1(6)(d)).

31. The IBN derives its authority to define the educational and clinical experience necessary to practice as an ARNP pursuant to Iowa Code § 152.1(6)(d). (Iowa Administrative Code § 655-7.2).

32. The Iowa Code does not provide IBN with unfettered discretion to allow ARNPs to engage in the practice of medicine and it specifically prohibits the expansion of nursing practice into areas of medicine absent recognition of the medical professions.

33. The Iowa Board of Nursing itself, both in its rulemaking process and in its support of the Iowa Department of Public Health rulemaking, could not set forth or point to any recognized standards showing that the medical or nursing professions have recognized ARNP supervision of fluoroscopy either in national training, education or curriculum standards. In fact, the Iowa Association of Nurse Anesthetists admitted during the rulemaking process that CRNAs - an even smaller subspecialty in the scope of nursing - do not receive sufficient training at the University of Iowa Nurse Anesthesia program to make CRNA's competent to utilize fluoroscopy in practice.

34. The medical profession's objections and IBN survey identified above demonstrate as a matter of law that ARNPs' "direct supervision" of fluoroscopy as the term is defined within these rules is not a recognized practice by the medical profession. As such the IBN's rule exceeds its statutorily delegated authority and violates Iowa law.

D. Action of the Iowa Department of Public Health

35. In an action taken subsequent to and in response to the IBN action, IDPH enacted its rule to allow ARNP's to supervise fluoroscopy.

36. In its Concise Statement regarding the rule enacted by IDPH, IDPH states, as justification for its action, "[t]he Iowa Board of Nursing has confirmed that it is within the ARNP's scope of practice to provide direct supervision in the use of fluoroscopic x-ray equipment . . .". (Certified Record of Agency Proceedings page IDPH 3).

37. It is apparent that IDPH relied upon the action of the Iowa Board of Nursing as to the scope of practice of ARNP's, as such, that action was premised upon the mistaken impression that IBN's action in expanding the scope of practice for ARNP's was a legitimate exercise of its statutory authority. That is not the case.

38. In addition to the above, IDPH serves as the state's radiation control agency responsible for regulating the use of radiation machines and radioactive materials, including fluoroscopy. (Iowa Code § 136C.3).

39. A person (other than a "licensed professional") may not operate or use radioactive materials for medical treatment or diagnostic purposes unless that person has completed a course of instruction approved by the department or has otherwise met the minimum training requirements established by the department. (Iowa Code § 136C.14).

40. A licensed professional is a person licensed or otherwise authorized by law to practice medicine, osteopathic medicine, podiatry, chiropractic, dentistry, dental hygiene, or veterinary medicine. ARNPs are not licensed professionals under this definition. (Iowa Code § 136C.1).

41. ARNPs are not "licensed practitioners". (IAC § 641-38.2).

42. IDPH must establish minimum criteria and safety standards, including continuing education requirements, and administer examinations and disciplinary procedures for operators of radiation machines and users of radioactive materials who are not "licensed professionals". (Iowa Code §136C.3(1); Iowa Code § 136C.3(2)(a)).

43. In order for ARNPs to provide "direct supervision" of fluoroscopy as the term is defined within the Iowa Administrative Code, they must satisfy minimum education and safety standards, including continuing education requirements and an examination established by the Iowa Department of Public Health. IDPH may not abrogate this duty to IBN.

44. Even if the expansion of practice by IBN had been valid, which is not the case, neither the IBN or IDPH rules establish a curriculum or minimum criteria and safety standards, including continuing education requirements and an examination as required by law for ARNPs to provide direct supervision of fluoroscopy; rather, the rules are the product of one board's work, setting forth broadly stated training requirements that neither reflect nor connect in any way to any curriculum, training and certification standards developed through the work and consensus of professional standard-setting bodies, whether in nursing or medicine, to assure nursing proficiency and public health safety in the field of radiology.

45. The record before this Court reflects that the desired expansion of nursing practice sought by IBN and IDPH has not been recognized by either the medical or nursing professions nor in standards of radiation health and safety. The Iowa General Assembly, both in Iowa Code Chapter 152 pertaining to nursing, and in the Radiation Machines and Radioactive Materials Act found at Iowa Code Chapter 136C, requires that this threshold be met, which is lacking in this case. Both the IBN and IDPH failed in their rulemaking to meet these minimal statutory requirements.

III. DECREE

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED, that judgment is entered in favor of the Petitioners, and that the enactment of ARC 7888B, now codified within Iowa Administrative Code §655-7.2 and ARC 8659B, now codified within Iowa Administrative Code §641-41.1(5)(n) are held to be invalid, illegal, void and of no effect, and further orders their removal from the Iowa Administrative Code forthwith. This ruling renders all other pending motions moot.

DATED this 31st day of October, 2011.

ARTIS I. REIS, JUDGE
5th Judicial District of Iowa

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