

INDEX FOR PETITION FOR DECLARATORY RULINGS
(UPDATED: SEPTEMBER 10, 2015)

1. John M. Rhodes, Sr., M.D., etal, Petitioners
RE: Delegation of drug dispensing duties
Petition filed: unknown
The Board provided answers to the questions asked.

2. St. Luke's Regional Medical Center, Sioux City, IA, Petitioner
RE: Signature on computerized medical records
Petition filed: December 12, 1985
Petition denied: unknown

3. Tom Mills, Physician's Assistant, Hubbard, IA, Petitioner
RE: Physician Assistant ownership of remote clinic
Petition filed: February 4, 1986
On June 4, 1986, the Board provided answers to the questions asked.

4. Iowa Osteopathic Medical Association, Des Moines, IA, Petitioner
RE: Acupuncture
Petition filed: December 7, 1989
Petition approved: February 15, 1990

5. Mayank K. Kothari, M.D., Petitioner
RE: Computer generated analysis reports
Petition filed: April 23, 1990
On August 1, 1990, the Board provided answers to the questions asked.

6. Iowa Academy of Ophthalmology, Petitioner
RE: Pre-Op & Post-Op responsibilities
Petition filed: May 29, 1992
On November 12, 1992, the Board provided answers to the questions asked.

7. Mary M. Conway, VP, Iowa State Board of Behavioral Sciences, Petitioner
RE: Psychiatric diagnosis by counselors and therapists
Petition filed: August 17, 1995
On October 19, 1995, the Board provided answers to the questions asked.

8. Michael M. Sellers, Attorney, Petitioner
RE: Disciplinary Proceedings
Petition filed: December 8, 1995
Petition denied: January 11, 1996

9. Eileen M. Wayne, M.D., Petitioner
RE: Malpractice
Petition filed: December 25, 1996
Petition denied: January 17, 1997

10. Norman Pawlewski, Iowa Osteopathic Medical Association, Petitioner
RE: Immunizations by Pharmacists
Petition filed: May 4, 1998
Petition denied: June 4, 1998
11. Lawrence C. Valin, M.D., Petitioner
RE: Free Exercise of Religion
Petition filed: October 18, 2006
Petition denied: November 9, 2006
12. Iowa Association of Nurse Anesthetists (IANA), Petitioner
Represented by James W. Carney, Carney & Appleby, P.L.C., Attorney At Law RE:
ARC 8579B, Notice of Intended Action, Establishes standards of practice for
interventional chronic pain management (practice of medicine definition.)
(Interventions: Iowa Dental Association's, Iowa Medical Society's; Iowa Society of
Anesthesiologist's)
Petition filed: April 7, 2010
Petition approved: June 11, 2010
13. Jill Cirivello, Petitioner
RE: Definition of sexual misconduct
Petition filed: July 10, 2015
Petition denied: September 10, 2015
14. Timothy Foley, Aditi Rao, Alex Bare, Petitioners
Re: Rules Relating to Sexual Orientation Change Practices
Petition Filed: February 23, 2016
Petition Denied: April 22, 2016

PETITION FOR DECLARATORY RULING
BEFORE THE IOWA STATE BOARD
OF MEDICAL EXAMINERS

IN THE MATTER OF:

JOHN M. RHODES, SR., M.D.,)	
PHILIP L. MYER, D.O.,)	PETITION FOR
ROBERT G. GERMAN, M.D.,)	DECLARATORY RULING
THOMAS R. WOLF, D.O.,)	
)	
Petitioners,)	

1. The Petitioners names, addresses and phone numbers are:

- a. John M. Rhodes, Sr., M.D.
608 N.W. 7th Street
Pocahontas, Iowa 50574
Telephone: A/C 712/335-3534
- b. Philip L. Myer, D.O.
116 Madison
Manning, Iowa 51455
Telephone: A/C 712/653-2551
- c. Robert G. German, M.D.
2318 Pershing Blvd.
Clinton, Iowa 52732
Telephone: A/C 319/242-3571
- d. Thomas R. Wolf, D.O.
Box 130
Richland, Iowa 52585
Telephone: 515/668-2262

2. On July 5, 1979 the attorney general released an opinion concerning the dispensing of prescription drugs in Iowa which would have restricted the dispensing practices of physicians.

3. Section 33(1) of Chapter 1036 of the Acts of the 68th General Assembly, 1980 session, became effective July 1, 1980. It provided in part that practitioners licensed under chapters 148, 150 and 150A ". . . shall be entitled to continue the practices with respect to dispensing of prescription drugs, including controlled substances, which those practitioners had followed under the laws of this state as amended to July 1, 1979, and as generally interpreted prior to July 5,

1979, notwithstanding the opinion of the attorney general to the secretary of the board of pharmacy examiners rendered on that date. .
."

4. Section 148.6(1) paragraph g provides that the Board of Medical Examiners has the power to revoke or suspend a physician's license to practice for ". . . failure to conform to, the minimal standard of acceptable and prevailing practice of medicine and surgery, osteopathic medicine and surgery or, osteopathy. . ."

5. Section 147.55(3) provides that engaging in a ". . . practice harmful or detrimental to the public" is grounds for revocation of suspension of a professional license.

6. Questions have arisen as to what the minimal standards of acceptable and prevailing practices were with respect to the delegation of certain functions in the dispensing of prescription drugs, including controlled substances, prior to July 5, 1979.

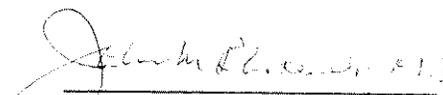
7. These petitioners request declaratory rulings on the following questions as to what the minimal standards of acceptable and prevailing practices are with respect to the delegation of certain functions in the dispensing of prescription drugs, including controlled substances.

(1) May a physician delegate the professional judgmental decision to dispense a prescription drug.

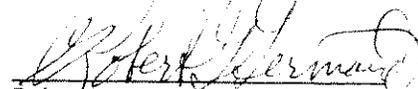
(2) May a physician delegate nonjudgmental functions relating to the dispensing of prescription drugs, including controlled substances, such as counting prepared dosage units and placing them into containers, pouring and measuring prepared liquids into containers, typing labels and delivering filled containers to patients, to assistants under the physician's supervision and direction.

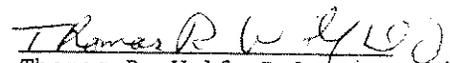
(3) If the answer to (2) is in the affirmative may a

physician so delegate if the physician is not physically present when the nonjudgmental functions are performed or when the prescription drugs are delivered to the patient.


John M. Rhodes, Sr., M.D.


Philip L. Myer, D.O.


Robert G. German, M.D.


Thomas R. Wolf, D.O.

BEFORE THE IOWA STATE
BOARD OF MEDICAL EXAMINERS

IN THE MATTER OF:

JOHN M. RHODES, SR., M.D.)	
PHILIP L. MYER, D.O.,)	DECLARATORY
ROBERT G. GERMAN, M.D.,)	RULING
THOMAS R. WOLF, D.O.,)	
)	
Petitioners,)	

Petitioners have submitted to the Board several questions relating to the dispensing of drugs by physicians.

Petitioners correctly point out that Section 33 (1) of Chapter 1036 of the Acts of the 68th G.A., 1980 session, which was effective July 1, 1980, provides that practitioners licensed under chapters 148, 150, and 150A " . . . shall be entitled to continue the practices with respect to dispensing of prescription drugs, including controlled substances, which those practitioners had followed under the laws of this state as amended to July 1, 1979, and as generally interpreted prior to July 5, 1979, notwithstanding the opinion of the attorney general to the secretary of the board of pharmacy examiners rendered on that date . . . "

Petitioners further correctly point out that the Board may under section 148.6 (1) (g) of the Code, revoke or suspend a physician's license for " . . . failure to conform to the minimal standard of acceptable and prevailing practice of medicine and surgery, osteopathic medicine and surgery or, osteopathy . . . "; and that under section 147.55 (3) of the Code, the Board may revoke or suspend a physician's license for engaging in a " . . . practice harmful or detrimental to the public."

Generally a "practice harmful or detrimental to the public" under section 147.55 (3) of the Code would be a practice less than the acceptable minimal standard under section 148.6 (1) (g) of the Code.

Similarly those practices with respect to dispensing which practitioners had followed prior to July 5, 1979, referred to in section 33 (1) of chapter 1036 of the Acts of the 68th G.A., 1980 session, would be generally the same as the "prevailing practice" under section 148.6 (1) (g) of the Code.

The Board therefore determines that the "minimal standard of acceptable and prevailing practice of medicine and surgery, osteopathic medicine and surgery or osteopathy" prior to July 5, 1979, with respect to the dispensing of prescription drugs is synonymous with "practices with respect to dispensing of prescription drugs, including controlled substances, which those practitioners had followed under the laws of this state as amended to July 1, 1979, as generally interpreted prior to July 5, 1979" and that failure of a physician to conform to such minimal standard of acceptable and prevailing practice may subject a physician to disciplinary action.

Petitioners pose several specific questions as to what such minimal standard of acceptable and prevailing practices relating to the dispensing of prescription drugs were prior to July 5, 1979. To respond to Petitioners questions the Board must make factual determinations as to what such minimal standard of acceptable and prevailing practices were. Upon a review of the facts, diligent investigation by the Board and evidence gathered by the Board and based upon the experience of the professional members of the Board, the Board makes the following

FINDINGS OF FACT

1. Prior to July 5, 1979, it was not the minimal standard of acceptable and prevailing practice for a physician to delegate the professional judgmental decision to dispense, prescribe or administer a prescription drug, including controlled substances.

2. Prior to July 5, 1979, it was the minimal standard of acceptable and prevailing practice for a physician to delegate nonjudgmental functions related to the dispensing of prescription drugs, including controlled substances, to assistants under the physician's supervision and direction.

3. Prior to July 5, 1979, it was the minimal standard of acceptable and prevailing practice for a physician to delegate nonjudgmental functions related to the dispensing of prescription drugs, including controlled substances, to assistants under the physician's supervision and direction when such functions were performed and where the prescription drugs are delivered to the patient by those assistants when the physician was not physically present, but the physician was physically within his or her normal geographic practice area and available to the patient.

RULING

The Board of Medical Examiners therefore rules in response to the specific questions submitted by Petitioners that:

1. A physician may not delegate the professional judgmental decision to dispense a prescription drug.

2. A physician may delegate nonjudgmental functions relating to the dispensing of prescription drugs, including controlled substances, such as counting prepared dosage units and placing them into containers, pouring and measuring prepared liquids into containers, typing labels and delivering filled containers to patients, to assistants under the physician's supervision and direction.

3. A physician may so delegate nonjudgmental functions relating to the dispensing of prescription drugs, including controlled substances, to assistants under the physician's supervision and direction when the physician is not physically present when the nonjudgmental functions are performed and the drugs are delivered to the patient, but only if the physician is physically within his or her normal geographic practice area and available to the patient.

IOWA BOARD OF MEDICAL EXAMINERS



Alexander Ervanian, M.D., Chairman
Iowa Board of Medical Examiners
State Capitol Complex
Executive Hills West
Des Moines, Iowa 50319

BEFORE THE IOWA STATE BOARD OF MEDICAL EXAMINERS

LUCAS STATE OFFICE BUILDING

DES MOINES, IOWA

IN THE MATTER OF THE PETITION : PETITION FOR DECLARATORY
OF : RULING

ST. LUKE'S REGIONAL MEDICAL CENTER :
FOR A DECLARATORY RULING ON THE :
USE OF COMPUTER ACCESS CODES AS : DOCKET NO. _____
A LEGAL SIGNATURE IN CONNECTION :
WITH COMPUTERIZED MEDICAL RECORDS :

1. The Petitioner's name is St. Luke's Regional Medical Center and its address is 2720 Stone Park Boulevard, P.O. Box 2000, Northside Station, Sioux City, Iowa 51104, telephone number (712) 279-3500.

2. Petitioner requests a declaratory ruling approving the use of the proposed procedures which are attached hereto and which are incorporated herein by reference approving the use of computer access codes as the legal equivalent of a signature in connection with the maintenance of medical records.

3. No specific statute, rule, written statement of law, or policy, decision or order is involved with this issue. The relevant authority is as follows:

Iowa Code 1985 Section 4.1(17)

Iowa Administrative Code 470-135.204(3)(d)

470-136.5(5)(b)(1)

470.51.5

The particular issue to which this request is addressed is the adequacy of a computer access code assuming adequate safeguards

are utilized, as the legal equivalent of a physical signature in connection with the maintenance of medical records.

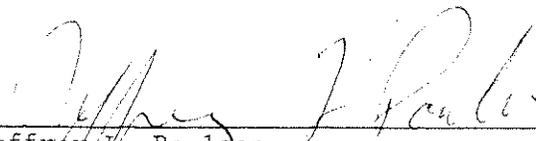
4. St. Luke's Regional Medical Center is presently implementing a computerized medical records system. All orders and medical records will be entered onto the computer and maintained in this system. A review of the law relevant to this issue establishes that there is no statute or regulation preventing the use of the user access code as a signature, nor is there controlling authority authorizing this and a clarification of these rules is needed to bring the medical record's rules into the computer age.

5. The nature of the Petitioner's interest in this question is that should the department issue a declaratory ruling approving the procedures which are hereby proposed, the Medical Center will be relying upon them in its normal operation and in the maintenance of medical records including the use of computer access codes as the legal equivalent of a written signature.

ST. LUKE'S REGIONAL MEDICAL CENTER

By: 
Robert F. Peck, President

CORBETT, ANDERSON, CORBETT & DANIELS

By: 
Jeffrey E. Poulson
330 Security Bank Building
P.O. Box 3527
Sioux City, IA 51102
(712) 277-1261
ATTORNEYS FOR ST. LUKE'S REGIONAL
MEDICAL CENTER

DEPARTMENT	INFORMATION RESOURCES	EFFECTIVE DATE		
		DATE	October 4, 1984	
SUBJECT	USER ACCESS CODES	NUMBER OF PAGES	2	PAGE NUMBER 1

PURPOSE: To ensure patient confidentiality; integrity and accuracy of data; appropriate usage of the Medical Information System; and protection of Medical Center assets against accidental/intentional disclosure, modification or destruction.

POLICY: Authorized individuals may have access to the Medical Information System (MIS) only after successful completion of the MIS Training Program. Access to MIS will be controlled by a user identification code referred to as the USER ACCESS CODE. The code limits individual access to only that patient information needed to perform job responsibilities, and the identity of the user will be recorded on all entries. The Director of Education Services will be responsible for the training of individuals. The Director of Information Resources will be responsible for the distribution of User Access Codes and maintaining the appropriate use of MIS.

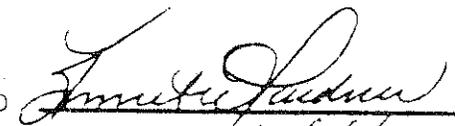
The Director of the Information Resources Department will be responsible for establishing department policy and procedure to ensure effective supervision of those individuals responsible for maintaining the integrity of MIS.

- PROCEDURE:
1. Medical Center personnel, Medical Staff members, and other approved user groups will successfully complete the Medical Center's Medical Information System Training Program prior to being eligible for a User Access Code.
 2. Individuals will sign a User Access Code Agreement prior to receiving their access code.
 3. User Access Codes are subject to change as required by changes in the individual's job responsibilities and/or at the discretion of the Information Resources Department.
 4. Individuals who have reason to believe that the confidentiality of their User Access Code has been violated will contact the Information Resources Department immediately so that the current code may be deleted and a new access code assigned.

APPROVED _____

DEPARTMENT	INFORMATION RESOURCES	EFFECTIVE DATE	
		DATE	October 4, 1984
SUBJECT	USER ACCESS CODES	NUMBER OF PAGES	PAGE NUMBER
		2	2

- 5. Department Directors are responsible to monitor employee performance with regard to MIS usage.
- 6. Individuals who knowingly violate their User Access Code Agreement are subject to disciplinary action. The matrix duty officer from Information Resources should be notified immediately whenever a violation of the user access code policy occurs, so that the matrix duty officer can immediately delete the user access code of the person violating the policy. Disciplinary action will be the responsibility of the Department Director and should be coordinated through the Human Resources Department for consistency.
- 7. User Access Codes will be deleted from the system upon termination/resignation of individuals affiliated with the Medical Center or a change in job responsibilities not requiring a User Access Code. The Department Directors will have the responsibility to notify the Human Resources Department of the date such changes will occur. The Director of Human Resources will then have responsibility to notify the Director of Information Resources.

APPROVED 
110-8-84

ST. LUKE'S REGIONAL MEDICAL CENTER
Sioux City, Iowa

USER ACCESS CODE AGREEMENT

Authorized Personnel

I, the undersigned, acknowledge receipt of my USER ACCESS CODE and understand that:

1. My USER ACCESS CODE is the legal equivalent of my signature; I will not disclose this code to anyone.
2. I will not attempt to learn another's USER ACCESS CODE and will not access information in the Medical Information System (MIS) by using a USER ACCESS CODE other than my own.
3. I will not access any unauthorized information via the Medical Information System.
4. If I have reason to believe that the confidentiality of my USER ACCESS CODE has been broken, I will contact the Department of Information Resources immediately so that the current code may be deleted and a new USER ACCESS CODE assigned to me.
5. I will protect the patient's right to the CONFIDENTIALITY of his/her medical information.

I understand that if I violate any of the above statements, I will be subject to disciplinary action, i.e., suspension, immediate termination, or loss of MIS privileges. Grievances will be handled according to the Medical Center's Personnel Manual.

I further understand that my USER ACCESS CODE will be deleted from the system as soon as I terminate my employment at St. Luke's Regional Medical Center; should I be re-employed at the Medical Center, a new USER ACCESS CODE will be issued at that time.

EMPLOYEE NAME (PLEASE PRINT)

SIGNATURE OF ISSUER

SIGNATURE OF EMPLOYEE

DATE

DATE

ST. LUKE'S REGIONAL MEDICAL CENTER
Sioux City, Iowa

MEDICAL STAFF USER ACCESS CODE AGREEMENT

USER ACCESS CODES are created to allow an individual access to the Medical Center's Medical Information System (MIS) for the purpose of entering and retrieving patient information. A physician USER ACCESS CODE limits the individual physician's access to specific patient data and system features that are necessary in providing medical care to patients under the direct care of the physician.

Because of the Medical Center's concern to maintain the integrity and confidentiality of patient information and to ensure that only authorized individuals may access the patient's medical record, it has become necessary to establish guidelines governing the use of the USER ACCESS CODE. The guidelines are listed below.

I, the undersigned, acknowledge receipt of my USER ACCESS CODE and understand that:

1. My USER ACCESS CODE is the legal equivalent of my signature.
2. My USER ACCESS CODE personally identifies me to the Medical Information System.
3. I will not disclose my USER ACCESS CODE to anyone.
4. I will not attempt to learn another's USER ACCESS CODE and will not access information in the Medical Information System (MIS) by using a USER ACCESS CODE other than my own.
5. If I have reason to believe that the confidentiality of my USER ACCESS CODE has been broken, I will contact the Department of Information Resources immediately so that the current code may be deleted and a new USER ACCESS CODE assigned to me.

I understand that if I violate any of the above statements, my MIS privileges will be summarily suspended and the suspension then reviewed in accordance with the Medical Staff Bylaws.

I further understand that my USER ACCESS CODE will be deleted from the system should I no longer be a member of the active, courtesy or affiliate staff at St. Luke's Regional Medical Center.

PHYSICIAN NAME (PLEASE PRINT)

SIGNATURE OF ISSUER

SIGNATURE OF PHYSICIAN

DATE

DATE

BEFORE THE IOWA STATE BOARD OF MEDICAL EXAMINERS
LUCAS STATE OFFICE BUILDING
DES MOINES, IOWA

IN THE MATTER OF THE PETITION : DOCKET NO. 1
OF :
ST. LUKE'S REGIONAL MEDICAL CENTER : BRIEF AND ARGUMENT IN
FOR A DECLARATORY RULING ON THE : SUPPORT OF PETITION FOR
USE OF COMPUTER ACCESS CODES AS : DECLARATORY RULING
A LEGAL SIGNATURE IN CONNECTION
WITH COMPUTERIZED MEDICAL RECORDS :

IOWA LAW

The Iowa Law in regards to signatures on medical orders has not yet entered the computer age. The only provision in the code which applies to this issue is Iowa Code Section 4.1(17) which provides in part that the words "written" or "in writing" include any mode of representing words or letters in general use. A signature, when required by law, must be made by the writing or writings of the person whose signature is required. Certain exceptions apply in the event of persons unable to make a written signature due to physical handicap.

What constitutes a "writing" or "writings" had one meaning in the era of quill pens and ink wells and has an entirely different meaning in the computer age. As computer access codes are in general use and as they fulfill the function of a signature there is sufficient latitude in the Iowa statutory law to accommodate the concept of a computer access code as a legal signature.

The present regulations of the Department of Health also follow the statute in not specifically dealing with the adequacy of a computer access code as a signature. For example, Section 470-51.5(1) requires that medical records be written and signed by the attending physician and stored in an accessible manner in the hospital. Once again, what is understood by the terms "written" or "signed" is determined by generally recognized usage.

As discussed above, as "written" or "signed" is to be defined by general usage, all that is needed is to recognize the use of computer codes as "signature" and the proposed regulations are consistent with this rule.

Section 470-135.204(3)(d) includes in the definition of professional incompetency under the category of practices harmful or detrimental to the public, the practice of using rubber stamps to affix signatures on prescriptions. The problem with the rubber stamp is the lack of safeguards assuring that the physician is actually signing the prescription. This problem is not applicable to the computer access code for the reason that the procedure proposed by St. Luke's Regional Medical Center provides extensive safeguards preventing unauthorized use. All of these safeguards are designed to prevent this occurrence and the rubber stamp example does not represent a valid analogy when dealing with the question of computer access codes.

An additional rule which touches on this issue is Section 470-126.5(5)(b)(1) which provides for the physician's countersignature on all physician's assistant's orders. Under the proposed regulations, the doctor would have his computer access code as would the physician's

assistant. Under the regulations and procedures proposed by St. Luke's Regional Medical Center, both codes would be used to indicate the assistant's "signature" as well as the physician's "co-signature." All safeguards that the co-signature is to provide would be completely satisfied by the proposed procedure.

A petition for declaratory ruling almost identical to this petition was presented to the Commissioner of Health. On October 9, 1985, the Commissioner ruled that "in view of the stated procedures and safeguards employed in the use of the Medical Information System by St. Luke's Regional Medical Center, this system of computerized medical records would be in compliance with 470 IAC 51.5(5) for purposes of state hospital licensure.

OTHER AUTHORITY

Despite the relative dirth of Iowa authority on this issue, there is extensive authority supporting the requested procedures from other sources. The most prominent is Standard 3 of the Medical Records Services Section, Page 68 of the Accreditation Manual for Hospitals promulgated by the Joint Commission on Accreditation of Hospitals (JCAH). This Section provides that, "all entries in the record must be dated and authenticated, and a method must be established to identify the authors of entries. Such identification may include written signatures, initials, or computer key."

Not only do the JCAH Standards specifically permit authentication, but the Medicare/Medicaid Conditions of Participation provide that hospitals currently accredited by the Joint Commission are deemed to meet all of the conditions of participation, (with some exceptions that do not apply here),

and any specific Medicare/Medicaid standards that are in conflict with this are not applicable. CCH Medicare and Medicaid Guides Subsection 12,330 page 5057.

Other states have adopted either the Medicare/Medicaid conditions which by reference adopt the JCAH standards, or have adopted similar standards. For example, the Minnesota Department of Health uses the Medicare Conditions of Participation standards, including the incorporation by reference of the JCHA standards. Letter dated June 10, 1982, from Supervisor, Records and Information Unit, Health Systems Division, Minnesota Department of Health.

Missouri has adopted rules similar to the JCAH Standards. "Authenticate" is defined as "To prove authorship - for example by written signature, identifiable initials, or computer key." Missouri Hospital Licensing Regulations 13 C.S.R. 50-20.11(2)1-15-83.

In addition, Missouri requires that "patient care shall be entered by members of the medical staff, nursing staff, and allied health professionals in the patient's medical records in a timely manner. Documentation shall be legible, dated, authenticated, and recorded in ink, typewritten or recorded electronically. ID, 13CSR 50-20.021(3)(d) 1-15-83.

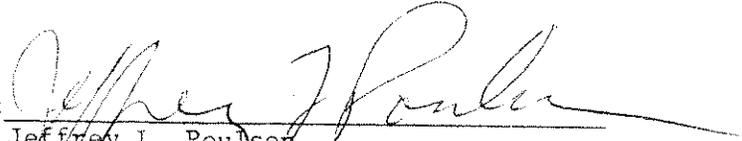
In Nebraska, physician's orders are specifically to be written and dated in ink or indelible pencil or entered into a computer using a physician code system, subject to individual hospital policies where appropriate safeguards have been taken to limit access and use of the facsimile or code to the individual physician. Regulations and Standards for Hospitals, Rule 30, State of Nebraska Department of Health, Part III Di(c), page 30-29 April 23, 1979.

CONCLUSION

The requested procedures do not violate any statutory or regulatory law. The procedures simply recognize a new form of "signature" which involves only an interpretation of ambiguous existing rules. The JCAH Standards are recognized by Medicare/Medicaid on a national basis. In addition, other states in this area have incorporated the JCAH Standards, or specifically adopted rules acknowledging the computer access code as a legal signature. Adoption of the proposed procedures and recognition by the Department of Health of the computer access code as a legal signature is consistent with how other states have resolved this question, and is consistent with good and safe health care as recognized by national standards.

Respectfully submitted.

CORBETT, ANDERSON, CORBETT & DANIELS

By: 

Jeffrey L. Poulson
330 Security Bank Building
P.O. Box 3527
Sioux City, IA 51102
(712) 277-1261
ATTORNEYS FOR ST. LUKE'S REGIONAL
MEDICAL CENTER

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF THE)
PETITION OF ST. LUKE'S REGIONAL) DECLARATORY RULING
MEDICAL CENTER)

PROCEDURE

On December 12, 1985, the Iowa Board of Medical Examiners received a Petition for Declaratory Ruling filed by attorney Jeffrey L. Poulson pursuant to 470 I.A.C. § 135.10. The Petitioner is identified as St. Luke's Regional Medical Center, 2720 Stone Park Boulevard, P.O. Box 2000, Northside Station, Sioux City, Iowa 51104.

FACTS

St. Luke's Regional Medical Center is presently implementing a computerized medical records system. All orders and medical records will be entered onto the computer and maintained in this system. Computer access codes will be used as the equivalent of a signature by physicians in connection with the maintenance of medical records. The system will be used in the manner described in Exhibit 1, 2 and 3. (Attached)

QUESTION PRESENTED

Will utilization of the computerized medical records system by licensees to sign medical records through use of a computer access code violate § 4.1(17) of The Code or 470 I.A.C. §§ 51.5, 135.204(3)d or 136.5(5)b(1) of the Iowa Administrative Code?

AUTHORITIES

Iowa Code § 4.1(17):

Written -- in writing -- signature. The words "written" and "in writing" may include any mode of representing words or letters in general use. A signature, when required by law, must be made by the writing or markings of the person whose signature is required. If a person is unable due to a physical handicap to make a written signature or mark, that person may substitute the following in lieu of a signature required by law:

- a. The handicapped person's name written by another upon the request and in the presence of the handicapped person; or,
- b. A rubber stamp reproduction of the handicapped person's name or facsimile of the actual signature when adopted by the handicapped person for all purposes requiring a signature and then only when affixed by that person or another upon request and in the presence of the handicapped person.

470 I.A.C. § 51.5:

51.5(1) Medical records. Accurate and complete medical records shall be written for all patients and signed by the attending physician; these shall be filed and stored in an accessible manner in the hospital and in accordance with the statute of limitations.

51.5(2) Hospital records.

a. Admission records. A register of all admissions to the hospital shall be kept in accordance with Iowa law.

b. Death records. A register of all deaths in the hospital shall be kept, including all information required on a standard certificate.

c. Birth records. A register of all births in the hospital shall be kept, including all information required on a standard certificate.

d. Narcotic records. Narcotic records shall be maintained in accordance with the laws and regulations pertaining thereto.

51.5(4) All hospitals shall submit annually to the commissioner the Hospital Price Information Survey in accordance with Iowa Administrative Code 465--8.2(145) and

shall post hospital price information in accordance with Iowa Administrative Code 465--8.3(145).

470 I.A.C. § 135.204(3)d:

135.204(3) Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of a profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

* * * *

d. Practice harmful or detrimental to the public includes, but is not limited to, the use of a rubber stamp to affix a signature to a prescription. A person who is unable, due to a physical handicap, to make a written signature or mark, however, may substitute in lieu of a signature a rubber stamp which is adopted by the handicapped person for all purposes requiring a signature and which is affixed by the handicapped person or affixed by another person upon the request of the handicapped person and in his/her presence.

470 I.A.C. § 136.5(5)b(1):

136.5(5) It shall be the responsibility of the supervising physician to ensure that:

* * * *

b. Adequate supervision and review of the work of the physician's assistant is provided.

(1) The supervising physician shall review at least weekly all patient care provided by the physician's assistant if such care is rendered without direct consultation with the physician and shall countersign all notes made by the physician's assistant.

RULING

The Board of Medical Examiners will issue a declaratory ruling only with respect to statutes and rules "under its jurisdiction." 470 I.A.C. § 135.10(1). Accordingly, we confine

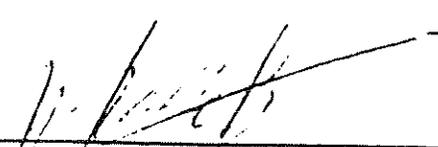
our declaratory ruling to interpretation of 470 I.A.C. §§ 135.204(3)d and 136.5(5)b(1) which are rules promulgated by this Board. We acknowledge § 4.1(17) of the Code as a codified principle of statutory construction. We, however, do not address 470 I.A.C. § 51.5 which is a rule promulgated by the Department of Health.

Disciplinary action may be initiated against a licensee on the basis of 470 I.A.C. § 135.204(3) which prohibits, in part, engaging in a practice harmful or detrimental to the public. We have promulgated subrule d to further define practice harmful or detrimental to the public to include the use of a rubber stamp to affix a signature to a prescription except under limited circumstances applicable to the handicapped. 470 I.A.C. § 135.204(3)d. Application of 470 I.A.C. § 135.204(3) in other circumstances is adjudicated on a case-by-case basis.

Use of a computer access code to sign medical records would not constitute a practice harmful or detrimental to the public under the facts set out in this declaratory ruling. All medical staff and authorized personnel who would use the computer access code must sign an agreement before the code is issued. Under the terms of this agreement, the code is confidential. The user, moreover, is obligated to report any break in confidentiality. A user who violates this confidentiality, furthermore, is subject to disciplinary action including possible termination. In view of these security measures, we cannot conclude that use of the computer access code to sign medical records in the manner set

out in this petition would constitute a practice harmful or detrimental to the public which would result in disciplinary action by this Board.

Different considerations govern the countersignature of medical records by a physician who provides supervision to a physician's assistant. Under 470 I.A.C. § 136.5(5)b(1), the supervising physician must review at least weekly all patient care provided by the physician's assistant if care is rendered without direct consultation and must countersign all notes made by the physician's assistant. Under these circumstances the physician's signature not only validates the notes made by the physician's assistant but also evinces a discharge of the duty to review all patient care. The security measures built into the computerized medical records system may be sufficient to insure that physician's signature is genuine. Adequate supervision of a physician's assistant, however, requires that the review of patient care be carried out on site. In view of the supervisory duties, therefore, we conclude a computer access code cannot be used to countersign the notes of a physician's assistant pursuant to 470 I.A.C. § 136.5(5)b(1).



HORMOZ/RASSEKH, M.D.
Chairman
Iowa Board of Medical Examiners

RECEIVED
10 15

DEPARTMENT	INFORMATION RESOURCES	EFFECTIVE DATE	DATE	October 4, 1984
SUBJECT	USER ACCESS CODES	NUMBER OF PAGES	2	PAGE NUMBER 1

PURPOSE: To ensure patient confidentiality; integrity and accuracy of data; appropriate usage of the Medical Information System; and protection of Medical Center assets against accidental/intentional disclosure, modification or destruction.

POLICY: Authorized individuals may have access to the Medical Information System (MIS) only after successful completion of the MIS Training Program. Access to MIS will be controlled by a user identification code referred to as the USER ACCESS CODE. The code limits individual access to only that patient information needed to perform job responsibilities, and the identity of the user will be recorded on all entries. The Director of Education Services will be responsible for the training of individuals. The Director of Information Resources will be responsible for the distribution of User Access Codes and maintaining the appropriate use of MIS.

The Director of the Information Resources Department will be responsible for establishing department policy and procedure to ensure effective supervision of those individuals responsible for maintaining the integrity of MIS.

- PROCEDURE:
1. Medical Center personnel, Medical Staff members, and other approved user groups will successfully complete the Medical Center's Medical Information System Training Program prior to being eligible for a User Access Code.
 2. Individuals will sign a User Access Code Agreement prior to receiving their access code.
 3. User Access Codes are subject to change as required by changes in the individual's job responsibilities and/or at the discretion of the Information Resources Department.
 4. Individuals who have reason to believe that the confidentiality of their User Access Code has been violated will contact the Information Resources Department immediately so that the current code may be deleted and a new access code assigned.

APPROVED _____



DEPARTMENT	INFORMATION RESOURCES	EFFECTIVE DATE	October 4, 1984	
SUBJECT	USER ACCESS CODES	NUMBER OF PAGES	2	PAGE NUMBER 2

5. Department Directors are responsible to monitor employee performance with regard to MIS usage.
6. Individuals who knowingly violate their User Access Code Agreement are subject to disciplinary action. The matrix duty officer from Information Resources should be notified immediately whenever a violation of the user access code policy occurs, so that the matrix duty officer can immediately delete the user access code of the person violating the policy. Disciplinary action will be the responsibility of the Department Director and should be coordinated through the Human Resources Department for consistency.
7. User Access Codes will be deleted from the system upon termination/resignation of individuals affiliated with the Medical Center or a change in job responsibilities not requiring a User Access Code. The Department Directors will have the responsibility to notify the Human Resources Department of the date such changes will occur. The Director of Human Resources will then have responsibility to notify the Director of Information Resources.

APPROVED



 110-8-84

ST. LUKE'S REGIONAL MEDICAL CENTER
Sioux City, Iowa

USER ACCESS CODE AGREEMENT

Authorized Personnel

I, the undersigned, acknowledge receipt of my USER ACCESS CODE and understand that:

1. My USER ACCESS CODE is the legal equivalent of my signature; I will not disclose this code to anyone.
2. I will not attempt to learn another's USER ACCESS CODE and will not access information in the Medical Information System (MIS) by using a USER ACCESS CODE other than my own.
3. I will not access any unauthorized information via the Medical Information System.
4. If I have reason to believe that the confidentiality of my USER ACCESS CODE has been broken, I will contact the Department of Information Resources immediately so that the current code may be deleted and a new USER ACCESS CODE assigned to me.
5. I will protect the patient's right to the CONFIDENTIALITY of his/her medical information.

I understand that if I violate any of the above statements, I will be subject to disciplinary action, i.e., suspension, immediate termination, or loss of MIS privileges. Grievances will be handled according to the Medical Center's Personnel Manual.

I further understand that my USER ACCESS CODE will be deleted from the system as soon as I terminate my employment at St. Luke's Regional Medical Center; should I be re-employed at the Medical Center, a new USER ACCESS CODE will be issued at that time.

EMPLOYEE NAME (PLEASE PRINT)

SIGNATURE OF ISSUER

SIGNATURE OF EMPLOYEE

DATE

DATE



ST LUKE'S REGIONAL MEDICAL CENTER
Sioux City, Iowa

MEDICAL STAFF USER ACCESS CODE AGREEMENT

USER ACCESS CODES are created to allow an individual access to the Medical Center's Medical Information System (MIS) for the purpose of entering and retrieving patient information. A physician USER ACCESS CODE limits the individual physician's access to specific patient data and system features that are necessary in providing medical care to patients under the direct care of the physician.

Because of the Medical Center's concern to maintain the integrity and confidentiality of patient information and to ensure that only authorized individuals may access the patient's medical record, it has become necessary to establish guidelines governing the use of the USER ACCESS CODE. The guidelines are listed below.

I, the undersigned, acknowledge receipt of my USER ACCESS CODE and understand that:

1. My USER ACCESS CODE is the legal equivalent of my signature.
2. My USER ACCESS CODE personally identifies me to the Medical Information System.
3. I will not disclose my USER ACCESS CODE to anyone.
4. I will not attempt to learn another's USER ACCESS CODE and will not access information in the Medical Information System (MIS) by using a USER ACCESS CODE other than my own.
5. If I have reason to believe that the confidentiality of my USER ACCESS CODE has been broken, I will contact the Department of Information Resources immediately so that the current code may be deleted and a new USER ACCESS CODE assigned to me.

I understand that if I violate any of the above statements, my MIS privileges will be summarily suspended and the suspension then reviewed in accordance with the Medical Staff Bylaws.

I further understand that my USER ACCESS CODE will be deleted from the system should I no longer be a member of the active, courtesy or affiliate staff at St. Luke's Regional Medical Center.

PHYSICIAN NAME (PLEASE PRINT)

SIGNATURE OF ISSUER

SIGNATURE OF PHYSICIAN

DATE

EXHIBIT

3

DATE

PETITION FOR DECLARATORY RULING
BEFORE THE IOWA STATE BOARD
OF MEDICAL EXAMINERS

IN THE MATTER OF:)	
)	
TOM MILLS, Physician's)	
Assistant,)	PETITION FOR
)	DECLARATORY RULING
Petitioner,)	

1. The Petitioner's name, address and phone number are:

Mr. Tom Mills
Hubbard Medical Clinic
Hubbard, Iowa 50122
(515) 864-3301

2. HYPOTHETICAL SITUATION NO. 1

a. Physician's assistant contracts with physician for the latter to provide all the medical supervision required by state statute and Board of Medical Examiner regulations. Physician's assistant agrees to pay a fixed fee to the physician for latter's supervisory services.

b. Physician's assistant performs the supervised medical services at a "place remote" from the physician's primary place.

c. Physician's assistant enters into lease for rental of medical clinic facility to be used at the "place remote" by supervising physician and physician's assistant.

d. Physician's assistant employs the clinic's staff. Clerical staff is supervised by the physician assistant. Nursing staff is supervised by supervising physician and physician's assistant.

e. Physician's assistant is responsible for all expenses of clinic and receives all clinic income (except for fees charged by supervising physician directly to patients seen by the physician). Physician's assistant is responsible for any financial deficit of the clinic.

f. Physician's assistant and supervising physician meet all other state requirements to qualify for approval of application to supervise the physician's assistant at this clinic.

3. HYPOTHETICAL SITUATION NO. 2

a. Physician's assistant agrees to be employed by supervising physician at a "place remote" clinic and enters into employment contract with supervising physician.

b. Employment contract duties of supervising physician:

1) Review and supervise physician's assistant's performance of medical services at the clinic as required by law and regulation.

2) Consult with and evaluate physician's assistant's overall performance.

c. Employment contract duties of physician's assistant:

1) Arrange suitable quarters for the clinic.

2) Attend to clinic's patients under the supervision of the supervising physician.

3) Organize and manage all non-medical aspects of the clinic including but not limited to the employment of the clinic's staff, the non-medical supervision of that staff, and the handling of billings and collections.

d. Compensation provisions of the employment contract:

1) Supervising physician will retain each month the first \$1,000 from the clinic's gross income and a sum sufficient to pay all employment taxes. In addition the supervising physician will receive the fees he charges for patient visits that he conducts at the clinic.

2) Physician's assistant will receive as salary all other clinic income less clinic expenses.

3) If clinic in a given month operates at a deficit, physician's assistant is responsible for the deficit.

e. Physician's assistant and supervising physician meet all other state requirements to qualify for approval of application to supervise the physician's assistant at this clinic.

4. HYPOTHETICAL SITUATION NO. 3

a. A non-licensed, private individual rents a medical clinic at a "place remote".

b. The private individual employs a supervising physician and physician's assistant to operate the clinic at the "place remote".

c. Employment contract duties of the supervising physician:

1) Supervise and review the physician's assistant's performance of medical services at the clinic as required by law and regulation.

2) Consult with and evaluate physician's assistant's overall performance.

3) Supervising physician will be compensated at an agreed upon rate in addition to the patient fees he charges.

d. Employment contract duties of physician's assistant:

1) Attend to clinic's patients under the supervision of the supervising physician.

2) Organize and manage all non-medical aspects of the clinic including but not limited to the employment of the clinic's staff, the non-medical supervision of that staff, and the handling of billings and collections.

3) Physician's assistant compensated at an agreed upon rate.

e. Non-licensed, private individual retains the net profits, if any, of the clinic and is responsible for any financial deficit of the clinic.

f. Non-licensed, private individual is the spouse of the physician's assistant.

g. Physician's assistant and supervising physician meet all other state requirements to qualify for approval of application to supervise the physician's assistant at this clinic.

5. This petition for declaratory ruling is sought for Chapter 148C of the Iowa Code and Chapter 136 of the Department of Health's regulations.

6. The specific statutory and regulation language which is the subject of this inquiry is:

a. Section 148C.4, Iowa Code: "A physician's assistant may perform medical service when such services are rendered under the supervision of a licensed physician or physicians approved by the board." (emphasis added)

b. 470 IAC 136.1(148C) ". . . The licensed physician shall in all cases be regarded as the employer of the physician's assistant and shall be responsible for establishing whatever supervision is necessary to ensure that the physician's assistant is performing properly in the field of medicine for which he or she is trained and the acts which he or she is authorized by law to perform." (emphasis added)

c. 470 IAC 136.5(5) 148C "It shall be the responsibility of the supervising physician to ensure that: (d) the employed physician's assistant performs only those tasks which have been authorized by the board."

7. The specific questions raised by this Petition for Declaratory Ruling are:

a. Will the Board of Medical Examiners, based on its authority to approve the use of physician's assistants to perform medical services, approve an application based on the facts outlined in Hypothetical Situation No. 1?

b. Will the Board of Medical Examiners, based on its authority to approve the use of physician's assistants to perform medical services, approve an application based on the facts outlined in Hypothetical Situation No. 2?

c. Will the Board of Medical Examiners, based on its authority to approve the use of physician's assistants to perform medical services, approve an application based on the facts outlined in Hypothetical Situation No. 3?

8. A brief in support of this Petition for Declaratory Ruling is attached hereto and incorporated herein by this reference.

BELIN HARRIS HELMICK,
A Professional Corporation

By *Dennis J. Nagel*
Dennis J. Nagel

2000 Financial Center
Des Moines, Iowa 50309
Phone: (515) 243-7100

ATTORNEYS FOR TOM MILLS

PETITION FOR DECLARATORY RULING
BEFORE THE IOWA STATE BOARD
OF MEDICAL EXAMINERS

IN THE MATTER OF:)	
)	
TOM MILLS, Physician's)	BRIEF IN SUPPORT OF
Assistant,)	PETITION FOR DECLARATORY
)	RULING
Petitioner,)	

INTRODUCTION

Chapter 148C of the Code was passed in 1971 to permit the use of physician's assistants under the supervision of physicians. Petitioner requests guidance from the Board of Medical Examiners (BME) on the general issue of whether the authority granted in Chapter 148C and the BME regulations impinges in any material way on the non-medical aspects of the relationship between the supervising physician and the physician's assistant. To that end, Petitioner submits three sets of hypothetical facts to which he desires responses from the BME. For the reasons advanced below, Petitioner respectfully urges the BME to respond affirmatively to each question.

- I. THE CODE AND THE BME REGULATIONS REGULATE ONLY MEDICAL SERVICES AND DO NOT RESTRICT NON-MEDICAL ASPECTS OF THE RELATIONSHIP BETWEEN A SUPERVISING PHYSICIAN AND A PHYSICIAN'S ASSISTANT.

The statutory and regulatory provisions governing the use of physician's assistants are directed solely at the medical services aspect of the relationship between a supervising

physician and a physician's assistant. "Physician's assistant" is defined by the Code as "a person who . . . is approved by the board to perform medical services under the supervision of one or more physician's . . ." §148C.1(6). (emphasis added) This focus is also found in the other key sections of Chapter 148C:

...A physician's assistant shall perform only those services for which the physician's assistant is qualified by training, and shall not perform a service that is not permitted by the Board..." §148C.3

A physician's assistant may perform medical service when such services are rendered under the supervision of a licensed physician or physicians approved by the Board. §148C.4. (emphasis added)

The singular focus of the statute on medical services is proper. The State's interest and purpose of licensing is to protect the welfare of its citizens in the delivery of health care. State, ex rel. Iowa Department of Health v. Van Wyk, 320 N.W.2d 599, 605 (1982); Craven v. Bierring, 269 N.W. 801, 804, 222 Iowa 613 (1936). The BME has adopted the same approach of focusing on the medical service aspect in its regulations governing the use of physician's assistants. (See 470 IAC Chapter 136 generally).

II. ANY LIMITING LANGUAGE IN THE BME REGULATIONS SHOULD BE READ TO ACCOMMODATE A POSITIVE RESPONSE TO PETITIONER.

Petitioner's Hypothetical Situation No. 1 states that the physician's assistant contracts with the supervising physician for the latter to provide the necessary medical supervi-

sion. An employer/employee relationship would not be established. One provision of the BME regulations might suggest that this hypothetical contractual relationship is not permitted ("The licensed physician shall in all cases be regarded as the employer of the physician's assistant...." 470 IAC 136.1.) The language of Chapter 148C makes no reference to a required employer/employee relationship. Instead, the Code keys on the medical "supervision" that is required and does not preclude any particular working or financial relationship between the supervising physician and the physician's assistant so long as medical supervision is provided for. §148C.4. Indeed, the BME regulations also reflect this thrust in the same sentence of 470 IAC 136.1 as previously quoted. The supervising physician is directed to be responsible for "establishing whatever supervision is necessary to insure that the physician's assistant is performing properly in the field of medicine...." 470 IAC 136.1. (emphasis added) Petitioner suggests that the use of the word "employer" in 470 IAC 136.1 refers solely to the medical supervisory relationship that is required by the Code. The basic prerogative of an "employer" is the right to direct and supervise his or her employees. That direction and supervision would be fully accomplished in each of the hypothetical situations that Petitioner has submitted to the BME. Accordingly, the "employer" provision of 470 IAC 136.1 should not be read to preclude an affirmative response to any of the three hypotheticals.

The BME was sensitive to the difficulty of defining what medical services could be provided by a physician's assistant at the time it adopted its current rules. The BME regulations provide an illustrative list of the type of medical services the Board will permit. 470 IAC 136.5(1)(a-n). While each of these examples relates to various aspects of medical care, subsection (i) does mention several tasks which also relate to the management of a medical office. This language should not be interpreted to suggest that the absence of other related management examples precludes a positive response to any of Petitioner's questions. The introductory language to 470 IAC 136.5(1) clearly states that the list of examples is not meant to be exhaustive. The regulation notes that the "ultimate role of the assistant to the physician cannot be rigidly defined." Furthermore, it should be noted that none of the examples speaks in any respect to the financial relationship that might exist between the supervising physician and the physician's assistant.

III. THE BME SHOULD RESPOND AFFIRMATIVELY TO THE QUESTIONS
POSED IN THE PETITION FOR DECLARATORY RULING.

Petitioner has submitted three sets of hypothetical facts to the BME each outlining an alternative relationship between the supervising physician and the physician's assistant. However, the common element to each of the three sets is that the physician's assistant performs medical services under

the direction and guidance of the supervising physician as required by the Code and the BME regulations. The supervising physician has complete authority in each set of facts to supervise, direct and review the medical services being provided at the clinic. None of the three situations would have any discernible impact on quality health care.

The hypotheticals differ from the normal supervising physician/physician's assistant relationship only in that the management responsibilities and the economic risk of operating the clinic are transferred from the supervising physician to the physician's assistant. The current statutory and regulatory provisions do not address the managerial and financial relationship permitted between a supervising physician and physician's assistant. However, §148C.7, the Code, does direct the BME to encourage the utilization of physician's assistants. Assuming as each of the Hypotheticals states that all the required medical supervision will be provided, a positive response to each of the Hypotheticals in the Petition is warranted and would be in the spirit of §148C.7.

BELIN HARRIS HELMICK,
A Professional Corporation

By Dennis J. Nagel
Dennis J. Nagel

2000 Financial Center
Des Moines, Iowa 50312
Telephone: (515)243-7100

ATTORNEYS FOR TOM MILLS

LAW OFFICES

BELIN HARRIS HELMICK
TESDELL LAMSON BLACKLEDGE MCCORMICK

A PROFESSIONAL CORPORATION

2000 FINANCIAL CENTER

DES MOINES, IOWA 50309

TELEPHONE (515) 243 7100

TELECOPIER (515) 282 7615

DAVID W. BELIN
CHARLES E. HARRIS
ROBERT H. HELMICK
E. S. TESDELL, JR.
JEFFREY E. LAMSON
FREDERICK C. BLACKLEDGE
MARK MCCORMICK
DAVID L. CLAYPOOL
JON L. STAUDT
SUE LUETTJOHANN SEITZ
JEFFREY A. KRAUSMAN
ROBERT E. JOSTEN
STEVEN E. ZUMBACH
JEREMY C. SHARPE

ROGER T. STETSON
MARK D. KLECKNER
CHARLES D. HUNTER
JOHN T. SEITZ
KEVIN M. ABEL
STEVEN J. DICKINSON
LINDA L. KNIEP
QUENTIN R. BOYKEN
LAURA GOECKE BURNS
DENNIS J. NAGEL
LINDA S. WEINDRUCH
JOSEPH R. GUNDERSON
DONALD G. HENRY

TWX
910-520-2625
(FINA DMS)

May 29, 1986

OF COUNSEL
MATTHEW J. HEARTNEY, JR.
LAWRENCE E. POPE

PHILIP C. LOVRIEN
1911-1980

Hormoz Rassekh, M.D.
Chairman
Iowa State Board of Medical Examiners
Executive Hills West
Des Moines, Iowa 50319

Dear Dr. Rassekh:

I have been provided copies of the comments submitted to the Board of Medical Examiners (BME) by the Iowa Medical Society, Dr. Paul Seebohm and the Iowa Osteopathic Medical Association relative to the Petition for Declaratory Ruling submitted by my client Tom Mills. Since each is adverse to the Petition, I submit this letter in response.

At the outset I note that each of the comments contains substantial misrepresentations of the facts presented in the Petition. While I will note those misrepresentations, I do not intend to respond to them since they are not at issue in this Petition.

Letter From Iowa Medical Society

1. The letter suggests that the physician assistant (P.A.) would provide independent medical services. This misstates the questions posed by the hypotheticals. None of them suggests that the P.A. would be providing independent medical services. In each, the P.A. would perform medical services under the supervision of a physician thus meeting the basic requirement contained in §148C.1(6) of the Iowa Code.

2. The letter suggests that the hypotheticals are "inconsistent" with the law and regulations. This assertion is unsupported by any examples or specifics. By contrast, the Brief in support of the Petition for Declaratory Ruling cited specific provisions of Iowa law and Board of Medical Examiners regulations that support a positive response to the Petition.

Letter From Dr. Paul Seebom

1. The letter misrepresents the hypotheticals by suggesting the physician would "serve as a figurehead supervisor to legitimize the practice." Each of the hypotheticals states clearly that supervision over the medical services would rest with the physician. The physician would not be a figurehead supervisor. He would be in direct charge of and responsible for the medical services performed at the clinic.
2. We concur with the letter's suggestion that it is permissible for the physician and the P.A. to have alternative business relationships, e.g. the P.A. leasing office space to the physician.
3. The rest of the letter is unclear which makes a more detailed response difficult.

Letter From Iowa Osteopathic Medical Association

1. The letter misstates each of the hypotheticals by suggesting that the physician would be the employee of the P.A. None of the hypotheticals suggests that situation.
2. While recognizing that the hypotheticals do provide that the medical supervision would be provided by the physician, the letter stresses an alleged incompatibility of that supervision with the P.A.'s right to hire or fire the physician. While none of the hypotheticals suggests that the P.A. would have the authority to "hire or fire" the physician, it must be recognized that under each of the hypotheticals the effective authority rests not with the P.A., but with the physician. If dissatisfied for any reason with the arrangement, the physician could simply decline to provide the medical supervision required by Iowa law. The P.A. could no longer work. He would be effectively and completely stymied by the physician.

3. The letter engages in an admittedly speculative discussion about how the hypothetical business relationships might affect the quality of care. It suggests that the supervising physician would be willing to consent to procedures contrary to the medical interests of the patients to increase business profits. It stretches the imagination to believe that any physician or P.A. would engage in medical practices contrary to the best interests of their patients. Surely, government regulations and the ethical canons of physicians could not permit this situation.
4. The letter suggests that it is inappropriate for a physician to be employed by one with inferior training. While it is unclear how the term "inferior training" is intended, it appears the letter suggests it is inappropriate for any unlicensed individual or institution to employ a physician. That will come as a surprise to the many physicians who are employed by non-licensed individuals.
5. The letter avers that the hypotheticals are "(an) assault on the patient/physician personal relationship and further demeans the profession of medicine." These are rash claims unsupported by the terms of the hypotheticals or any evidence supplied by the Iowa Osteopathic Medical Association. It is regrettable that the Association would engage in such unfounded hyperbole.

My client renews his request for a positive response to his Petition for Declaratory Ruling. To that end, I encourage you to review the Brief that was submitted in support of the Petition and the comments of the Iowa Physician Assistant Society.

Also in support of the Petition, I submit to the Board that:

1. Notwithstanding the provision of 470 I.A.C. §136.1 that the physician must be the employer of the P.A., this Board has already established the unwritten policy that it will permit third parties, e.g., hospitals and universities rather than a physician, to be the employer of the P.A. and take the managerial responsibility and economic risk for the clinic. These third parties have, in turn, contracted with or employed physicians to provide the medical supervision of the P.A. The hypotheticals of the Petition are similar to these arrangements already approved by the Board.

2. The federal government recognizes the propriety of a P.A. owning a rural health clinic. The Department of Health and Human Services provides in its standards for reimbursement of rural health clinics under Medicare and Medicaid that:

(a) Staffing.

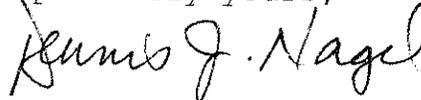
(1) The clinic has a health care staff that includes one or more physicians and one or more physician's assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the clinic, an employee of the clinic, or under agreement with the clinic to carry out the responsibilities required under this section.

(3) The physician's assistant or nurse practitioner member of the staff may be the owner of the clinic or an employee of the clinic. (emphasis added) 42 CFR §491.8(a)

We appreciate the Board's consideration of the material submitted herein.

Respectfully yours,



Dennis J. Nagel
For the Firm

DJN/njm

The University of Iowa

Iowa City, Iowa 52242

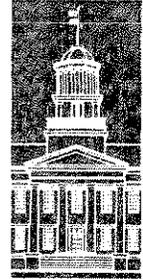
College of Medicine
Office of the Dean

(319) 353-4843

RECEIVED

MAY 27 1986

IA BD MED EXAM



1847

May 23, 1986

Hormoz Rassekh, M.D., Chairman
Iowa State Board of Medical Examiners
1209 Court Avenue
Des Moines, Iowa 50319

Dear Doctor Rassekh:

I have reviewed the petition for a declaratory ruling on the legality of a physician's assistant (P.A.) contracting with a physician to provide medical supervision for the P.A. for which the P.A. would pay a fixed fee to the physician. The three hypothetical situations presented imply the medical clinic and a P.A. have a revenue generating capacity beyond the fees for the services of the physician. I would submit one does not have a "medical" clinic until there is a physician in or in charge of the space called a clinic, and therefore no capacity to practice medicine or generate income from same. If a P.A. has a space suitable for a medical office that he wishes to rent, lease or sell to a physician in exchange for a payment and tie-in employment of a P.A. and his wife, both the P.A. and the physician are free to make such a contract without fear of sanction from the Board of Medical Examiners. It does not seem that a physician's supervisory skills are saleable to a supervisee.

Would a butler hire a master to supervise his opening of the front door of the butler's home? Would a million dollar quarterback hire a coach and football team to supervise his play?

The College of Medicine trains physician's assistants to extend the services of physicians. They are not trained to set up medical practices for which they hire a physician to serve as a figurehead supervisor to legitimize the practice. It would appear that the role of the Board of Medical Examiners is first to establish the professional competence of the physician and the P.A., and secondly, to authorize the physician to employ the P.A. to assist him or her in the practice of medicine. If the P.A. is bringing to this arrangement patient good will or other medical business, the P.A. would appear to be in the illegal practice of medicine and therefore ethically unqualified for certification by the Board.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Paul M. Seebohm".

Paul M. Seebohm, M.D.
Executive Associate Dean

PMS/mb

H. Rassekh, M.D. 4/17/86
at 04/20/86

RECEIVED
MAY 20 1986
IA BD MED EXAM

IOWA MEDICAL SOCIETY

MAY 19, 1986

HORMOZ RASSEKH, M.D., CHAIRMAN
IOWA STATE BOARD OF MEDICAL EXAMINERS
1209 COURT AVENUE
DES MOINES, IOWA 50319

DEAR DOCTOR RASSEKH:

ON APRIL 17, 1986, THE IOWA STATE BOARD OF MEDICAL EXAMINERS BRIEFLY CONSIDERED A DRAFT DECLARATORY RULING BY THE BOARD IN THE MATTER OF THE PETITION OF TOM MILLS, PHYSICIAN'S ASSISTANT. THE IOWA MEDICAL SOCIETY ASKED FOR AND WAS PROVIDED OPPORTUNITY TO REVIEW AND COMMENT UPON THE DRAFT RULING PRIOR TO BOARD ACTION. THE FOLLOWING ARE THE COMMENTS OF THE IOWA MEDICAL SOCIETY.

ALTHOUGH THE IOWA MEDICAL SOCIETY DOES NOT DISAGREE WITH THE REASONING OF THE DRAFT RULING, WE BELIEVE THE BOARD MUST ANSWER NO WITH RESPECT TO THE LIMITED FACTUAL SITUATIONS POSED. THEY ALL SEEM TO CONTEMPLATE THAT THE PHYSICIAN ASSISTANT IS PROVIDING SERVICES IN THE FURTHERANCE OF HIS OR HER, OR A THIRD PERSON'S, MEDICAL BUSINESS. THIS IS INCONSISTENT WITH PROVISIONS OF CHAPTER 148C OF THE CODE AND PURSUANT RULES OF THE BOARD OF MEDICAL EXAMINERS AND COMPLETELY MISAPPREHENDS THE ROLE OF THE PHYSICIAN ASSISTANT.

A PHYSICIAN ASSISTANT IS A PHYSICIAN EXTENDER WHO IS UTILIZED BY THE PHYSICIAN IN HIS OR HER PRACTICE IN SERVING THE PHYSICIAN'S PATIENTS UNDER THE SUPERVISION OF THE PHYSICIAN. WE BELIEVE THAT THIS SHOULD BE THE THRUST OF THE BOARD'S DECLARATORY RULING.

SINCERELY,

L. D. Caraway M.D.

L. DEAN CARAWAY M.D.
PRESIDENT

LDC:BJD



May 22, 1986

Hormoz Rassekh, M.D., Chairman
Iowa State Board of Medical Examiners
Executive Hills West
Des Moines, Iowa 50319

RECEIVED
MAY 23 1986
IA BD MED EXAM

Dear Dr. Rassekh:

This is in reply to your request for comment by the Iowa Osteopathic Medical Association, "In the Matter of the Petition of Tom Mills, Physician's Assistant."

The hypothetical situations (1,2,3) described in the proposed declaratory ruling, although varying slightly in the "business" or "economic" arrangement, are essentially the same. In each case the roles of the physician and the physician's assistant are for all practical purposes the reverse of the relationship described in rules (470 I.A.C. 5136.1) and experienced in practice. Although the physician is titled "supervising physician" in the description of duties, the physician is an employee of the "assistant," in our opinion a contradiction of terms. A supervisory role, in any business, professional, teaching, or governmental undertaking implies and, in some cases, mandates a hiring, disciplinary, and firing authority. A person designated an assistant is one who helps or assists. According to Webster's Dictionary, to assist is "to give support or aid" and clearly connotes an inferior position to the one being assisted, in this case the physician. We believe this role to be appropriate and in our opinion the one envisioned by the legislature when they created this new health care professional they entitled "physician's assistant." Had they intended an even slightly broader role than that of helper or extender, they might have created a "physician's associate" or a completely different title of independent health care practitioner, or some such other professional.

Our members supported the legislation creating the physician's assistant as a licensed profession to enable those in our profession who needed to provide medical care to more people, especially in rural areas which had difficulty attracting and supporting a full time physician. Many are currently supervising and utilizing talented, well trained physician's assistants. To the best of our knowledge, none of the members has expressed any interest in or approval of becoming employees of their assistants or the spouse of an assistant.

Although the hypothetical situations stress the "medical" supervisory authority of the physician over the assistant and other clinical personnel, pragmatically, the assistant will be viewed by all as the authority figure since he or she would have the right to hire and fire, offering no higher appeal authority figure. How such an arrangement could affect quality of care would be speculative. A situation could arise however, where the physician's assistant delays, for economic reasons, referral to a

Hormoz Rassekh, M.D.

May 22, 1986

Page Two

specialist beyond what is medically prudent. The supervisory physician, who may be profiting from the business arrangement may hesitate in challenging such decisions for fear he or she would be replaced by another supervisory physician who might be more cooperative.

It is hard to imagine physicians who would accept such a strictly business role and allow themselves to be employed by professionals with inferior training. The reality of the marketplace and the current view of health care as just another business and not the art, science, and sometimes mission it was once perceived to be, suggests we should not be surprised if it happens. The Iowa Osteopathic Medical Association would review the status of any of its members who would become a party to any arrangements similar to Hypothetical Situations 1, 2 or 3 to determine whether the arrangement violates its Code of Ethics or in any way demeans the profession of osteopathic medicine.

In our opinion, the provision of health care services is already too commercialized. Entrepreneurs are attempting to manipulate and dominate the delivery system. Who receives what care, how much and at what cost is being decided in board rooms of corporations, not by patients and their doctors. This proposed business arrangement between a physician's assistant is yet another assault on the patient/physician personal relationship and further demeans the profession of medicine. We are opposed to any business arrangements that circumvents the intended roles of the physician and the assistant and suggest that if petitioner wishes a more independent practice environment, he enroll in the medical school of his choice.

Should you require additional information from us or our appearance before your board to discuss in more detail our position, please let me know.

Sincerely,



Norman L. Pawlewski
Executive Director

/jr



Iowa Physician Assistant Society

March 4, 1986

Mr. Ron Saf
Executive Director
Iowa State Board of Medical Examiners
State Capitol Complex
Executive Hills West
Des Moines, IA 50319

Dear Mr. Saf,

Thank you for the opportunity to comment on PA Tom Mills' request for a Declaratory Ruling from the Iowa State Board of Medical Examiners. The hypothetical situations presented raise two basic concerns: 1) that adequate medical supervision and PA skills exist to ensure that medical care is safely provided to the public, 2) that the business relationship between the physician and PA be in compliance with Iowa law.

The PA law authorizes a physician to supervise a PA and allows the PA to perform "medical services" to help doctors extend quality medical care to the citizens of Iowa (148C). Under 148C rules were promulgated to outline the basic criteria for deciding whether to approve a physician/PA application. Accordingly, the physician/PA application does not require any description of the business relationship. In each of the hypothetical situations, safe and lawful medical services and adequate medical supervision could be provided.

Physician supervision of the PA is the key to the success of the physician/PA approach to medical care. Physician latitude in organizing a medical practice is necessary to allow for that essential ingredient of quality medical care - individualized care tailored to the needs of the community and the patient.

The supervising physician's and PA's business relationships should be those allowed by the business regulating sections of the Iowa law and should be consistent with the rights and privileges accorded to all other citizens under the free enterprise system.

Thank you for considering these comments. Please contact me if further information is needed.

Sincerely,

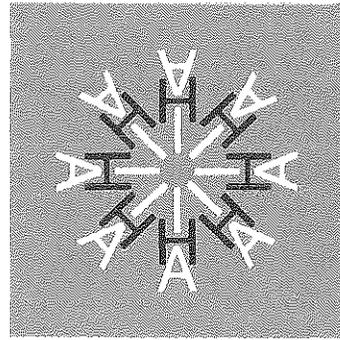
Allen Dale, PA

Allen Dale
Past President
Iowa PA Society
1710 Mar Ella Trail
Des Moines, IA 50310
(H) 255-0401
(O) 255-2173 Ext 5800

THE IOWA HOSPITAL ASSOCIATION

Suite R • 600 Fifth Ave. • Des Moines, Iowa 50309 • Phone (515) 288-1955

DONALD W. DUNN, President



May 28, 1986

Hormoz Rassekh, M.D.
Chairperson
Iowa Board of Medical Examiners
State Capitol Complex
Des Moines, Iowa 50319

RE: IN THE MATTER OF THE PETITION
OF TOM MILLS, PHYSICIAN'S ASSISTANT

Dear Dr. Rassekh and Members of the Board:

The Iowa Hospital Association, representing 127 hospital members in the state of Iowa, appreciates the opportunity to briefly comment on the proposed declaratory ruling of the Iowa Board of Medical Examiners regarding physician's assistants. In so commenting, IHA recognizes that the subject matter of the declaratory ruling may not be as of direct significance to hospitals as it may be to medical practitioners. Nonetheless, the parameters of the relationship between supervising physicians and physician's assistants certainly may bear upon the relationship of hospitals with these same practitioners in the delivery of health care services in the hospital setting.

The primary question posed by the three hypotheticals is not an easy one. IHA agrees that the Board generally is not and should not be involved in evaluating the business relationships of physicians and physician's assistants. IHA further agrees, though, that where that business relationship thwarts the underlying purposes of Iowa law and regulation, that relationship may be a factor in evaluating an application for supervision of a physician's assistant. The proposed declaratory ruling states that the business relationships contemplated by the hypotheticals are not consistent with the underlying premise of Iowa law and regulation, namely that a physician will supervise a physician's assistant in order to assist the physician in his or her practice. And yet, the Board concludes that it would grant qualified approval to applications in all three hypothetical situations.

As the proposed ruling states, the supervisory role of the physician is pivotal in the performance of medical services of a physician's assistant; the hypotheticals appear to recognize and account for that requisite supervision.

Hormoz Rassekh, M.D.
Iowa Board of Medical Examiners
May 28, 1986
Page Two

What the hypotheticals appear to be asking, however, and what the declaratory ruling fails to address is whether a properly supervised physician's assistant can essentially operate an office or a medical clinic and not run afoul of Iowa law as set forth in either Iowa Code chapter 148 or chapter 148C. To answer that question, it seems that greater analysis of the intent of those Code chapters, especially chapter 148C, is in order. Without greater explanation, the qualified response of the Board appears inconsistent with the closing paragraphs of the declaratory ruling.

Thank you for the opportunity to present concerns on this particular matter.

Sincerely yours,



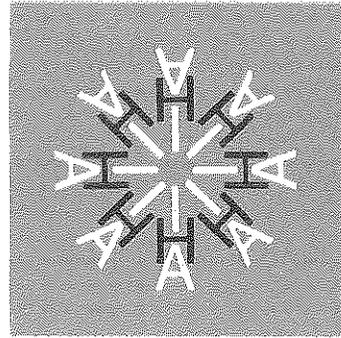
Jeanine Freeman
Vice President/Staff Legal Counsel

cc: Donald W. Dunn
Ronald V. Saf

THE IOWA HOSPITAL ASSOCIATION

Suite R • 600 Fifth Ave. • Des Moines, Iowa 50309 • Phone (515) 288-1955

DONALD W. DUNN, President



May 28, 1986

Hormoz Rassekh, M.D.
Chairperson
Iowa Board of Medical Examiners
State Capitol Complex
Des Moines, Iowa 50319

RE: IN THE MATTER OF THE PETITION
OF TOM MILLS, PHYSICIAN'S ASSISTANT

Dear Dr. Rassekh and Members of the Board:

The Iowa Hospital Association, representing 127 hospital members in the state of Iowa, appreciates the opportunity to briefly comment on the proposed declaratory ruling of the Iowa Board of Medical Examiners regarding physician's assistants. In so commenting, IHA recognizes that the subject matter of the declaratory ruling may not be as of direct significance to hospitals as it may be to medical practitioners. Nonetheless, the parameters of the relationship between supervising physicians and physician's assistants certainly may bear upon the relationship of hospitals with these same practitioners in the delivery of health care services in the hospital setting.

The primary question posed by the three hypotheticals is not an easy one. IHA agrees that the Board generally is not and should not be involved in evaluating the business relationships of physicians and physician's assistants. IHA further agrees, though, that where that business relationship thwarts the underlying purposes of Iowa law and regulation, that relationship may be a factor in evaluating an application for supervision of a physician's assistant. The proposed declaratory ruling states that the business relationships contemplated by the hypotheticals are not consistent with the underlying premise of Iowa law and regulation, namely that a physician will supervise a physician's assistant in order to assist the physician in his or her practice. And yet, the Board concludes that it would grant qualified approval to applications in all three hypothetical situations.

As the proposed ruling states, the supervisory role of the physician is pivotal in the performance of medical services of a physician's assistant; the hypotheticals appear to recognize and account for that requisite supervision.

Hormoz Rassekh, M.D.
Iowa Board of Medical Examiners
May 28, 1986
Page Two

What the hypotheticals appear to be asking, however, and what the declaratory ruling fails to address is whether a properly supervised physician's assistant can essentially operate an office or a medical clinic and not run afoul of Iowa law as set forth in either Iowa Code chapter 148 or chapter 148C. To answer that question, it seems that greater analysis of the intent of those Code chapters, especially chapter 148C, is in order. Without greater explanation, the qualified response of the Board appears inconsistent with the closing paragraphs of the declaratory ruling.

Thank you for the opportunity to present concerns on this particular matter.

Sincerely yours,



Jeanine Freeman
Vice President/Staff Legal Counsel

cc: Donald W. Dunn
Ronald V. Saf



Iowa Physician Assistant Society

March 4, 1986

Mr. Ron Saf
Executive Director
Iowa State Board of Medical Examiners
State Capitol Complex
Executive Hills West
Des Moines, IA 50319

Dear Mr. Saf,

Thank you for the opportunity to comment on PA Tom Mills' request for a Declaratory Ruling from the Iowa State Board of Medical Examiners. The hypothetical situations presented raise two basic concerns: 1) that adequate medical supervision and PA skills exist to ensure that medical care is safely provided to the public, 2) that the business relationship between the physician and PA be in compliance with Iowa law.

The PA law authorizes a physician to supervise a PA and allows the PA to perform "medical services" to help doctors extend quality medical care to the citizens of Iowa (148C). Under 148C rules were promulgated to outline the basic criteria for deciding whether to approve a physician/PA application. Accordingly, the physician/PA application does not require any description of the business relationship. In each of the hypothetical situations, safe and lawful medical services and adequate medical supervision could be provided.

Physician supervision of the PA is the key to the success of the physician/PA approach to medical care. Physician latitude in organizing a medical practice is necessary to allow for that essential ingredient of quality medical care - individualized care tailored to the needs of the community and the patient.

The supervising physician's and PA's business relationships should be those allowed by the business regulating sections of the Iowa law and should be consistent with the rights and privileges accorded to all other citizens under the free enterprise system.

Thank you for considering these comments. Please contact me if further information is needed.

Sincerely,

Allen Dale, P.A.C.

Allen Dale
Past President
Iowa PA Society
1710 Mar Ella Trail
Des Moines, IA 50310
(H) 255-0401
(O) 255-2173 Ext 5800

RECEIVED
JUN 5 1986
IA BD MED EXAM

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF THE PETITION)
OF TOM MILLS, PHYSICIAN'S) DECLARATORY RULING
ASSISTANT)

PROCEDURE

On February 4, 1986, the Iowa Board of Medical Examiners received a Petition for Declaratory Ruling filed by attorney Dennis J. Nagel pursuant to 470 I.A.C. § 135.10. The petitioner is identified as Mr. Tom Mills, Hubbard Medical Clinic, Hubbard, Iowa 50122.

FACTS

The petitioner has posed three hypothetical situations:

HYPOTHETICAL SITUATION NO. 1

a. Physician's assistant contracts with physician for the latter to provide all the medical supervision required by state statute and Board of Medical Examiner regulations. Physician's assistant agrees to pay a fixed fee to the physician for latter's supervisory services.

b. Physician's assistant performs the supervised medical services at a "place remote" from the physician's primary place.

c. Physician's assistant enters into lease for rental of medical clinic facility to be used at the "place remote" by supervising physician and physician's assistant.

d. Physician's assistant employs the clinic's staff. Clerical staff is supervised by the physician assistant. Nursing staff is supervised by supervising physician and physician's assistant.

e. Physician's assistant is responsible for all expenses of clinic and receives all clinic income (except for fees charged by supervising physician directly to patients seen by the physician). Physician's assistant is responsible for any financial deficit of the clinic.

f. Physician's assistant and supervising physician meet all other state requirements to qualify for approval of application to supervise the physician's assistant at this clinic.

HYPOTHETICAL SITUATION NO. 2

a. Physician's assistant agrees to be employed by supervising physician at a "place remote" clinic and enters into employment contract with supervising physician.

b. Employment contract duties of supervising physician:

1) Review and supervise physician's assistant's performance of medical services at the clinic as required by law and regulation.

2) Consult with and evaluate physician's assistant's overall performance.

c. Employment contract duties of physician's assistant:

1) Arrange suitable quarters for the clinic.

2) Attend to clinic's patients under the supervision of the supervising physician.

3) Organize and manage all non-medical aspects of the clinic including but not limited to the employment of the clinic's staff, the non-medical supervision of that staff, and the handling of billings and collections.

d. Compensation provisions of the employment contract:

1) Supervising physician will retain each month the first \$1,000 from the clinic's gross income and a sum sufficient to pay all employment taxes. In addition the supervising physician will receive the fees he charges for patient visits that he conducts at the clinic.

2) Physician's assistant will receive as salary all other clinic income less clinic expenses.

3) If clinic in a given month operates at a deficit, physician's assistant is responsible for the deficit.

e. Physician's assistant and supervising physician meet all other state requirements to qualify for approval of application to supervise the physician's assistant at this clinic.

HYPOTHETICAL SITUATION NO. 3

a. A non-licensed, private individual rents a medical clinic at a "place remote".

b. The private individual employs a supervising physician and physician's assistant to operate the clinic at the "place remote".

c. Employment contract duties of the supervising physician:

1) Supervise and review the physician's assistant's performance of medical services at the clinic as required by law and regulation.

2) Consult with and evaluate physician's assistant's overall performance.

3) Supervising physician will be compensated at an agreed upon rate in addition to the patient fees he charges.

d. Employment contract duties of physician's assistant:

1) Attend to clinic's patients under the supervision of the supervising physician.

2) Organize and manage all non-medical aspects of the clinic including but not limited to the employment of the clinic's staff, the non-medical supervision of that staff, and the handling of billings and collections.

3) Physician's assistant compensated at an agreed upon rate.

e. Non-licensed, private individual retains the net profits, if any, of the clinic and is responsible for any financial deficit of the clinic.

f. Non-licensed, private individual is the spouse of the physician's assistant.

g. Physician's assistant and supervising physician meet all

other state requirements to qualify for approval of application to supervise the physician's assistant at this clinic.

QUESTIONS PRESENTED

1. Will the Board of Medical Examiners, based on its authority to approve the use of physician's assistants to perform medical services, approve an application based on the facts outlined in Hypothetical Situation No. 1?

2. Will the Board of Medical Examiners, based on its authority to approve the use of physician's assistants to perform medical services, approve an application based on the facts outlined in Hypothetical Situation No. 2?

3. Will the Board of Medical Examiners, based on its authority to approve the use of physician's assistants to perform medical services, approve an application based on the facts outlined in Hypothetical Situation No. 3?

AUTHORITIES

Iowa Code § 148C.4 (1985):

148C.4 Services performed by assistants.

A physician's assistant may perform medical service when such services are rendered under the supervision of a licensed physician or physicians approved by the board. A trainee may perform medical services when such services are rendered within the scope of an approved program.

470 I.A.C. § 136.1:

470-136.1(148C) **General.** A physician's assistant is a person qualified by general education, training, experience, and personal

character to provide patient services under the direction and supervision of an actively licensed physician in good standing. The purpose of the physician's assistant program is to enable the physician to extend high quality medical care to more people throughout the state.

The licensed physician shall in all cases be regarded as the employer of the physician's assistant and shall be responsible for establishing whatever supervision is necessary to ensure that the physician's assistant is performing properly in the field of medicine for which he or she is trained and the acts which he or she is authorized by law to perform.

These rules are not intended to affect or limit a physician's existing right to delegate various medical tasks to aides, assistants or others acting under his or her supervision or direction. Aides, assistants or others who perform only those tasks which can be so delegated shall not be required to qualify as physicians' assistants.

470 I.A.C. § 136.5(5):

136.5(5) It shall be the responsibility of the supervising physician to ensure that:

. . . .

d. The employed physician's assistant performs only those tasks which have been authorized by the board. If the physician's assistant is being trained to perform additional tasks beyond those authorized, such training may be carried out only under the direct, personal supervision of the supervising physician or a qualified person designated by the responsible physician.

RULING

The petitioner has posed a series of three hypothetical situations concerning the business relationship between the supervising physician and the physician's assistant. Under

hypothetical situation number one the physician's assistant contracts with the physician for the physician to perform supervisory functions required by statute and rule for a fixed fee. Under hypothetical situation number two the physician's assistant enters into an employment contract with a supervising physician for the physician to perform supervisory functions required by statute and rule and to consult with and evaluate the physician's assistant's overall performance for which the supervising physician retains \$1,000 plus a sum sufficient to pay all employment taxes from the clinic gross income. Under hypothetical situation number three both the physician and the physician's assistant are employed by a non-licensed, private individual. The physician's employment contract duties include performance of supervisory functions required by statute and rule and consultation and evaluation of the physician's assistant's overall performance for which the supervising physician is compensated at an agreed upon rate. For each hypothetical situation the narrow question posed is whether the Iowa Board of Medical Examiners will approve an application by a licensed physician to supervise a physician's assistant based on the facts outlined.

Due to the narrowness of the questions posed, we are presented with a procedural dilemma. An application for approval of a physician's assistant would not be denied based on the hypothetical business relationships simply because this Board

will not evaluate the business relationship when considering an application.

Section 148C.3 delineates the items to be submitted in an application to the Board. Iowa Code § 148C.3 (1985). Subsection 148C.3(2)(d) specifically includes a "description by the physician of the physician's practice, and a description of how the physician's assistant is to be used." Iowa Code § 148C.3(2)(d) (1985). These "descriptions", however, apply to the medical practice itself rather than the underlying business relationship. Neither § 148C.3 generally nor § 148C.3(2)(d) specifically elicit information concerning the business relationship. It has not been the practice of this Board, moreover, to make such inquiries at the point of application.

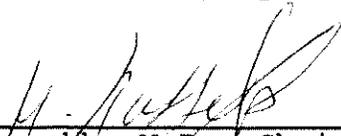
Although we are limited by the procedural posture of the issues, we do not wish to mislead the petitioner to believe that failure to evaluate the business relationship at the application phase would foreclose any further consideration of these issues. The supervisory role of the physician is pivotal in the performance of medical services by a physician's assistant. Chapter 148C creates no independent authority for a physician's assistant to engage in the provision of medical services. The physician's assistant may perform medical services only under the supervision of a licensed physician "approved by the board to supervise such assistant." Iowa Code § 148C.1(6) (1985). Indeed, the application process itself cannot be initiated by the physician's assistant but is undertaken by a licensed physician to seek

approval to supervise a physician's assistant. Id. The licensed physician, in fact, must describe in the application "how the physician's assistant is to be used." Iowa Code § 148C.3(2)(d) (1985). Our rules echo this supervisory emphasis by expressly stating that the licensed physician "shall in all cases be regarded as the employer of the physician's assistant." 470 I.A.C. § 136.1.

The underlying premise of these statutes and rules is that the physician will supervise a physician's assistant in order to assist the physician in his or her practice. Although the hypothetical situations delineated in this petition cast the physician in the role of "supervisor" in contractual terms, the true relationship is inconsistent with this premise. None of these hypothetical situations depict a physician supervising a physician's assistant to assist the physician in his or her practice. Rather, these hypothetical situations depict a physician's assistant establishing a medical business and contracting with a physician to satisfy supervisory functions for a fee.

It is the role of this Board to enforce the statutes and rules under which its licensees function. When the business relationship thwarts the purpose of our statutes and rules it may become an inextricable element of a contested case proceeding. The business relationships delineated in the three hypothetical situations, therefore, may be a factor in determining whether the practice of the physician and his or her physician's assistant conform to our statutes and rules which require the physician to

provide supervision to and to be regarded as the employer of the
physician's assistant.



Hormoz Rassekh, M.D., Chairman,
Iowa Board of Medical Examiners

Dated this 4 day of June, 1986.

**PETITION FOR DECLARATORY RULING BEFORE THE IOWA STATE
BOARD OF MEDICAL EXAMINERS**

89 DEC -7 AM 10:41

IN THE MATTER OF THE PETITION :
OF THE IOWA OSTEOPATHIC : PETITION FOR DECLARATORY
MEDICAL ASSOCIATION : RULING

IOWA BOARD OF MED. EXAMINERS

COMES NOW the Petitioner, The Iowa Osteopathic Medical Association, and states as follows:

1. The Iowa Osteopathic Medical Association is a non-profit organization representing Osteopathic physicians and surgeons licensed under Chapters 150 and 150A of the Iowa Code.

2. That on behalf of its members, The Iowa Osteopathic Medical Association requests the Board of Medical Examiners to issue a declaratory ruling pursuant to Iowa Code Section 17A.9 and Iowa Administrative Code Chapter 653, Section 10.10.

3. The subject matter of the requested ruling involves the issue as to what constitutes the practice of medicine and surgery, the practice of osteopathy and the practice of osteopathic medicine and surgery as defined in Iowa Code Sections 148.1, 150.2 and 150A.1.

4. The specific provisions of the aforementioned Code sections are as follows:

a. Section 148.1, which states in part:

For purposes of this title, the following classes of persons shall be deemed to be engaged in the practice of medicine and surgery:

1. Persons who publicly profess to be physicians or surgeons or who publicly profess to assume the duties incident to the practice of medicine or surgery.

b. Section 150.2, which states in part:

For the purposes of this title, the following classes of persons shall be deemed to be engaged in the practice of osteopathy:

1. Persons publicly professing to be osteopathic

physicians or persons publicly professing to assume the duties incident to such practice of osteopathy.

c. Section 150A.1, which states in part:

For purposes of this title, the following classes of persons shall be deemed to be engaged in the practice of osteopathic medicine and surgery:

1. Persons who publicly profess to be osteopathic physicians and surgeons or who publicly profess to assume the duties incident to the practice of osteopathic medicine and surgery.

5. The following hypothetical fact situation is to be used to answer the questions set forth in Paragraph 6 below:

A person not licensed under Chapters 148, 150 or 150A holds themselves out to the public as providing the public the treatment modality of acupuncture for the following conditions:

- a. Immediate Pain Relief;
- b. Headaches;
- c. Sports Injuries;
- d. Smoking;
- e. Weight Loss; and
- f. Arthritis.

The person who performs the treatment is not under the supervision of a person licensed under Chapters 148, 150 or 150a. Additionally, the modality of acupuncture is not being administered pursuant to the direction of a person licensed under Chapter 148, 150 or 150A.

It appears that all treatment decisions, including but not limited to, the necessity for treatment, suitability of the patient for treatment, the extent of treatment and duration of treatment, are being made by the person not licensed under Chapters 148, 150 and 150A of the Iowa Code.

6. The specific questions presented for declaratory ruling are as follows:

- a. Is the practice of acupuncture as outlined above considered the practice of medicine and surgery as defined in Iowa Code Section 148.1(1)?
- b. Is the practice of acupuncture as outlined above considered the practice of osteopathy as defined in Iowa Code Section 150.2(1)?
- c. Is the practice of acupuncture the practice of osteopathic medicine and surgery as defined in Iowa Code Section 150A.1?
- d. Is the determination and/or diagnosis of the need for acupuncture considered the practice of medicine and surgery as

defined in Iowa Code Section 148.1(1)?

e. Is the determination and/or diagnosis of the need for acupuncture considered the practice of osteopathy as defined in Iowa Code Section 150.2(1)?

f. Is the determination and/or diagnosis of the need for acupuncture considered the practice of osteopathic medicine and surgery as defined in Iowa Code Section 150A.1?

g. Is the determination and/or diagnosis that a person can medically withstand the treatment of acupuncture considered the practice of medicine and surgery as defined in Iowa Code Section 148.1(1)?

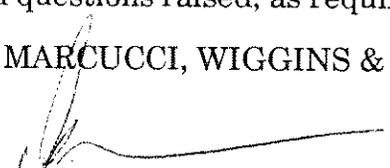
h. Is the determination and/or diagnosis that a person can medically withstand the treatment of acupuncture considered the practice of osteopathy as defined in Iowa Code Section 150.2(1)?

i. Is the determination and/or diagnosis that a person can medically withstand the treatment of acupuncture considered the practice of osteopathic medicine and surgery as defined in Iowa Code Section 150A.1?

j. Can a person who is not licensed under Chapters 148, 150 and 150A practice acupuncture as set forth in the example contained in paragraph 5 above?

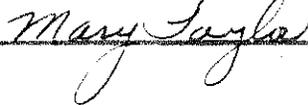
WHEREFORE, the Iowa Osteopathic Medical Association requests a determination on all of these issues and questions raised, as required by law.

MARCUCCI, WIGGINS & ANDERSON, P.C.


DAVID S. WIGGINS
700 West Towers
1200 Valley West Drive
West Des Moines, Iowa 50265
Telephone: (515) 225-4844
ATTORNEY FOR PETITIONER

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served on the parties to the above cause by _____ on _____ 12/16 89.


Mary Taylor

Copy to:

Julie Pottorff
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF THE)	
PETITION OF THE IOWA)	
OSTEOPATHIC MEDICAL)	DECLARATORY RULING
ASSOCIATION)	

PROCEDURE

The Iowa Osteopathic Medical Association filed a Petition for Declaratory Ruling with the Iowa Board of Medical Examiners [hereinafter the Board] on December 7, 1989, pursuant to Iowa Code § 17A.9 and 653 Iowa Admin. Code § 10.10. The petitioner is identified as the Iowa Osteopathic Medical Association, a non-profit organization representing osteopathic physicians and surgeons licensed under Iowa Code chapters 150 and 150A.

HYPOTHETICAL FACTS

A person not licensed under Chapters 148, 150 or 150A holds themselves out to the public as providing the public the treatment modality of acupuncture for the following conditions:

- a. Immediate Pain Relief;
- b. Headaches;
- c. Sports Injuries;
- d. Smoking;
- e. Weight Loss; and
- f. Arthritis.

The person who performs the treatment is not under the supervision of a person licensed under Chapters 148, 150 or 150A. Additionally, the modality of acupuncture is not being ad-

ministered pursuant to the direction of a person licensed under Chapter 148, 150 or 150A.

It appears that all treatment decisions, including but not limited to, the necessity for treatment, suitability of the patient for treatment, the extent of treatment and duration of treatment, are being made by the person not licensed under Chapters 148, 150 and 150A of the Iowa Code.

QUESTIONS PRESENTED

1. Is the practice of acupuncture as outlined above considered the practice of medicine and surgery as defined in Iowa Code Section 148.1(1)?

2. Is the practice of acupuncture as outlined above considered the practice of osteopathy as defined in Iowa Code Section 150.2(1)?

3. Is the practice of acupuncture the practice of osteopathic medicine and surgery as defined in Iowa Code Section 150A.1?

4. Is the determination and/or diagnosis of the need for acupuncture considered the practice of medicine and surgery as defined in Iowa Code Section 148.1(1)?

5. Is the determination and/or diagnosis of the need for acupuncture considered the practice of osteopathy as defined in Iowa Code Section 150.2(1)?

6. Is the determination and/or diagnosis of the need for

acupuncture considered the practice of osteopathic medicine and surgery as defined in Iowa Code Section 150A.1?

7. Is the determination and/or diagnosis that a person can medically withstand the treatment of acupuncture considered the practice of medicine and surgery as defined in Iowa Code Section 148.1(1)?

8. Is the determination and/or diagnosis that a person can medically withstand the treatment of acupuncture considered the practice of osteopathy as defined in Iowa Code Section 150.2(1)?

9. Is the determination and/or diagnosis that a person can medically withstand the treatment of acupuncture considered the practice of osteopathic medicine and surgery as defined in Iowa Code Section 150A.1?

10. Can a person who is not licensed under Chapters 148, 150 and 150A practice acupuncture as set forth in the example contained in paragraph 5 above?

AUTHORITIES

148.1 Persons engaged in practice.

For the purpose of this title the following classes of persons shall be deemed to be engaged in the practice of medicine and surgery:

1. Persons who publicly profess to be physicians or surgeons or who publicly profess to assume the duties incident to the practice of medicine or surgery.

2. Persons who prescribe, or prescribe and furnish medicine for human ailments or treat the same by surgery.

3. Persons who act as representatives of any person in doing any of the things mentioned in this section.

150.2 Persons engaged in practice.

For the purpose of this title the following classes of persons shall be deemed to be engaged in the practice of osteopathy:

1. Persons publicly professing to be osteopathic physicians or publicly professing to assume the duties incident to such practice of osteopathy.

2. Persons who treat human ailments by that school of healing art hereinbefore defined as osteopathy.

150A.1 Definitions.

For the purpose of this title, the following classes of persons shall be deemed to be engaged in the practice of osteopathic medicine and surgery:

1. Persons who publicly profess to be osteopathic physicians and surgeons, or who publicly profess to assume the duties incident to the practice of osteopathic medicine and surgery.

2. Persons who prescribe, or prescribe and furnish medicine for human ailments or treat the same by surgery.

3. Persons who act as representatives of any person in doing any of the things mentioned in this section.

RULING

The petitioner poses hypothetical facts under which a person not licensed to practice medicine and surgery, osteopathic medicine and surgery or osteopathy holds himself/herself out as

providing treatment through acupuncture for "immediate pain relief, headaches, sports injuries, smoking, weight loss and arthritis." Ten questions are posed. For the purpose of clarity, however, the questions are consolidated into the following inquiry: Does the determination and/or diagnosis of the need for acupuncture, including the determination and/or diagnosis of whether the person can withstand the treatment of acupuncture, and the practice of acupuncture constitute the practice of medicine and surgery, the practice of osteopathic medicine and surgery, or the practice of osteopathy under Iowa Code §§ 148.1, 150A.1 and 150.2, respectively? With limited qualifications, the Board answers affirmatively.

For the purpose of this Declaratory Ruling, we need not distinguish whether the hypothetical facts posed constitute the practice of medicine and surgery, osteopathic medicine and surgery, or osteopathy. The persons engaged in the practice of medicine and surgery and the practice of osteopathic medicine and surgery are defined in parallel terms. Compare Iowa Code § 148.1 (1989) with § 150A.1 (1989). Each definition encompasses persons who assume the "duties incident" to the practice of the profession. Although the practice of osteopathy is more specifically delineated in Iowa Code §§ 150.1(1) and 150.1(2), persons engaged in the practice of osteopathy are similarly defined to encompass persons who assume the "duties incident" to the practice of the profession. Because diagnosis and determination of treatment are

common "incidents" to each profession, our resolution of the questions is applicable to each profession. Our references to the practice of medicine and surgery which follow, therefore, are applicable to the practice of osteopathic medicine and surgery and osteopathy as well.

In construing the statutory provisions of chapters 148, 150 and 150A, we are guided by decisions of the Iowa Supreme Court. The Court has long construed the practice of medicine and surgery to encompass diagnosis and the prescription of the proper treatment. As early as 1929 the Court analyzed the role of prescribing treatment in the practice of medicine in State v. Hughey, 208 Iowa 842, 226 N.W. 371 (1929). The defendant in Hughey was indicted for the unlawful practice of medicine based on evidence that he held himself out to be a "magnetic healer," diagnosed ailments and prescribed the proper treatment as a "laying on of hands." 208 Iowa at 843-44, 226 N.W. at 371-72. Construing the 1927 statutory predecessor to § 148.1(1), which in identical language defined persons engaged in the practice of medicine and surgery as "[p]ersons who publicly profess to be physicians or surgeons or publicly profess to assume the duties incident to the practice of medicine or surgery," the Court held:

The argument for defendant is that, inasmuch as he gave no medicine he could not be guilty of practicing medicine. The term 'practice of medicine' is defined by section 2538. It is not confined to the administering of drugs. Under this statute one who publicly professes to be a physician, and induces

others to seek his aid as such, is practicing medicine. Nor is it requisite that he shall profess in terms to be a physician. It is enough under the statute if he publicly profess to assume the duties incident to the practice of medicine. What are 'duties incident to the practice of medicine'? Manifestly the first duty of a physician to his patient is to diagnose his ailment. Manifestly, also, a duty follows to prescribe the proper treatment therefor. If, therefore, one publicly profess to be able to diagnose human ailments, and to prescribe proper treatments therefor, then he is engaged in the practice of medicine, within the definition of section 2538.

208 Iowa at 846-47, 226 N.W. at 373.

Three years later the Court focused on diagnosis in the practice of medicine. In State v. Howard, 216 Iowa 545, 245 N.W. 871 (1932), the Court reviewed a suit to enjoin an unlicensed person from diagnosing and treating "so-called common diseases, including appendicitis, rheumatism, arthritis, neuritis, flus and colds" by a process called naprapathy. Noting that the defendant purported to diagnose the ailments of his patrons before embarking on a naprapathy treatment, the Court ruled:

Correct diagnosis is one of the first duties of the qualified physician. Purported diagnosis is also the first resort of the disqualified one, and the first requisite of a miraculous cure. The ailments, curable or incurable, which he professes to discover, and to cure, are such only as his own diagnosis declares Diagnosis, as a guide to treatment, is therefore clearly one of the duties of the physician.

216 Iowa at 551, 245 N.W. at 874.

Diagnosis and treatment have been determined to constitute the practice of medicine and surgery in other contexts. See State v. Robinson, 236 Iowa 752, 19 N.W.2d 214 (1945) (healing through power of thought and laying on of hands constitutes practice of medicine); State v. Baker, 212 Iowa 571, 235 N.W. 313 (1931) (treatment of cancer through secret preparations constitutes practice of medicine); 1966 Op.Att'yGen. 13 (diagnosis and treatment of mental conditions constitutes the practice of medicine). The Iowa Supreme Court, however, has not considered acupuncture in particular in this light.

The Iowa Supreme Court did indicate that acupuncture is within the field of medicine in State v. Van Wyk, 320 N.W.2d 599 (Iowa 1982). In Van Wyk the Department of Health sought to enjoin a chiropractor from, inter alia, performing acupuncture. The Iowa Supreme Court upheld the injunction on the rationale that the modalities for the practice of chiropractic were specifically delineated by statute and acupuncture was not enumerated. Id. at 603-04. The Court noted that the statutes governing the practice of medicine and osteopathic medicine are less restrictive. Id. at 602. Implicit in the Court's ruling was that acupuncture is within the realm of the practice of medicine. Id. at 602-03.

Applying the principles developed by the Iowa Supreme Court to the hypothetical facts and the questions posed, we conclude that the diagnosis of pain, headaches, sports injuries, and

arthritis, the prescription of acupuncture as a treatment, as well as the practice of acupuncture to treat these ailments would constitute the practice of medicine and surgery. The hypothetical facts as posed indicate that acupuncture directly involves diagnosis and treatment of these ailments. The decisions in Hughey and Howard leave little doubt these activities would, therefore, constitute the practice of medicine and surgery.

Application of these principles to smoking and weight loss is somewhat more troublesome. The definition of the practice of medicine and surgery under our statutes is a functional definition. Diagnosis and treatment are keys in the analysis. The role of diagnosis and treatment in practicing acupuncture on people who smoke or are overweight is less clear than practicing acupuncture on people who have the other listed ailments. The hypothetical facts do not delineate specific facts from which we may infer that diagnosis and treatment occur. Rather, the questions are posed in conclusory terms. Acupuncture performed on smokers and overweight people, however, may involve some diagnosis and treatment. Acupuncture generally involves an assessment of the body's condition for which the acupuncture process is intended as a treatment. Where diagnosis and treatment do occur, acupuncture becomes the practice of medicine and surgery.

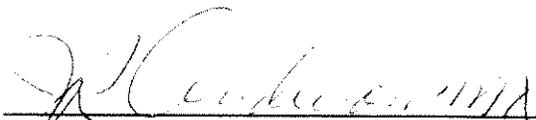
We are aware that legal limitations on the practice of acupuncture have been subject to litigation in other jurisdic-

tions. Comparison of our approach with the approach taken by other states is difficult because the statutes which define the practice of medicine are worded differently from state to state. Other states, however, have reached results consistent with this ruling.

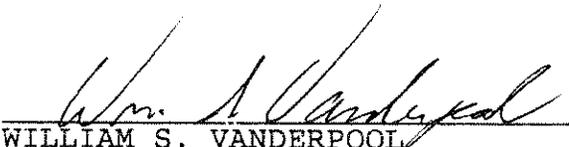
The New York Supreme Court decided in People v. Amber, 76 Misc.2d 267, 349 N.Y.S.2d 604 (N.Y. Sup. Ct. 1973), that acupuncture constitutes the practice of medicine. The statutes in New York defined the practice of medicine to include "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition." The Court determined that the statute encompassed all diagnosing and treating. Acupuncture, in turn, involved diagnosis to determine the condition of the organs in order to choose the appropriate acupuncture points. The Court, therefore, concluded that acupuncture was the practice of medicine for which a license was required. Id. at 274, 349 N.Y.S.2d at 611.

The practice of acupuncture has also been the subject of dispute concerning whether licensed professionals, other than physicians, may engage in acupuncture. Compare, State v. Van Wyk, 320 N.W.2d at 606 (chiropractors prohibited); State v. Won, 19 Or.App. 580, 528 P.2d 594 (1975) (chiropractor prohibited); State v. Rich, 44 Ohio 2d 195, 339 N.E.2d 630 (1975) (chiropractors prohibited) with Acupuncture Society v. Kansas State Board of Healing Arts, 226 Kan. 639, 602 P.2d 1311 (1979) (chiroprac-

tors permitted). Some jurisdictions have separately licensed and regulated acupuncturists. See, e.g., Mass. Ann. Laws ch. 112, §§ 148 et. seq. We find little authority, however, suggesting that the practice of acupuncture may be left completely unregulated to unlicensed persons.



JOHN R. ANDERSON, M.D.
Chairman, Iowa Board of
Medical Examiners



WILLIAM S. VANDERPOOL
Executive Director, Iowa Board
of Medical Examiners

BEFORE THE IOWA STATE BOARD OF MEDICAL EXAMINERS

LUCAS STATE OFFICE BUILDING

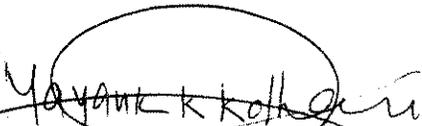
DES MOINES, IOWA

IN THE MATTER OF THE PETITION : PETITION FOR DECLARATORY
OF : RULING

Mayank K. Kothari, M.D. for a :
declaratory ruling on the use :
of computer generated signature :
of a licenced physician :

1. The name of the Petitioner is Mayank K. Kothari. His address is 1221 Center Street, Suite 3, Des Moines, Iowa 50309. Telephone number 515-243-1878.
2. Petitioner requests a declaratory ruling in regard to usage of "computer generated signature" of a licenced physician. The evolutionary data in the production of such a signature are attached hereto (Exhibit A).
3. The petitioner is requesting a comprehensive 'definition' of a "computer generated licenced physician's signature". It further requests whether the hypothetical case attached hereto falls within the 'definition'.
4. The petitioner is persuaded to believe that such aforementioned hypothetical case is in deviation of the statutory definition of a physician's signature. Authority relied upon include:
 - A. Iowa Code 1985 Section 4.1(17)
Iowa Administrative Code 470-135.204(3)(d)
470-136.5(5)(b)(1)
470.51.5
 - B. Declaratory Ruling of December, 1985 by the Board of Medical Examiners of the state of Iowa in the matter of the petition of St. Luke's

Regional Medical Center, Sioux City, Iowa.

Handwritten signature of Mayank K. Kothari in black ink, enclosed in a hand-drawn oval.

Mayank K. Kothari, M.D.
1221 Center Street
Suite 3
Des Moines, Iowa 50309
(515) 243-1878

EXHIBIT A

A copy of a report of arterial blood gases with interpretation is presented in this exhibit. The report contains the computer generated signature of a licenced physician in Iowa. At the very beginning the physician has developed an exclusive medical software for a computer pursuant to his expertise and training among his other skills. Blood specimin is submitted to the department of Respiratory Therapy from an acute care case in the middle of the night for analysis. The physician whose computer software has produced what appears to be a final and full report is not present nor is aware of the fact that such a report is being issued under his 'signature'. The computer software has taken over the licencee and the 'signature' is not on hands-on basis. It is a 'rubber stamp' by a computer.



IOWA
LUTHERAN
HOSPITAL

University at Penn Avenue, Des Moines, Iowa 50316-2392
515-263-5612

*Dr. Kothari -
Hope this helps you -
Sax*

April 23, 1990

N. L. Saxton, M.D.
Medical Director
Iowa Lutheran Hospital
University at Penn
Des Moines, IA 50316

Greg A. Hicklin, M.D.
Medical Director
Iowa Lutheran Hospital
University at Penn Ave.
Des Moines, Iowa 5031

RE: Arterial Blood Gas Interpretations

Dear Dr. Saxton,

Recently you asked about the interpretation of blood gases and my signature on blood gas reports.

Arterial blood gases are performed by Respiratory Therapy. These results are then entered into a computer, the program of which was developed by the Respiratory Therapy Department at Iowa Lutheran Hospital under my direction. This is not a pre-purchased program, it is not a commercially available program but reflects my opinions on blood gas interpretation, my experience and knowledge of pulmonacy physiology. Because of the STAT nature of the blood gas test, I feel that it is important that an interpretation go out with the blood gas results. This interpretation is based on my medical knowledge and is signed with a signature stamp by my direction. There are a specified set of "Panic Values", again, developed under my direction, that will trigger a direct call to the floor or the nursing unit responsible for the patient and through that nursing unit to the physician.

Daily, the blood gas results are reviewed by me personally, the results checked and a hand written signature applied to

the report. A computer log is kept in the Respiratory Department. Changed interpretations are sent to the Medical Records Department as well as all out patient interpretations.

I feel that this is a good service for the patient. It insures a prompt and accurate reporting not only of the arterial blood values, but an interpretation of the arterial blood gases. This interpretation is based on my medical knowledge and opinions and as such is reported over my signature stamp. The signature stamp is controlled by me through the Respiratory Therapy Department.

This system has been in place at least since 1979 and seems to be well received by the medical staff as a whole.

Please feel free to contact me if I can provide any further information to you.

(sincerely)
Greg A. Hicklin MD

Greg A. Hicklin, M.D.

This copy is provided for educational use only along with the petition for Declaratory Ruling. It is not a complaint for the record.

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF THE
PETITION OF MAYANK K.
KOTHARI, M.D.,

)
)
)

DECLARATORY RULING

PROCEDURE

Mayank K. Kothari, M.D., filed a Petition for Declaratory Ruling with the Iowa Board of Medical Examiners [hereinafter the Board] pursuant to Iowa Code § 17A.9 and 653 Iowa Admin. Code § 10.10. The petitioner is identified as Mayank K. Kothari, M.D., a licensed physician practicing at 1221 Center Street, Suite 3, Des Moines, Iowa 50309.

HYPOTHETICAL FACTS

The petitioner has submitted the following factual statement:

A copy of a report of arterial blood gases with interpretation is presented in this exhibit.¹ The report contains the computer generated signature of a licensed physician in Iowa. At the very beginning the physician has developed an exclusive medical software for a computer pursuant to his expertise and training among his other skills. Blood specimen is submitted to the department of Respiratory Therapy from an acute care case in the middle of the night for analysis. The physician whose computer software has produced what appears to be a final and full report is not present nor is aware of the fact that such a report is being issued under his 'signature'. The computer software has taken over the licensee and the 'signature'

¹No report of arterial blood gases has been received.

is not on hands-on basis. It is a 'rubber stamp' by a computer.

In addition a letter dated May 16, 1990, has been submitted by the petitioner as supplementary material. (Exhibit A) The letter, signed by Greg A. Hicklin, M.D., indicates that the computer generated blood gas interpretation referred to by the petitioner is the product of a computer program developed by the physician whose computer signature is ultimately affixed.

QUESTION PRESENTED

Does the use of the computer generated licensed physician's signature to sign computer generated blood gas interpretations violate Iowa Code § 4.1(17), 653 Iowa Admin. Code § 12.4(3), 641 Iowa Admin. Code § 51.5, or 653 Iowa Admin. Code § 20.5(5)b(1)²?

AUTHORITIES

Iowa Code § 4.1(17) (1989):

Written -- in writing -- signature. The words "written" and "in writing" may include any mode of representing words or letters in general use. A signature, when required by law, must be made by the writing or markings of the person whose signature is required. If a person is unable due to a physical handicap to make a written signature or mark, that person may substitute the following in lieu of a signature required by law:

²The petition refers to rules in the Iowa Administrative Code by outdated chapter numbers. All rule references have been updated to the current chapter number.

a. The handicapped person's name written by another upon the request and in the presence of the handicapped person; or,

b. A rubber stamp reproduction of the handicapped person's name or facsimile of the actual signature when adopted by the handicapped person for all purposes requiring a signature and then only when affixed by that person or another upon request and in the handicapped person's presence.

641 Iowa Admin. Code § 51.5:

51.5(1) Medical records. Accurate and complete medical records shall be written for all patients and signed by the attending physician; these shall be filed and stored in an accessible manner in the hospital and in accordance with the statute of limitations.

51.5(2) Hospital records.

a. Admission records. A register of all admissions to the hospital shall be kept in accordance with Iowa law.

b. Death records. A register of all deaths in the hospital shall be kept, including all information required on a standard certificate.

c. Birth records. A register of all births in the hospital shall be kept, including all information required on a standard certificate.

d. Narcotic records. Narcotic records shall be maintained in accordance with the laws and regulations pertaining thereto.

51.5(3) All hospitals shall use the uniform hospital billing form (Form UB-82 HCFA-1450) and manual (Iowa Uniform Billing Data Element Specifications) when billing for inpatient or outpatient services in accordance with Iowa Administrative Code 411-5.3(145)).

51.5(4) All hospitals shall submit annually to the commissioner the Hospital Price Information Survey in accordance with Iowa Administrative Code 411--8.2(145) and shall post hospital price information in accordance with Iowa Administrative Code 411--8.3(145).

653 Iowa Admin. Code § 12.4(3):

12.4(3) Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of a profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

* * *

d. Practice harmful or detrimental to the public includes, but is not limited to, the use of a rubber stamp to affix a signature to a prescription. A person who is unable, due to a physical handicap, to make a written signature or mark, however, may substitute in lieu of a signature a rubber stamp which is adopted by the handicapped person for all purposes requiring a signature and which is affixed by the handicapped person or affixed by another person upon the request of the handicapped person and in their presence.

653 Iowa Admin. Code § 20.5(5)b(1):

It shall be the responsibility of the supervising physician to ensure that:

* * *

b. Adequate supervision and review of the work of the physician's assistant is provided.

(1) The supervising physician shall review at least weekly all patient care provided by the physician's assistant if such care is rendered without direct consultation

with the physician and shall countersign all notes made by the physician's assistant.

RULING

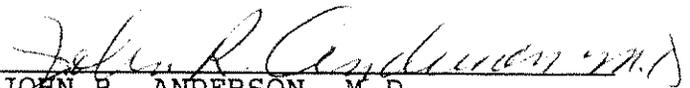
The petitioner in this case essentially asks the Board to re-evaluate a Declaratory Ruling issued in 1986 concerning computer generated signatures in light of their use on computer generated blood gas interpretations. A copy of our previous ruling is attached as Exhibit B.

We find no additional facts in the current petition which would alter our analysis of the utilization of computer generated signatures themselves. The petitioner's underlying concern appears to be that the computer generated signature is affixed to a blood gas interpretation which is, itself, computer generated. As a result the physician whose "signature" appears on the blood gas interpretation is not personally involved in the interpretation at the time it is issued.

The computer process described by the petitioner and the concerns raised in the hypothetical facts focus on whether blood gas interpretation can be carried out by computer program consistent with acceptable standards of patient care. Assessment of the patient care provided by the practitioner under this process would require consideration of the adequacy of the computer program and the existence of any variables in patient care which the computer program is unable to address. This issue exceeds the scope of our Declaratory Ruling and requires further

consideration of medical issues not suited to resolution by this
Declaratory Ruling.

Dated this 1st day of August, 1990.



JOHN R. ANDERSON, M.D.
Chairman, Iowa Board
of Medical Examiners



WILLIAM S. VANDERPOOL
Executive Director, Iowa Board
of Medical Examiners



University at Penn Avenue, Des Moines, Iowa 50316-2392
515-263-5612

*Dr. Kothari -
Hope this helps you -
Jax*

April 23, 1990

N. L. Saxton, M.D.
Medical Director
Iowa Lutheran Hospital
University at Penn
Des Moines, IA 50316

Greg A. Hicklin, M.D.
Medical Director
Iowa Lutheran Hospital
University at Penn Ave.
Des Moines, Iowa 5031

RE: Arterial Blood Gas Interpretations

Dear Dr. Saxton,

Recently you asked about the interpretation of blood gases and my signature on blood gas reports.

Arterial blood gases are performed by Respiratory Therapy. These results are then entered into a computer, the program of which was developed by the Respiratory Therapy Department at Iowa Lutheran Hospital under my direction. This is not a pre-purchased program, it is not a commercially available program but reflects my opinions on blood gas interpretation, my experience and knowledge of pulmonacy physiology. Because of the STAT nature of the blood gas test, I feel that it is important that an interpretation go out with the blood gas results. This interpretation is based on my medical knowledge and is signed with a signature stamp by my direction. There are a specified set of "Panic Values", again, developed under my direction, that will trigger a direct call to the floor or the nursing unit responsible for the patient and through that nursing unit to the physician.

Daily, the blood gas results are reviewed by me personally, the results checked and a hand written signature applied to



the report. A computer log is kept in the Respiratory Department. Changed interpretations are sent to the Medical Records Department as well as all out patient interpretations.

I feel that this is a good service for the patient. It insures a prompt and accurate reporting not only of the arterial blood values, but an interpretation of the arterial blood gases. This interpretation is based on my medical knowledge and opinions and as such is reported over my signature stamp. The signature stamp is controlled by me through the Respiratory Therapy Department.

This system has been in place at least since 1979 and seems to be well received by the medical staff as a whole.

Please feel free to contact me if I can provide any further information to you.

Sincerely,
Greg A. Hicklin MD

Greg A. Hicklin, M.D.

This copy is provided for educational use only along with the petition for Declaratory Ruling. It is not a complaint for the record.

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF THE)
PETITION OF ST. LUKE'S REGIONAL) DECLARATORY RULING
MEDICAL CENTER)

PROCEDURE

On December 12, 1985, the Iowa Board of Medical Examiners received a Petition for Declaratory Ruling filed by attorney Jeffrey L. Poulson pursuant to 470 I.A.C. § 135.10. The Petitioner is identified as St. Luke's Regional Medical Center, 2720 Stone Park Boulevard, P.O. Box 2000, Northside Station, Sioux City, Iowa 51104.

FACTS

St. Luke's Regional Medical Center is presently implementing a computerized medical records system. All orders and medical records will be entered onto the computer and maintained in this system. Computer access codes will be used as the equivalent of a signature by physicians in connection with the maintenance of medical records. The system will be used in the manner described in Exhibit 1, 2 and 3. (Attached)

QUESTION PRESENTED

Will utilization of the computerized medical records system by licensees to sign medical records through use of a computer access code violate § 4.1(17) of The Code or 470 I.A.C. §§ 51.5, 135.204(3)d or 136.5(5)b(1) of the Iowa Administrative Code?



AUTHORITIES

Iowa Code § 4.1(17):

Written -- in writing -- signature. The words "written" and "in writing" may include any mode of representing words or letters in general use. A signature, when required by law, must be made by the writing or markings of the person whose signature is required. If a person is unable due to a physical handicap to make a written signature or mark, that person may substitute the following in lieu of a signature required by law:

- a. The handicapped person's name written by another upon the request and in the presence of the handicapped person; or,
- b. A rubber stamp reproduction of the handicapped person's name or facsimile of the actual signature when adopted by the handicapped person for all purposes requiring a signature and then only when affixed by that person or another upon request and in the handicapped person's presence.

470 I.A.C. § 51.5:

51.5(1) Medical records. Accurate and complete medical records shall be written for all patients and signed by the attending physician; these shall be filed and stored in an accessible manner in the hospital and in accordance with the statute of limitations.

51.5(2) Hospital records.

a. Admission records. A register of all admissions to the hospital shall be kept in accordance with Iowa law.

b. Death records. A register of all deaths in the hospital shall be kept, including all information required on a standard certificate.

c. Birth records. A register of all births in the hospital shall be kept, including all information required on a standard certificate.

d. Narcotic records. Narcotic records shall be maintained in accordance with the laws and regulations pertaining thereto.

51.5(4) All hospitals shall submit annually to the commissioner the Hospital Price Information Survey in accordance with Iowa Administrative Code 465--8.2(145) and

shall post hospital price information in accordance with Iowa Administrative Code 465--8.3(145).

470 I.A.C. § 135.204(3)d:

135.204(3) . Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of a profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

* * * *

d. Practice harmful or detrimental to the public includes, but is not limited to, the use of a rubber stamp to affix a signature to a prescription. A person who is unable, due to a physical handicap, to make a written signature or mark, however, may substitute in lieu of a signature a rubber stamp which is adopted by the handicapped person for all purposes requiring a signature and which is affixed by the handicapped person or affixed by another person upon the request of the handicapped person and in his/her presence.

470 I.A.C. § 136.5(5)b(1):

136.5(5) It shall be the responsibility of the supervising physician to ensure that:

* * * *

b. Adequate supervision and review of the work of the physician's assistant is provided.

(1) The supervising physician shall review at least weekly all patient care provided by the physician's assistant if such care is rendered without direct consultation with the physician and shall countersign all notes made by the physician's assistant.

RULING

The Board of Medical Examiners will issue a declaratory ruling only with respect to statutes and rules "under its jurisdiction." 470 I.A.C. § 135.10(1). Accordingly, we confine

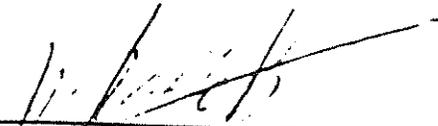
our declaratory ruling to interpretation of 470 I.A.C. §§ 135.204(3)d and 136.5(5)b(1) which are rules promulgated by this Board. We acknowledge § 4.1(17) of the Code as a codified principle of statutory construction. We, however, do not address 470 I.A.C. § 51.5 which is a rule promulgated by the Department of Health.

Disciplinary action may be initiated against a licensee on the basis of 470 I.A.C. § 135.204(3) which prohibits, in part, engaging in a practice harmful or detrimental to the public. We have promulgated subrule d to further define practice harmful or detrimental to the public to include the use of a rubber stamp to affix a signature to a prescription except under limited circumstances applicable to the handicapped. 470 I.A.C. § 135.204(3)d. Application of 470 I.A.C. § 135.204(3) in other circumstances is adjudicated on a case-by-case basis.

Use of a computer access code to sign medical records would not constitute a practice harmful or detrimental to the public under the facts set out in this declaratory ruling. All medical staff and authorized personnel who would use the computer access code must sign an agreement before the code is issued. Under the terms of this agreement, the code is confidential. The user, moreover, is obligated to report any break in confidentiality. A user who violates this confidentiality, furthermore, is subject to disciplinary action including possible termination. In view of these security measures, we cannot conclude that use of the computer access code to sign medical records in the manner set

out in this petition would constitute a practice harmful or detrimental to the public which would result in disciplinary action by this Board.

Different considerations govern the countersignature of medical records by a physician who provides supervision to a physician's assistant. Under 470 I.A.C. § 136.5(5)b(1), the supervising physician must review at least weekly all patient care provided by the physician's assistant if care is rendered without direct consultation and must countersign all notes made by the physician's assistant. Under these circumstances the physician's signature not only validates the notes made by the physician's assistant but also evinces a discharge of the duty to review all patient care. The security measures built into the computerized medical records system may be sufficient to insure that physician's signature is genuine. Adequate supervision of a physician's assistant, however, requires that the review of patient care be carried out on site. In view of the supervisory duties, therefore, we conclude a computer access code cannot be used to countersign the notes of a physician's assistant pursuant to 470 I.A.C. § 136.5(5)b(1).



HORMOZ/RAËSEKH, M.D.
Chairman
Iowa Board of Medical Examiners

REVISION
10 85

DEPARTMENT	INFORMATION RESOURCES	EFFECTIVE DATE	DATE	October 4, 1984
SUBJECT	USER ACCESS CODES	NUMBER OF PAGES	2	PAGE NUMBER 1

PURPOSE: To ensure patient confidentiality; integrity and accuracy of data; appropriate usage of the Medical Information System; and protection of Medical Center assets against accidental/intentional disclosure, modification or destruction.

POLICY: Authorized individuals may have access to the Medical Information System (MIS) only after successful completion of the MIS Training Program. Access to MIS will be controlled by a user identification code referred to as the USER ACCESS CODE. The code limits individual access to only that patient information needed to perform job responsibilities, and the identity of the user will be recorded on all entries. The Director of Education Services will be responsible for the training of individuals. The Director of Information Resources will be responsible for the distribution of User Access Codes and maintaining the appropriate use of MIS.

The Director of the Information Resources Department will be responsible for establishing department policy and procedure to ensure effective supervision of those individuals responsible for maintaining the integrity of MIS.

- PROCEDURE:
1. Medical Center personnel, Medical Staff members, and other approved user groups will successfully complete the Medical Center's Medical Information System Training Program prior to being eligible for a User Access Code.
 2. Individuals will sign a User Access Code Agreement prior to receiving their access code.
 3. User Access Codes are subject to change as required by changes in the individual's job responsibilities and/or at the discretion of the Information Resources Department.
 4. Individuals who have reason to believe that the confidentiality of their User Access Code has been violated will contact the Information Resources Department immediately so that the current code may be deleted and a new access code assigned.

APPROVED _____



DEPARTMENT	INFORMATION RESOURCES	EFFECTIVE DATE	
		DATE	October 4, 1984
SUBJECT	USER ACCESS CODES	NUMBER OF PAGES	PAGE NUMBER
		2	2

5. Department Directors are responsible to monitor employee performance with regard to MIS usage.
6. Individuals who knowingly violate their User Access Code Agreement are subject to disciplinary action. The matrix duty officer from Information Resources should be notified immediately whenever a violation of the user access code policy occurs, so that the matrix duty officer can immediately delete the user access code of the person violating the policy. Disciplinary action will be the responsibility of the Department Director and should be coordinated through the Human Resources Department for consistency.
7. User Access Codes will be deleted from the system upon termination/resignation of individuals affiliated with the Medical Center or a change in job responsibilities not requiring a User Access Code. The Department Directors will have the responsibility to notify the Human Resources Department of the date such changes will occur. The Director of Human Resources will then have responsibility to notify the Director of Information Resources.

APPROVED



 110-8-84

ST. LUKE'S REGIONAL MEDICAL CENTER
Sioux City, Iowa

USER ACCESS CODE AGREEMENT

Authorized Personnel

I, the undersigned, acknowledge receipt of my USER ACCESS CODE and understand that:

1. My USER ACCESS CODE is the legal equivalent of my signature; I will not disclose this code to anyone.
2. I will not attempt to learn another's USER ACCESS CODE and will not access information in the Medical Information System (MIS) by using a USER ACCESS CODE other than my own.
3. I will not access any unauthorized information via the Medical Information System.
4. If I have reason to believe that the confidentiality of my USER ACCESS CODE has been broken, I will contact the Department of Information Resources immediately so that the current code may be deleted and a new USER ACCESS CODE assigned to me.
5. I will protect the patient's right to the CONFIDENTIALITY of his/her medical information.

I understand that if I violate any of the above statements, I will be subject to disciplinary action, i.e., suspension, immediate termination, or loss of MIS privileges. Grievances will be handled according to the Medical Center's Personnel Manual.

I further understand that my USER ACCESS CODE will be deleted from the system as soon as I terminate my employment at St. Luke's Regional Medical Center; should I be re-employed at the Medical Center, a new USER ACCESS CODE will be issued at that time.

EMPLOYEE NAME (PLEASE PRINT)

SIGNATURE OF ISSUER

SIGNATURE OF EMPLOYEE

DATE

DATE



ST LUKE'S REGIONAL MEDICAL CENTER
Sioux City, Iowa

MEDICAL STAFF USER ACCESS CODE AGREEMENT

USER ACCESS CODES are created to allow an individual access to the Medical Center's Medical Information System (MIS) for the purpose of entering and retrieving patient information. A physician USER ACCESS CODE limits the individual physician's access to specific patient data and system features that are necessary in providing medical care to patients under the direct care of the physician.

Because of the Medical Center's concern to maintain the integrity and confidentiality of patient information and to ensure that only authorized individuals may access the patient's medical record, it has become necessary to establish guidelines governing the use of the USER ACCESS CODE. The guidelines are listed below.

I, the undersigned, acknowledge receipt of my USER ACCESS CODE and understand that:

1. My USER ACCESS CODE is the legal equivalent of my signature.
2. My USER ACCESS CODE personally identifies me to the Medical Information System.
3. I will not disclose my USER ACCESS CODE to anyone.
4. I will not attempt to learn another's USER ACCESS CODE and will not access information in the Medical Information System (MIS) by using a USER ACCESS CODE other than my own.
5. If I have reason to believe that the confidentiality of my USER ACCESS CODE has been broken, I will contact the Department of Information Resources immediately so that the current code may be deleted and a new USER ACCESS CODE assigned to me.

I understand that if I violate any of the above statements, my MIS privileges will be summarily suspended and the suspension then reviewed in accordance with the Medical Staff Bylaws.

I further understand that my USER ACCESS CODE will be deleted from the system should I no longer be a member of the active, courtesy or affiliate staff at St. Luke's Regional Medical Center.

PHYSICIAN NAME (PLEASE PRINT)

SIGNATURE OF ISSUER

SIGNATURE OF PHYSICIAN

EXHIBIT
2

PETITION FOR DECLARATORY RULING
BEFORE THE IOWA STATE BOARD OF MEDICAL EXAMINERS

PETITION BY THE IOWA ACADEMY)	
OF OPHTHALMOLOGY FOR A)	NO. _____
DECLARATORY RULING CONCERNING)	
PROVISIONS OF CHAPTERS 147, 148,)	PETITION FOR
AND 154 OF THE CODE OF IOWA (1991))	DECLARATORY RULING

COMES NOW Petitioner, the Iowa Academy of Ophthalmology, an association of ophthalmologists practicing in the state of Iowa, and in support of its Petition for Declaratory Ruling states to the Iowa State Board of Medical Examiners as follows:

A. Statement of Facts Upon Which Petitioner Requests the Board to Issue Its Declaratory Ruling.

1. An ophthalmologist has a patient he has been following for many years. The patient is a 65-year old insulin-dependent diabetic who has had decreasing vision for some time. The ophthalmologist performs a complete examination in order to determine the cause for the patient's decreased visual acuity. A reasonable determination of whether or not removal of cataracts would be of benefit to the patient is made. Because cataracts are determined to be the likely cause for the patient's complaint of decreasing vision, a discussion is had with the patient concerning whether or not the severity of the reduction in vision warrants the risk of cataract surgery. The surgeon determines which cataract procedure would be of greatest benefit to the individual patient. The surgeon determines whether or not other ophthalmic or medical conditions are present which warrant treatment prior to cataract surgery (such as blepharitis, diabetic retinopathy, retinal tears, or unstable medical conditions). The surgeon determines the power of the lens implant to be used. The surgeon decides with the patient's help and if needed, with the input of the patient's family and physician whether local or general or other anesthetic arrangements should be made. The surgeon performs the cataract extraction. The ophthalmologist performs all aspects of the patient's postoperative care in most situations. In some situations the ophthalmologist may

directly supervise a resident medical physician who assists the ophthalmologist in providing postoperative care. In some situations an ophthalmologist's peer working in the same office or department may also assist with the postoperative care.

2. An ophthalmologist who previously had performed cataract surgery and who now no longer performs cataract surgery refers a patient to an ophthalmic surgeon for cataract surgery. The operating surgeon takes responsibility for completely evaluating the patient, determining whether or not cataracts are the cause for the patient's symptoms, determines whether or not there is a reasonable expectation of benefit to the patient with relief of the patient's symptoms following surgery, and discusses with the patient and his family the risks and benefits involved with cataract surgery. The operating surgeon determines which type of surgery is best undertaken for that particular patient, determines the power of lens implant, determines what sort of anesthesia would be best in the given circumstances and consults with the patient's family physician as needed preoperatively. The surgical ophthalmologist performs the cataract surgery with or without the assistance or observation of the medical ophthalmologist who referred the patient to the surgeon. If it is agreeable to the patient, and the patient has had an opportunity to discuss this with the medical and surgical ophthalmologist preoperatively, the medical ophthalmologist may undertake postoperative care of the patient provided that this is agreeable to all parties involved, and has been discussed and documented in advance, and there have been no complications during surgery which will require ongoing surgical intervention.

3. A patient is referred by a family physician to an ophthalmologist because of complaints of decreased vision. The patient is a 70-year hypertensive with stable angina. The ophthalmologist determines the cause for the patient's complaints. The complaints are attributable to cataracts, and the patient has a reasonable expectation of benefit from cataract surgery, and wishes to undertake the risks of cataract surgery in an effort to improve the vision. The surgeon arranges for determination of lens implant power, anesthesia as needed, and further medical evaluation and treatment of the patient preoperatively by the patient's family physician if indicated. The ophthalmologist may perform a history and physical, or if it is in the best interests of the patient, the

family physician may perform a preoperative history and physical examination. The surgical ophthalmologist performs the surgery and provides for all aspects of the patient's postoperative care.

4. A patient is referred to an ophthalmologist by an optometrist because of decreased vision. The patient is a 50-year old with no evidence of medical diseases and with persistently decreasing vision which interferes with the patient's ability to maintain employment. The ophthalmologist performs the necessary examinations to determine the cause of the patient's visual complaints. The ophthalmologist makes an estimation of the potential benefit which the patient may reasonably expect if cataract surgery is undertaken. The surgeon discusses the risks of cataract surgery with the patient and makes arrangements for appropriate anesthesia if necessary. The patient may be asked by the surgeon to have a history and physical examination performed by his family physician, or the ophthalmologist may wish to proceed with the history and physical examination without the assistance of a family physician. The surgeon determines the type of surgery best suited for the patient's needs and determines the lens implant power and type most suitable for the particular patient. The surgeon performs the surgery and provides for all aspects of the patient's postoperative care. The surgeon may provide the patient with a postoperative refraction. The surgeon may elect to return the patient to the referring optometrist for evaluation and prescription of a postoperative lens.

5. A patient is referred to an ophthalmologist by an optometrist to have an evaluation of decreasing vision which is thought to be due to cataracts. The surgical ophthalmologist evaluates the patient with a complete ophthalmic examination. A determination is made that cataracts are the cause for the patient's complaints, and that the patient would benefit from surgical intervention. The surgeon discusses with the patient the potential risks and benefits of cataract surgery. The surgeon determines whether or not additional ophthalmic or medical conditions warrant further intervention prior to surgery. The ophthalmologist may perform a history and physical examination with or without the assistance of the patient's own medical physician. The ophthalmologist determines the power and type of implant and surgery most suitable for the patient. The ophthalmologist performs the surgery. The ophthalmologist evaluates

the patient for a limited time in the postoperative period. The remainder of the postoperative period is the responsibility of the optometrist. The optometrist makes the decisions about the progress of the patient postoperatively, adjusts medications, determines whether or not complications are present, and refers complications to an ophthalmologist or family physician as the optometrist feels is indicated. The patient, surgeon and optometrist have all agreed on the scenario preoperatively, and have put this in writing. The optometrist represents his care to a third party payor as being a portion of the postoperative care, and splits the reimbursement fee for postoperative care with the ophthalmologist.

6. An optometrist refers a patient to a surgeon for cataract surgery. The ophthalmologist confirms the optometrist's findings with a limited evaluation. The optometrist or ophthalmologist may determine the power of the lens implant to be used intraoperatively. The optometrist or ophthalmologist determines what type of surgical procedure and anesthesia are indicated. A preoperative history and physical may be performed by the ophthalmologist or family physician. The ophthalmologist performs the surgery with or without the observation of the optometrist. The ophthalmologist does not provide postoperative care. From the first day postoperatively the optometrist assumes 100% of the responsibility for postoperative care. The optometrist represents his care to the third party payor as being deserving of compensation for the entire postoperative period. The optometrist is responsible for evaluation of the eye postoperatively, monitoring its progress, evaluation for complications, adjustment of medications and referral to physicians as needed as felt indicated by the optometrist. The patient is aware preoperatively and is in agreement with the surgeon and optometrist to have the optometrist provide the entirety of the postoperative care.

7. An ophthalmologist comes from out of state and is prepared to operate on a number of patients who have been prepared for surgery by an optometrist. The optometrist determines whether or not the patient has a problem which would benefit from cataract surgery. The optometrist does preoperative testing for intraocular lens power and selects a type to be used intraoperatively. A history and physical examination is performed by the optometrist. The surgeon does the surgery, and is not available within Iowa

postoperatively. The optometrist is completely responsible for the entirety of the patients' postoperative care, including the monitoring of the eye postoperatively for normal healing, complications and adjustment of medications. The optometrist has the entire responsibility to seek assistance from some physician or ophthalmologist should complications develop. The patient, surgeon and optometrist are entirely aware of this situation preoperatively, and agree to this arrangement in writing. The optometrist presents his care to a third party payor as being the entirety of postoperative care splitting the global fee for cataract surgery with the surgeon.

8. A patient is referred to an ophthalmologist by an optometrist for consideration of a laser procedure. This laser procedure could be for opacification of the posterior capsule following cataract surgery, uncontrolled glaucoma, proliferative or background diabetic retinopathy, angle closure glaucoma, a retinal tear, or treatment of venous stasis retinopathy or other condition. The ophthalmologist evaluates the patient preoperatively to determine whether or not the laser procedure is indicated. The ophthalmologist then performs the laser procedure using retrobulbar or topical anesthesia or no anesthesia depending upon the particular needs of the patient. Postoperatively, the patient is referred back to the optometrist for further care. The patient, surgeon and optometrist have all agreed on this scenario preoperatively and have put this in writing. The optometrist represents his care to a third party payor as being a portion of the postoperative care and splits the reimbursement fee for postoperative care with the ophthalmologist.

B. Statutes, Rules, Policies, Decisions, or Orders For Which a Ruling is Sought.

Section 147.2 of the Code of Iowa provides as follows:

A person shall not engage in the practice of medicine and surgery, podiatry, osteopathy, osteopathic medicine and surgery, psychology, chiropractic, physical therapy, nursing, dentistry, dental hygiene, optometry, speech pathology, audiology, occupational therapy, pharmacy, cosmetology, barbering, dietetics, or mortuary science or shall not practice as a physician assistant as defined in the following

chapters of this title, unless the person has obtained from the department a license for that purpose.

Section 147.107 of the Code of Iowa provides in pertinent part:

1. A person, other than a pharmacist, physician, dentist, podiatrist, or veterinarian who dispenses as an incident to the practice of the practitioner's profession, shall not dispense prescription drugs or controlled substances.

2. A pharmacist, physician, dentist, or podiatrist who dispenses prescription drugs, including but not limited to controlled substances, for human use, may delegate nonjudgmental dispensing functions to staff assistants only when verification of the accuracy and completeness of the prescription is determined by the pharmacist or practitioner in the pharmacist's or practitioner's physical presence.

A physician, dentist, or podiatrist who dispenses prescription drugs, other than drug samples, pursuant to this subsection, shall annually register the fact that they dispense prescription drugs with the practitioner's respective examining board.

A physician, dentist, or podiatrist who dispenses prescription drugs, other than drug samples, pursuant to this subsection, shall offer to provide the patient with a written prescription that may be dispensed from a pharmacy of the patient's choice or offer to transmit the prescription to a pharmacy of the patient's choice.

. . . .

5. Notwithstanding subsection 1 and any other provision of this section to the contrary, a physician may delegate the function of prescribing drugs, controlled substances, and medical devices to a physician assistant licensed pursuant to Chapter 148C. When delegated prescribing occurs, the supervising physician's name shall be used, recorded, or otherwise indicated in connection with each individual prescription so that the individual who dispenses or administers the prescription knows under whose delegated authority the physician assistant is prescribing. . . .

Section 148.1 of the Iowa Code provides:

For the purposes of this title the following classes of persons shall be deemed to be engaged in the practice of medicine and surgery:

1. Persons who publicly profess to be physicians or surgeons or who publicly profess to assume the duties incident to the practice of medicine or surgery.

2. Persons who prescribe, or prescribe and furnish medicine for human ailments, or treat the same by surgery.

3. Persons who act as representatives of any person in doing any of the things mentioned in this section.

Section 154.1 of the Iowa Code provides in pertinent part as follows:

For the purpose of this title the following classes of persons shall be deemed to be engaged in the practice of optometry:

1. Persons employing any means other than the use of drugs, medicine or surgery for the measurement of the visual power and visual efficiency of the human eye; the prescribing and adopting of lenses, prisms, and contact lenses, and the using or employment of visual training or ocular exercise, for the aid, relief, or correction of vision.

2. Persons who allow the public to use any mechanical device for such purpose.

3. Persons who publicly profess to be optometrists and to assume the duties incident to said profession.

Certified licensed optometrists may employ cycloplegics, mydriatics, and topical anesthetics as diagnostic agents topically applied to determine the condition of the human eye for proper optometric practice or referral for treatment to a person licensed under Chapter 148 or 150A. . . .

Therapeutically certified optometrists may employ the following pharmaceuticals: topical pharmaceutical agents, oral antimicrobial agents, oral antihistamines, oral antiglaucoma agents, and oral analgesic agents, and notwithstanding §147.107 may without charge supply any of the above-listed pharmaceuticals to commence a course of therapy. Superficial foreign bodies may be removed from the human eye and adnexa. These therapeutic efforts are intended for the purpose of examination, diagnosis, and treatment of visual defects, abnormal conditions and diseases of the human eye and adnexa, for proper optometric practice or referral or for consultation or treatment to persons licensed under Chapter 148 or 150A.

. . .

Iowa Administrative Code §653-10.1(17A,147) provides in pertinent part as follows:

"The practice of medicine and surgery" shall mean holding one's self out as being able to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition and who shall either offer or undertake, by any means or methods to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition. This rule shall not apply to licensed. . . optometrists... who are exclusively engaged in the practice of their . . . profession.

Iowa Administrative Code §653-12.4(258A) provides in pertinent part as follows:

Grounds for Discipline. The board may impose any of the disciplinary sanctions set forth in Rule 12.2 (258A), including civil penalties in an amount not to exceed \$10,000, when the board determines that the licensee is guilty of any of the following acts or offenses:

12.4(12) Knowingly aiding, assisting, procuring, or advising a person to unlawfully practice medicine and surgery, osteopathic medicine and surgery or osteopathy.

12.4(27) Negligence and failing to exercise due care in the delegation of medical services to or supervision of nurses, physician's assistants, employees or other individuals, whether or not injury results.

C. Questions Presented For Declaratory Ruling.

1. Has the ophthalmologist in factual situation No. 1 fulfilled his responsibility to his patient?

2. Has the ophthalmic surgeon in factual situation No. 2 fulfilled his responsibility to his patient?

3. Has the surgical ophthalmologist in factual situation No. 3 fulfilled his responsibility to his patient?

4. Has the ophthalmologist in factual situation No. 4 fulfilled his responsibility to his patient?

a. Is the optometrist in factual situation No. 4 engaging in the practice of medicine?

5. Has the surgeon in factual situation No. 5 fulfilled his responsibility to his patient?

a. Is the optometrist in factual situation No. 5 engaging in the practice of medicine?

6. Has the ophthalmologist in factual situation No. 6 fulfilled his responsibility to his patient?

a. Is the optometrist in factual situation No. 6 engaging in the practice of medicine?

7. Has the ophthalmologist in factual situation No. 7 fulfilled his responsibility to his patient?

a. Is the optometrist in factual situation No. 7 engaging in the practice of medicine?

8. Has the ophthalmologist in factual situation No. 8 fulfilled his responsibilities to his patient?

a. Is the optometrist in factual situation No. 8 engaging in the practice of medicine?

D. Answers to Questions Desired by the Petitioner.

1. The ophthalmologist in factual situation No. 1 has provided for all aspects of the patient's operative care including preoperative and postoperative management. The preoperative and postoperative management are inherent to the practice of surgical ophthalmology. The ophthalmologist, as a practitioner of medicine and surgery, has fulfilled his responsibility to his patient.

2. Because the ophthalmic surgeon in factual situation No. 2 provided for all aspects of preoperative care and arranged for the provision of postoperative care by another ophthalmologist with the patient's permission in advance, the surgeon has fulfilled his responsibility to his patient. If the patient had not given his informed consent to allow another ophthalmologist to provide postoperative care, the patient's expectation that the surgeon would provide postoperative care would not be met, and the surgeon would have abrogated his responsibility. The patient must have a full understanding of who will be responsible for which aspects of his operative care if the operating surgeon is not going to be providing for all aspects of operative care. Likewise, the operating surgeon and referring ophthalmologist must agree in advance of the surgery what the postoperative arrangements for provision of care to the patient will be. In this situation, the physician providing the postoperative care to the patient is an ophthalmologist with an ophthalmologist's unique education, training, experience, and ability.

3. The surgical ophthalmologist in factual situation No. 3 has provided for all aspects of preoperative, operative, and postoperative care, with the assistance of a licensed family practitioner, and therefore has fulfilled his responsibility to his patient.

4. The ophthalmologist in factual situation No. 4 has fulfilled his responsibility to his patient by providing for all aspects of the patient's preoperative and postoperative care.

a. The optometrist in factual situation No. 4 is not engaging in the practice of medicine by providing an evaluation of the postoperative refraction and prescription of a postoperative lens. A postoperative refraction and prescription of the postoperative lens does not constitute the practice of medicine.

5. The surgeon in factual situation No. 5 has not fulfilled his responsibility to his patient because he has not provided for all aspects of the patient's postoperative care. The patient is still at risk for postoperative complications since the patient was still on postoperative medications and the eye was apparently not completely healed. The surgeon is allowing an optometrist, a non-physician, to determine the presence or absence of surgical complications.

a. The optometrist in factual situation No. 5 is engaging in the practice of medicine by providing postoperative care. The evaluation of the progress of the patient, adjustment of the medications, and determination of whether or not complications are present all constitute the practice of medicine, and in particular, postoperative surgical care. The optometrist has been wrongly given the responsibility in this situation of determining whether or not complications are present. With that responsibility go the risks of missing potential complications or not providing for their referral in a sufficiently timely manner so as to prevent permanent ophthalmic injury.

6. The ophthalmologist in factual situation No. 6 has not provided for all aspects of the patient's preoperative and postoperative care. The ophthalmologist's preoperative involvement with the patient was cursory and inadequate. The surgeon completely abrogated his responsibility to the patient by not providing for any postoperative care.

a. The optometrist in factual situation No. 6, in assuming the entire postoperative management of the patient is engaged in the practice of medicine. Postoperative management requires evaluation of the eye for postoperative progress, adjustment of medications, and the detection of complications with their treatment or referral as felt indicated by the optometrist. This requires the judgment and experience which are the unique qualifications of an ophthalmologist.

7. The ophthalmologist in factual situation No. 7 has not fulfilled his responsibility to his patient in that he has provided an incomplete surgical service to the patient. There has been a total abrogation of preoperative and postoperative responsibility, and the surgeon has therefore provided an incomplete surgical service.

a. The optometrist is engaged in the practice of medicine in factual situation No. 7 by determining that a surgical procedure must be undertaken, performing a history and physical examination prior to surgery, and monitoring the eye postoperatively for progress, adjusting the medications, and detecting the complications. It is not clear in this situation who the optometrist would consult should complications occur. In this situation all of the surgical care, with the exception of the operation itself, is provided by a non-physician without the unique qualifications and experience of an ophthalmologist or other licensed medical doctor.

8. The ophthalmologist in factual situation No. 8 has not fulfilled his responsibility to his patient in that he has provided an incomplete surgical service to the patient. There has been an abrogation of postoperative responsibility and the surgeon has, therefore, provided an incomplete service.

a. The optometrist is engaged in the practice of medicine in the factual situation No. 8, by monitoring the eye postoperatively for progress, adjusting the medications, and detecting complications. The range of complications related to laser surgery is similar to that involved with cataract surgery with the exception that wound related complications do not exist. However, retinal detachments, cystoid macular edema, glaucoma, and iritis all can and do occur.

E. Reasons For Requesting the Declaratory Ruling.

The Iowa Academy of Ophthalmology is requesting a declaratory ruling because with the recent extension by the Health Care Financing Administration of the global surgical period to 90 days postoperatively, see 56 Fed. Reg. 59502-59819 (1991) (to be codified at 42 C.F.R. 405, 413, and 415), a number of ophthalmologists in the state have felt increasing pressure to refer patients back to referring optometrists at increasingly early times postoperatively. This potentially compromises the patient's expectation for excellent surgical results because of the possibility of the failure of an optometrist to recognize complications appropriately.

Although the popular impression of cataract surgery is that of a quick and easy procedure from the patient's point of view, unfortunately serious complications do occur in the postoperative period. Surgical complications such as loss of a portion of the nucleus into vitreous requires immediate intervention by a vitrectomy surgeon with coordination of the referral by the cataract surgeon. Immediate postoperative pressure rises require medical or surgical intervention. Glaucomatous response to postoperative steroid drops, suture abscesses, and iritis all require medical treatment, and sometimes surgical intervention. Endophthalmitis can be acute and dramatic or indolent and insidious. Retinal tears, detachments, and cystoid macular edema need expert detection and treatment.

The ophthalmologists in the Iowa Academy of Ophthalmology were polled and indicated overwhelmingly that it would be helpful to have the Iowa State Board of Medical Examiners issue a declaratory ruling specifically outlining a surgeon's postoperative responsibilities.

F. Statement As To Other Proceedings.

Petitioner, the Iowa Academy of Ophthalmology, is not currently a party to another proceeding involving the questions at issue in this Petition for Declaratory Ruling. Further, to the Petitioner's knowledge, these questions have not been decided by, are not pending determination by, and are not under investigation by, any governmental entity.

G. Class of Persons Interested in the Questions Presented.

It is the Petitioner's belief that the class of persons affected by or interested in the questions presented in this Petition include all licensed physicians practicing in the area of ophthalmology and/or ophthalmic surgery. The Board may find that optometrists as a class would be affected by the Board's determination.

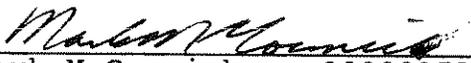
H. Request for a Meeting.

Petitioner, the Iowa Academy of Ophthalmologists, does request a brief and informal meeting with some representative of the Iowa State Board of Medical Examiners to discuss the Petition.

Although the Iowa Academy of Ophthalmology is an entity separate and distinct from the University of Iowa Department of Ophthalmology, it uses the following mailing address and telephone number: Iowa Academy of Ophthalmology, Department of Ophthalmology, the University of Iowa Hospitals & Clinics, Iowa Code, Iowa 52242, telephone (319) 356-4321.

Respectfully submitted on behalf of the Iowa Academy of Ophthalmology by its attorneys.

BELIN HARRIS LAMSON MCCORMICK,
A PROFESSIONAL CORPORATION

BY 
Mark McCormick 000003525

Robert D. Sharp
2000 Financial Center
Des Moines, IA 50309
Telephone: (515) 243-7100

ATTORNEY FOR IOWA ACADEMY
OF OPHTHALMOLOGY

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF THE PETITION
BY THE IOWA ACADEMY OF
OPHTHALMOLOGY CONCERNING
PROVISIONS OF CHAPTERS 147,
148, AND 154 OF THE CODE
OF IOWA (1991)

DECLARATORY RULING

PROCEDURE

On May 29, 1992, the Iowa Board of Medical Examiners received a Petition for Declaratory Ruling filed by attorney Mark McCormick. The petitioner is the Iowa Academy of Ophthalmology, Department of Ophthalmology, University of Iowa Hospitals and Clinics, Iowa City, Iowa 52242.

FACTS

The petitioner has posed eight, complex hypothetical situations:

HYPOTHETICAL SITUATION NO. 1

An ophthalmologist has a patient he has been following for many years. The patient is a 65-year old insulin-dependent diabetic who has had decreasing vision for some time. The ophthalmologist performs a complete examination in order to determine the cause for the patient's decreased visual acuity. A reasonable determination of whether or not removal of cataracts would be of benefit to the patient is made. Because cataracts are determined to be the likely cause for the patient's complaint of decreasing vision, a discussion is had with the patient concerning whether or not the severity of the reduction in vision warrants the risk of cataract surgery. The surgeon determines which cataract procedure would be of greatest benefit to the individual patient. The surgeon determines whether or not other ophthalmic or medical conditions are present which warrant treatment prior to cataract surgery (such as blepharitis, diabetic retinopathy, retinal tears, or unstable medical conditions). The surgeon determines the power of the lens implant to be used. The surgeon decides with the patient's help and if needed, with the input of the patient's family and physician whether local or general or other anesthetic arrangements should be made. The surgeon performs the cataract extraction. The ophthalmologist performs all aspects of the patient's postoperative care in most situations. In some situations the ophthalmologist may directly supervise a resident medical physician who assists the ophthalmologist in providing postoperative care. In some situations an ophthalmologist's peer working in the same office or department may also assist with the postoperative care.

HYPOTHETICAL SITUATION NO. 2

An ophthalmologist who previously had performed cataract surgery and who now no longer performs cataract surgery refers a patient to an ophthalmic surgeon for cataract surgery. The operating surgeon takes responsibility for completely evaluating the patient, determining whether or not cataracts are the cause for the patient's symptoms, determines whether or not there is a reasonable expectation of benefit to the patient with relief of the patient's symptoms following surgery, and discusses with the patient and his family the risks and benefits involved with cataract surgery. The operating surgeon determines which type of surgery is best undertaken for that particular patient, determines the power of lens implant, determines what sort of anesthesia would be best in the given circumstances and consults with the patient's family physician as needed preoperatively. The surgical ophthalmologist performs the cataract surgery with or without the assistance or observation of the medical ophthalmologist who referred the patient to the surgeon. If it is agreeable to the patient, and the patient has had an opportunity to discuss this with the medical and surgical ophthalmologist preoperatively, the medical ophthalmologist may undertake postoperative care of the patient provided that this is agreeable to all parties involved, and has been discussed and documented in advance, and there have been no complications during surgery which will require ongoing surgical intervention.

HYPOTHETICAL SITUATION NO. 3

A patient is referred by a family physician to an ophthalmologist because of complaints of decreased vision. The patient is a 70-year hypertensive with stable angina. The ophthalmologist determines the cause for the patient's complaints. The complaints are attributable to cataracts, and the patient has a reasonable expectation of benefit from cataract surgery, and wishes to undertake the risks of cataract surgery in an effort to improve the vision. The surgeon arranges for determination of lens implant power, anesthesia as needed, and further medical evaluation and treatment of the patient preoperatively by the patient's family physician if indicated. The ophthalmologist may perform a history and physical, or if it is in the best interests of the patient, the family physician may perform a preoperative history and physical examination. The surgical ophthalmologist performs the surgery and provides for all aspects of the patient's postoperative care.

HYPOTHETICAL SITUATION NO. 4

A patient is referred to an ophthalmologist by an optometrist because of decreased vision. The patient is a 50-year old with no evidence of medical diseases and with

persistently decreasing vision which interferes with the patient's ability to maintain employment. The ophthalmologist performs the necessary examinations to determine the cause of the patient's visual complaints. The ophthalmologist makes an estimation of the potential benefit which the patient may reasonably expect if cataract surgery is undertaken. The surgeon discusses the risks of cataract surgery with the patient and makes arrangements for appropriate anesthesia if necessary. The patient may be asked by the surgeon to have a history and physical examination performed by his family physician, or the ophthalmologist may wish to proceed with the history and physical examination without the assistance of a family physician. The surgeon determines the type of surgery best suited for the patient's needs and determines the lens implant power and type most suitable for the particular patient. The surgeon performs the surgery and provides for all aspects of the patient's postoperative care. The surgeon may provide the patient with a postoperative refraction. The surgeon may elect to return the patient to the referring optometrist for evaluation and prescription of a postoperative lens.

HYPOTHETICAL SITUATION NO. 5

A patient is referred to an ophthalmologist by an optometrist to have an evaluation of decreasing vision which is thought to be due to cataracts. The surgical ophthalmologist evaluates the patient with a complete ophthalmic examination. A determination is made that cataracts are the cause for the patient's complaints, and that the patient would benefit from surgical intervention. The surgeon discusses with the patient the potential risks and benefits of cataract surgery. The surgeon determines whether or not additional ophthalmic or medical conditions warrant further intervention prior to surgery. The ophthalmologist may perform a history and physical examination with or without the assistance of the patient's own medical physician. The ophthalmologist determines the power and type of implant and surgery most suitable for the patient. The ophthalmologist performs the surgery. The ophthalmologist evaluates the patient for a limited time in the postoperative period. The remainder of the postoperative period is the responsibility of the optometrist. The optometrist makes the decisions about the progress of the patient postoperatively, adjusts medications, determines whether or not complications are present, and refers complications to an ophthalmologist or family physician as the optometrist feels is indicated. The patient, surgeon and optometrist have all agreed on the scenario preoperatively, and have put this in writing. The optometrist represents his care to a third party payor as being a portion of the postoperative care, and splits the reimbursement fee for postoperative care with the ophthalmologist.

HYPOTHETICAL SITUATION NO. 6

An optometrist refers a patient to a surgeon for cataract surgery. The ophthalmologist confirms the optometrist's findings with a limited evaluation. The optometrist or ophthalmologist may determine the power of the lens implant to be used intraoperatively. The optometrist or ophthalmologist determines what type of surgical procedure and anesthesia are indicated. A preoperative history and physical may be performed by the ophthalmologist or family physician. The ophthalmologist performs the surgery with or without the observation of the optometrist. The ophthalmologist does not provide postoperative care. From the first day postoperatively the optometrist assumes 100% of the responsibility for postoperative care. The optometrist represents his care to the third party payor as being deserving of compensation for the entire postoperative period. The optometrist is responsible for evaluation of the eye postoperatively, monitoring its progress, evaluation for complications, adjustment of medications and referral to physicians as needed as felt indicated by the optometrist. The patient is aware preoperatively and is in agreement with the surgeon and optometrist to have the optometrist provide the entirety of the postoperative care.

HYPOTHETICAL SITUATION NO. 7

An ophthalmologist comes from out of state and is prepared to operate on a number of patients who have been prepared for surgery by an optometrist. The optometrist determines whether or not the patient has a problem which would benefit from cataract surgery. The optometrist does preoperative testing for intraocular lens power and selects a type to be used intraoperatively. A history and physical examination is performed by the optometrist. The surgeon does the surgery, and is not available within Iowa postoperatively. The optometrist is completely responsible for the entirety of the patients' postoperative care, including the monitoring of the eye postoperatively for normal healing, complications and adjustment of medications. The optometrist has the entire responsibility to seek assistance from some physician or ophthalmologist should complications develop. The patient, surgeon and optometrist are entirely aware of this situation preoperatively, and agree to this arrangement in writing. The optometrist presents his care to a third party payor as being the entirety of postoperative care splitting the global fee for cataract surgery with the surgeon.

HYPOTHETICAL SITUATION NO. 8

A patient is referred to an ophthalmologist by an optometrist for consideration of a laser procedure. This laser procedure could be for opacification of the posterior capsule following cataract surgery, uncontrolled glaucoma, proliferative or background diabetic retinopathy, angle closure glaucoma, a retinal tear, or treatment of venous stasis retinopathy or other condition. The ophthalmologist evaluates the patient preoperatively to determine whether or not the laser procedure is indicated. The ophthalmologist then performs the laser procedure using retrobulbar or topical anesthesia or no anesthesia depending upon the particular needs of the patient. Postoperatively, the patient is referred back to the optometrist for further care. The patient, surgeon and optometrist have all agreed on this scenario preoperatively and have put this in writing. The optometrist represents his care to a third party payor as being a portion of the postoperative care and splits the reimbursement fee for postoperative care with the ophthalmologist.

QUESTIONS PRESENTED

1. Has the ophthalmologist in factual situation No. 1 fulfilled his responsibility to his patient?
2. Has the ophthalmic surgeon in factual situation No. 2 fulfilled his responsibility to his patient?
3. Has the surgical ophthalmologist in factual situation No. 3 fulfilled his responsibility to his patient?
4. Has the ophthalmologist in factual situation No. 4 fulfilled his responsibility to his patient? Is the optometrist in factual situation No. 4 engaging in the practice of medicine?
5. Has the ophthalmic surgeon in factual situation No. 5 fulfilled his responsibility to his patient? Is the optometrist in factual situation No. 5 engaging in the practice of medicine?
6. Has the ophthalmologist in factual situation No. 6 fulfilled his responsibility to his patient? Is the optometrist in factual situation No. 6 engaging in the practice of medicine?
7. Has the ophthalmologist in factual situation No. 7 fulfilled his responsibility to his patient? Is the optometrist in factual situation No. 7 engaging in the practice of medicine?
8. Has the ophthalmologist in factual situation No. 8 fulfilled his responsibility to his patient? Is the optometrist in factual situation No. 8 engaging in the practice of medicine?

AUTHORITIES

Section 147.2 of the Code of Iowa provides as follows:

A person shall not engage in the practice of medicine and surgery, podiatry, osteopathy, osteopathic medicine and surgery, psychology, chiropractic, physical therapy, nursing, dentistry, dental hygiene, optometry, speech pathology, audiology, occupational therapy, pharmacy, cosmetology, barbering, dietetics, or mortuary science or shall not practice as a physician assistant as defined in the following chapters of this title, unless the person has obtained from the department a license for that purpose.

Section 147.107 of the Code of Iowa provides in pertinent part:

1. A person, other than a pharmacist, physician, dentist, podiatrist, or veterinarian who dispenses as an incident to the practice of the practitioner's profession, shall not dispense prescription drugs or controlled substances.

2. A pharmacist, physician, dentist, or podiatrist who dispenses prescription drugs, including but not limited to controlled substances, for human use, may delegate nonjudgmental dispensing functions to staff assistants only when verification of the accuracy and completeness of the prescription is determined by the pharmacist or practitioner in the pharmacist's or practitioner's physical presence. A physician, dentist, or podiatrist who dispenses prescription drugs, other than drug samples, pursuant to this subsection, shall annually register the fact that they dispense prescription drugs with the practitioner's respective examining board. A physician, dentist, or podiatrist who dispenses prescription drugs, other than drug samples, pursuant to this subsection, shall offer to provide the patient with a written prescription that may be dispensed from a pharmacy of the patient's choice or offer to transmit the prescription to a pharmacy of the patient's choice.

* * * *

5. Notwithstanding subsection 1 and any other provision of this section to the contrary, a physician may delegate the function of prescribing drugs, controlled substances, and medical devices to a physician assistant licensed pursuant to Chapter 148C. When delegated prescribing occurs, the supervising physician's name shall be used, recorded, or otherwise indicated in connection with each individual prescription so that the individual who dispenses or administers the prescription knows under whose delegated authority the physician assistant is prescribing. . . .

Section 148.1 of the Iowa Code provides:

For the purposes of this title the following classes of persons shall be deemed to be engaged in the practice of medicine and surgery:

1. Persons who publicly profess to be physicians or surgeons or who publicly profess to assume the duties incident to the practice of medicine or surgery.
2. Persons who prescribe, or prescribe and furnish medicine for human ailments, or treat the same by surgery.
3. Persons who act as representatives of any person in doing any of the things mentioned in this section.

Section 154.1 of the Iowa Code provides in pertinent part as follows:

For the purpose of this title the following classes of persons shall be deemed to be engaged in the practice of optometry:

1. Persons employing any means other than the use of drugs, medicine or surgery for the measurement of the visual power and visual efficiency of the human eye; the prescribing and adopting of lenses, prisms, and contact lenses, and the using or employment of visual training or ocular exercise, for the aid, relief, or correction of vision.
2. Persons who allow the public to use any mechanical device for such purpose.
3. Persons who publicly profess to be optometrists and to assume the duties incident to said profession.

Certified licensed optometrists may employ cycloplegics, mydriatics, and topical anesthetics as diagnostic agents topically applied to determine the condition of the human eye for proper optometric practice or referral for treatment to a person licensed under Chapter 148 or 150A. . . .

Therapeutically certified optometrists may employ the following pharmaceuticals: topical pharmaceutical agents, oral antimicrobial agents, oral antihistamines, oral antiglaucoma agents, and oral analgesic agents, and notwithstanding §147.107 may without charge supply any of the above-listed pharmaceuticals to commence a

course of therapy. Superficial foreign bodies may be removed from the human eye and adnexa. These therapeutic efforts are intended for the purpose of examination, diagnosis, and treatment of visual defects, abnormal conditions and diseases of the human eye and adnexa, for proper optometric practice or referral or for consultation or treatment to persons licensed under Chapter 148 or 150A.

Iowa Administrative Code §653-10.1(17A, 147) provides in pertinent part as follows:

"The practice of medicine and surgery" shall mean holding one's self out as being able to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition and who shall either offer or undertake, by any means or methods to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition. This rule shall not apply to licensed. . . optometrists... who are exclusively engaged in the practice of their . . . profession.

Iowa Administrative Code §653-12.4(258A) provides in pertinent part as follows:

Grounds for Discipline. The board may impose any of the disciplinary sanctions set forth in Rule 12.2 (258A), including civil penalties in an amount not to exceed \$10,000, when the board determines that the licensee is guilty of any of the following acts or offenses:

12.4(12) Knowingly aiding, assisting, procuring, or advising a person to unlawfully practice medicine and surgery, osteopathic medicine and surgery or osteopathy.

12.4(27) Negligence and failing to exercise due care in the delegation of medical services to or supervision of nurses, physician's assistants, employees or other individuals, whether or not injury results.

RULING

(Legal Authorities)

In construing the statutory provisions of chapters 148 we are guided by decisions of the Iowa Supreme Court. The Court has long construed the practice of medicine and surgery to encompass

diagnosis and the prescription of the proper treatment. As early as 1929 the Court analyzed the role of prescribing treatment in the practice of medicine in State v. Hughey, 208 Iowa 842, 226 N.W. 371 (1929). Construing the 1927 statutory predecessor to § 148.1(1), which in identical language defined persons engaged in the practice of medicine and surgery as "[p]ersons who publicly profess to be physicians or surgeons or publicly profess to assume the duties incident to the practice of medicine or surgery," the Court held:

The argument for defendant is that, inasmuch as he gave no medicine he could not be guilty of practicing medicine. The term 'practice of medicine' is defined by section 2538. It is not confined to the administering of drugs. Under this statute one who publicly professes to be a physician, and induces others to seek his aid as such, is practicing medicine. Nor is it requisite that he shall profess in terms to be a physician. It is enough under the statute if he publicly profess to assume the duties incident to the practice of medicine. What are 'duties incident to the practice of medicine'? Manifestly the first duty of a physician to his patient is to diagnose his ailment. Manifestly, also, a duty follows to prescribe the proper treatment therefor. If, therefore, one publicly profess to be able to diagnose human ailments, and to prescribe proper treatments therefor, then he is engaged in the practice of medicine, within the definition of section 2538.

208 Iowa at 846-47, 226 N.W. at 373.

Three years later the Court focused on diagnosis in the practice of medicine. In State v. Howard, 216 Iowa 545, 245 N.W. 871 (1932), the Court reviewed a suit to enjoin an unlicensed person from diagnosing and treating "so-called common diseases, including appendicitis, rheumatism, arthritis, neuritis, flus and colds" by a process called naprapathy. Noting that the defendant

purported to diagnose the ailments of his patrons before embarking on a naprapathy treatment, the Court ruled:

Correct diagnosis is one of the first duties of the qualified physician. Purported diagnosis is also the first resort of the disqualified one, and the first requisite of a miraculous cure. The ailments, curable or incurable, which he professes to discover, and to cure, are such only as his own diagnosis declares.... Diagnosis, as a guide to treatment, is therefore clearly one of the duties of the physician.

216 Iowa at 551, 245 N.W. at 874.

Diagnosis and treatment have been determined to constitute the practice of medicine and surgery in other contexts. See State v. Robinson, 236 Iowa 752, 19 N.W.2d 214 (1945) (healing through power of thought and laying on of hands constitutes practice of medicine); State v. Baker, 212 Iowa 571, 235 N.W. 313 (1931) (treatment of cancer through secret preparations constitutes practice of medicine); 1966 Op.Att'yGen. 13 (diagnosis and treatment of mental conditions constitutes the practice of medicine).

Most recently, in State v. Van Wyk, 320 N.W.2d 599 (Iowa 1982), the Department of Health sought to enjoin a chiropractor from performing a number of procedures, including acupuncture, withdrawal of blood and prescribing a dietary course of treatment, which were alleged to be outside the scope of the practice of chiropractic.¹ The Iowa Supreme Court upheld the

¹Following the Van Wyk decision, the statutes governing the practice of chiropractic were amended to add withdrawal or ordering withdrawal of blood for diagnostic purposes and rendering nutritional advice to the scope of chiropractic.

injunction on the rationale that the modalities for the practice of chiropractic were specifically delineated by statute and the procedures in question were not enumerated. Id. at 603-04. The Court explained the justification for this restriction as follows:

The reason for all laws restricting this and other professions is the protection of the public, and to that end the legislature has seen fit to enact laws and provide means for enforcing the regulations governing the practice of the various forms of the art of healing, permitting each practitioner to follow his profession according to its established principles. Each may have its merits; but those persons who are authorized to practice one form of the art may not encroach upon another form for which they have no authority from the state.

Id. at 603, quoting from, State v. Boston, 226 Iowa at 437-38, 284 N.W. at 144. The Van Wyk Court further noted that the statutes governing the practice of medicine and osteopathic medicine are less restrictive, stating "unless some restrictions be placed thereon by the legislature, the whole field of medicine and surgery is open to the practitioner." Id. at 602, 603.

(Professional Standards)

In order to respond to the questions presented, it is helpful to review statements made by professional associations and other governmental agencies regarding the issues here in question. We first discuss the difference between ophthalmologists and optometrists. That difference has been described as follows:

An ophthalmologist is a duly licensed physician who specializes in the care of the eyes. An optometrist examines eyes for refractive error, recognizes (but

does not treat) diseases of the eye, and fills prescriptions for eyeglasses.

Williamson v. Lee Optical of Oklahoma, Inc., 348 U.S.483, 75 S.Ct 461, 99 L.Ed. 1256 (1955).

The Office of Technology Assessment (OTA) of the United States Congress issued a staff paper in October of 1988, titled "Appropriate Care for Cataract Surgery Patients Before and After Surgery." This OTA Staff Paper similarly discussed the difference between these two professions:

Ophthalmology is a surgical specialty of medicine, and ophthalmologists must spend 4 years in medical school, 1 year as an intern in a hospital, and 3 years as a hospital-based ophthalmology resident. Optometry is not a specialty of medicine, and optometrists undergo a 4-year professional training program.

As a physician, an ophthalmologist gets 3 years of clinical training (2 years as a medical student and 1 year as a hospital intern) in the evaluation and treatment of patients with a variety of medical conditions. This experience may enable an ophthalmologist to evaluate a patient's fitness for surgery, taking into account the patient's systemic conditions. This experience may also enable an ophthalmologist to initiate management of postoperative complications that require certain systemic drugs or surgery. At no point during training does an optometrist receive clinical training in the evaluation and treatment of patients with a range of medical problems.

As an ophthalmology resident, an ophthalmologist gets 3 years of clinical training in the evaluation and treatment of patients with serious eye problems. An optometrist gets clinical training in the evaluation of patients for refraction, but significantly less experience in the management of patients with serious eye problems. Finally, an ophthalmology resident performs cataract and other eye surgery and manages the postoperative care of many of the patients on whom he or she operates. An optometrist gets considerably less clinical exposure to patients who have undergone eye surgery.

OTA Staff Paper at 6-7.

As set forth previously, the Iowa General Assembly has delineated the scope of practice of an optometrist. Optometry must employ "means other than the use of drugs, medicine, or surgery for the measurement of visual power and visual efficiency of the human eye." Iowa Code § 154.1(1) (1991). Although optometrists may use certain specifically designated anesthetics and pharmaceuticals, Iowa Code § 154.1(3), the optometrist is not generally empowered to prescribe or dispense drugs as is a physician or surgeon. See Iowa Code §§ 147.107, 148.1(2). By comparison, "unless some restrictions be placed thereon by the legislature, the whole field of medicine and surgery is open to the [physician] practitioner." State v. Van Wyk, 320 N.W.2d at 603.

We turn now to a discussion of the responsibilities for the preoperative, operative, and postoperative care of cataract surgery patients. Although the public perception may be that cataract surgery has become routine, it is still major surgery and involves the risk of numerous postoperative complications. See OTA Staff Paper at 37; Policy Statement, American Academy of Ophthalmology, June 1992, at 1-2. Such complications include:

...endophthalmitis, severe postoperative inflammation, corneal edema, bullous keratopathy, pupillary block, secondary glaucoma, intraocular hemorrhage, wound leakage or rupture, cystoid macular edema, detached retina, pupillary displacement, iris prolapse, subluxation or dislocation of the lens, touching of the cornea by the IOL, and opacities of the posterior capsule.

OTA Staff Paper at 37 (citations omitted). These complications must be managed appropriately if the surgery is to be as successful as possible. Id. at 33-34 (citations omitted).

Generally speaking, preoperative care is "the process of examining and performing diagnostic tests on a patient to assess a patient's fitness for surgery." OTA Staff Paper at n. 1. That process includes evaluation:

...to determine whether cataract surgery is a justifiable risk given the state of the patient's cataract, health of the patient's eyes, and the patient's overall health; which cataract extraction procedure to use, and whether to implant an intraocular lens (IOL); and whether surgery should be done in the hospital or can safely be done in an outpatient setting. Such judgments should be based in part on knowledge of how concurrent eye or systemic disease affects the risks and potential complications of cataract surgery, as well as familiarity with the various surgical techniques and IOLs. [Id. at 5.]

In our view an ophthalmologist must be responsible for the preoperative care of a cataract surgery patient. The preoperative care includes independent evaluation, diagnosis of the condition warranting surgery, and discussion with the patient. It is appropriate for a physician licensed under Iowa Code chapters 148, 150 or 150A, including a family practitioner, to perform a preoperative history and physical for that patient.

The operative care itself is clearly the responsibility of the ophthalmologist. Operative care must be provided by an ophthalmic surgeon.

Postoperative care, "which begins with completion of a surgical procedure and continues until the patient's wound has healed, is the process of patient management following surgery

that is necessary to ensure the best possible surgical outcome." OTA Staff Paper, n. 1. The American Medical Association has stated "that physicians performing surgery have an ethical responsibility to continue the care of their individual patients through the post surgical recovery and healing period." American Medical Association Policy Statement No. 8, "Postoperative Care; Responsibility and Reimbursement."

In our view the surgical ophthalmologist is responsible for providing all postoperative care during the usual and customary postoperative period, unless that care is delegated to an equivalently-trained physician. Postoperative management of cataract patients is inseparable from the entire surgical process. It requires evaluation of the eye for postoperative progress; adjustment of medications; and the detection, diagnosis, and treatment of post-surgical complications. Postoperative care may require the diagnosis of complications, intervention of drugs, or additional surgery. Such postoperative care requires the education, training, and experience of an ophthalmologist. Management of postoperative ophthalmic care constitutes the practice of medicine and cannot be managed by other health care practitioners, except under the direct supervision of the surgical ophthalmologist.

We note that physician licensing agencies in at least thirteen other jurisdictions have taken the position that postoperative care of cataract patients shall be provided by physicians rather than optometrists.

Before responding to the specific questions posed, we note the following caveats regarding use of the declaratory ruling procedure to address these issues. Although we have decided to proceed with a declaratory ruling, there are some difficulties with the procedure that need to be addressed specifically.

First, a declaratory ruling does not allow input from optometrists who are necessarily interested in the result. Although proceeding instead by rulemaking to address these issues would have permitted input from optometrists, we have been reluctant to codify the practice of medicine in rule form. We are proceeding, therefore, by declaratory ruling with the recognition that our ruling does not bind optometrists.

Second, the petitioner is a professional organization which cannot bind its members through the declaratory ruling procedure. A declaratory ruling is intended to be binding between the petitioner and the agency issuing the ruling in order that the petitioner can conform behavior to the ruling. The Iowa Academy of Ophthalmology, however, is not an individual practitioner that can conform its behavior to the ruling. Ophthalmologists, moreover, have not petitioned individually for the ruling. As a result, the ruling may be advisory with respect to the individual ophthalmic practitioners in this state.

Third, violation of some of the statutes and rules involved may carry criminal penalties. Violation of § 147.2, which prohibits practicing medicine and surgery without a license, is a serious misdemeanor. Iowa Code § 147.86 (1991). Rule 12.4(12),

which prohibits knowingly aiding or assisting a person to unlawfully practice medicine and surgery, carries administrative penalties but also addresses potentially criminal conduct. Generally, criminal charges are directed at those who practice medicine and surgery with no license at all rather at those who cross lines that are drawn between the practice of separate licensed professions. Because optometrists are not participating in this proceeding and because a declaratory ruling is not an appropriate vehicle to determine criminal conduct, we do not intend to resolve any issues of criminal conduct in this ruling.

With these caveats in mind, applying the principles developed by the Iowa Supreme Court in defining the practice of medicine and surgery and cognizant of the applicable professional standards, we provide the following answers to your questions.

1. The ophthalmologist in hypothetical situation no. 1 has not violated any statutes or rules of the Iowa Board of Medical Examiners. The ophthalmologist has provided all of the patient's preoperative, operative, and postoperative care.

2. The ophthalmic surgeon in hypothetical situation no. 2 has not violated any statutes or rules of the Iowa Board of Medical Examiners. The ophthalmic surgeon has provided all preoperative and operative care and has arranged for postoperative care by a medical ophthalmologist who has equivalent education and training as the ophthalmic surgeon. The ophthalmic surgeon has also appropriately secured the patient's

approval prior to surgery for the arrangements for postoperative care by another ophthalmologist.

3. The surgical ophthalmologist in hypothetical situation no. 3 has not violated any statutes or rules of the Iowa Board of Medical Examiners. The surgical ophthalmologist has provided all preoperative, operative, and postoperative care of the patient, with the appropriate assistance of a licensed family practitioner in performing a preoperative history and physical.

4. The ophthalmologist in hypothetical situation no. 4 has not violated any statutes or rules of the Iowa Board of Medical Examiners. The ophthalmologist has provided for all of the patient's preoperative, operative, and postoperative care, with appropriate referral to an optometrist for services which fall within the scope of the practice of optometry. The optometrist in hypothetical situation no. 4, moreover, has not engaged in the practice of medicine. A postoperative refraction and prescription of the postoperative lens fall within the scope of the practice of optometry under § 154.1(1), and therefore, do not constitute the practice of medicine.

5. The ophthalmic surgeon in hypothetical situation no. 5 has been negligent in the delegation of medical services to the optometrist postoperatively in violation of rule 12.4(27).² The ophthalmologist has provided all of the patient's preoperative

²The term "negligent" as used in the context of the rules of the Iowa Board of Medical Examiners is not necessarily synonymous with negligence in tort. The Board, in an appropriate contested case, would determine whether to construe this term to impose a different standard of conduct for disciplinary purposes.

and operative care, but has not provided for all of the patient's postoperative care. The patient was still at risk for postoperative complications since the patient was on postoperative medications at the time the patient was referred to the optometrist, indicating the eye was not completely healed. By wrongly delegating responsibility for diagnosing postoperative complications to an optometrist, the ophthalmologist has created a situation in which potential complications may be missed or not referred in a sufficiently timely manner so as to prevent permanent ophthalmic injury.

By agreeing that an optometrist may determine the presence or absence of surgical complications and adjust medications, the ophthalmic surgeon may have knowingly assisted in the unlawful practice of medicine in violation of rule 12.4(12). The optometrist in hypothetical situation no. 5, in turn, may have engaged in the practice of medicine to the extent that his conduct exceeds that authorized in Iowa Code § 154.1. We decline to determine in this declaratory ruling whether such conduct is unlawful or to further construe the scope of the optometrist's authority under Iowa Code § 154.1.

6. The ophthalmologist in hypothetical situation No. 6 has been negligent in the delegation of medical services to the optometrist in violation of rule 12.4(27). The ophthalmologist provided insufficient preoperative care to the patient by conducting only a limited preoperative evaluation and by allowing an optometrist to determine the power of the lens

implant to be used intraoperatively and to determine what type of surgical procedure and anesthesia are indicated. The ophthalmologist also failed to provide any postoperative care to the patient.

The ophthalmic surgeon may have assisted in the unlawful practice of medicine and surgery by allowing an optometrist to determine the power of the lens implant to be used intraoperatively, to determine what type of surgical procedure and anesthesia are indicated, and to provide all postoperative care to the patient. The optometrist in hypothetical situation no. 6, similarly, may have engaged in the practice of medicine to the extent that his conduct exceeds that authorized in Iowa Code § 154.1. We decline to determine in this declaratory ruling whether such conduct is unlawful or to further construe the scope of the optometrist's authority under Iowa Code § 154.1.

7. The ophthalmologist in hypothetical situation no. 7 has been negligent in the delegation of medical services to the optometrist in violation of rule 12.4(27) by totally abrogating preoperative and postoperative responsibility for the patient.

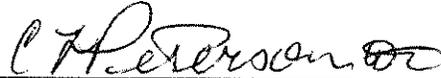
By allowing an optometrist to assume responsibility for preoperative and postoperative care of his surgical patient, the ophthalmologist may have assisted in the unlawful practice of medicine and surgery. The optometrist in hypothetical situation no. 7, similarly, may have engaged in the practice of medicine to the extent that all preoperative and postoperative care for the patient, including performing a history and physical evaluation

preoperatively, monitoring the eye postoperatively for progress, adjusting medications, detecting complications, and providing other postoperative care, fall outside the scope of the practice of optometry authorized in Iowa Code § 154.1. We decline to determine in this declaratory ruling whether such conduct is unlawful or to further construe the scope of the optometrist's authority under Iowa Code § 154.1.

8. The ophthalmologist in hypothetical situation no. 8 has been negligent in the delegation of medical services to the optometrist in violation of rule 12.4(27) by totally abrogating postoperative responsibility for the patient. The standards set forth above for provision of postoperative care of cataract surgery patients are equally applicable to laser surgery patients.

By allowing an optometrist to assume responsibility for the postoperative care of his surgical patient, the ophthalmologist may have assisted the unlawful practice of medicine and surgery. The optometrist in hypothetical situation no. 8, moreover, may have engaged in the practice of medicine to the extent that providing all postoperative care for the patient, including monitoring the eye post-operatively for progress, adjusting medications, and detecting complications, exceeds the scope of the practice of optometry under Iowa Code § 154.1. We decline to determine in this declaratory ruling whether such conduct is unlawful or to further construe the scope of the optometrist's authority under Iowa Code § 154.1.

Issued this 12TH day of November, 1992.



C. L. PETERSON, D.O.
Chairman, Iowa Board of
Medical Examiners



DENNIS M. CARR
Acting Executive Director, Iowa
Board of Medical Examiners



TERRY E. BRANSTAD, GOVERNOR

BOARD OF MEDICAL EXAMINERS
ANN M. MARTINO, PH.D., EXECUTIVE DIRECTOR

November 18, 1993

Dear Physicians:

Late last year the Iowa Board of Medical Examiners issued a Declaratory Ruling in response to a petition filed by the Iowa Academy of Ophthalmology. The petition stated eight hypothetical situations involving the pre-operative, operative and post-operative care of cataract surgery patients and posed a series of questions relating to the applicability of the Board's statute and rules in each.

During the last several months, the Board has received reports from several Iowa physicians indicating that there is considerable uncertainty about the Ruling's scope and effect, particularly with respect to the billing of post-operative care for surgery patients. These reports suggest that the Ruling unintentionally compounded the confusion existing among various providers about the appropriate scope of post-operative care for cataract surgery patients. Given the apparent conflict this has created in the state's health care community, the Board is seeking to clarify its intent in issuing the Ruling.

In response to specific questions posed in the petition on post-operative care, the Board determined that as a matter of sound medical practice the physician performing the surgery is responsible for providing the patient's post-operative care. The Board also stated that a physician who delegates responsibility for diagnosing post-operative complications risks violating the Board's administrative rule prohibiting the negligent delegation of medical services. The Board did not specifically define the parameters of post-operative care or the surgeon's specific responsibilities in the Ruling. It is the Board's position that these are clinical decisions that are most appropriately made by the surgeon on a case-by-case basis in accordance with prevailing standards of quality medical care.

It is important to note that the issue of proper billing for post-operative care which has caused much of the confusion and controversy over the Declaratory Ruling was not directly posed in the petition. However, the Board recognizes that federal reimbursement policy has established a 90 day global billing period that includes a Medicare modifier permitting other providers to bill for certain aspects of a cataract surgery patient's post-operative care. Although the Declaratory Ruling cautions surgeons against the negligent delegation of post-operative care, the Board is aware that certain Iowa surgeons use the Medicare modifier to justify delegating some post-operative responsibilities to other, non-physician providers. Consequently, the Board is concerned that federal reimbursement policies may be influencing important clinical decisions about the scope of post-operative care in ways that could pose risks to the health and safety of patients.

Board of Medical Examiners
Re: Ophthalmology Ruling
Page 2

In issuing the Declaratory Ruling, the Board did not address the question of whether another health care provider is either qualified to provide the patient's post-operative care or eligible to bill and receive reimbursement for these services. By law, Declaratory Rulings are limited in scope to determinations about how the statutes and rules cited in the petition are applicable to the issues posed within the narrow context of the Board's regulatory authority. Accordingly, a Declaratory Ruling is not the appropriate forum for resolving questions that have an impact on the practice of providers other than the petitioner or that are largely outside the Board's jurisdiction, as is the case in billing matters.

Inasmuch as the Declaratory Ruling has had consequences that far exceed its expected scope, it is incumbent upon the Board to deal with its unintended effects. Toward this end, the Board is prepared to take the actions necessary to ensure that cataract surgery patients receive the appropriate level of post-operative care. Physicians who fail to provide patients with the prevailing standard of high quality medical care are subject to sanction under the Board's statutes and rules. Be advised that use of the Medicare modifier may prompt a Board investigation if there is any indication that post-operative care has been delegated in a negligent manner that poses a risk to patients. Physicians should also be aware that improper use of the modifier may result in allegations of fraud by federal health regulatory authorities. Physicians should direct any questions they might have about billing to the state's Medicare provider -- Blue Cross/Blue Shield of Iowa.

Note that the Board's position on post-operative care for cataract surgery patients is consistent with the policies of adjoining states and the clinical practice guidelines on cataract care issued by the Agency for Health Care Policy and Research (AHCPR), of the U.S. Department of Health and Human Services. Physicians who perform cataract surgery are invited to review the federal clinical guidelines on cataract surgery and take particular note of those pertaining to post-operative care. The federal guidelines may be obtained, free-of-charge, by contacting the AHCPR Publications Clearinghouse at 1-800-358-9295.

The Board is confident that compliance with the Declaratory Ruling will not unduly inconvenience or create financial hardships for Iowans. Surgeons are expected to take the necessary steps to ensure their patients can make informed decisions about where to seek the surgical services they need. At a minimum, patients should always be apprised in advance that the physician who performs the surgery is also responsible for providing post-operative care. Surgeons should also make a concerted effort to arrange their work schedules to accommodate patients traveling long distances from their homes to receive post-operative care. Access to high quality care is of paramount concern to the Board. Following these sound medical practices assures that every Iowan will receive the post-operative care surgeons are required to provide.

Board of Medical Examiners

Re: Ophthalmology Ruling

Page 3

The Board welcomes the opportunity to meet with consumers and with the appropriate state authorities regulating non-physician health care providers concerned about the Rulings impact on patient care. Requests to meet with the Board or for further information about the Declaratory Ruling should be made in writing to the Board's office.

Sincerely,

Charlotte A. Cleavenger, D.O.

Charlotte A. Cleavenger, D.O.,
Chairperson

Ann M. Martino

Ann M. Martino, Ph.D.,
Executive Director

October 9, 1995

Mary M. Conway, Vice-President
Iowa State Board of Behavioral Sciences
P.O. Box 316
Emmetsburg, Iowa 50536

Dear Ms. Conway:

The Iowa Board of Medical Examiners (IBME) has received your Petition for a Declaratory Ruling. The Executive Committee of the Board reviewed the Petition at its September 6, 1995 meeting and referred it for final recommendation to the full Board. The IBME is scheduled to consider the Petition at its October 19, 1995 meeting. At that time, the Board will make a determination about how to proceed with the Petition. You will be notified of the Board's decision subsequent to the meeting.

Please do not hesitate to contact me if I can in any way be of further assistance.

Sincerely,

Ann M. Martino, Ph.D.
Executive Director

AMM/me

cc: Dennis Carr, Associate Director
Theresa Weeg, AAG
Board Members

F:\MrsConway.dr

P.O. Box 316
Emmetsburg, Iowa 50536
August 17, 1995

Ann M. Martino, PhD
Executive Director
Iowa State Board of Medical Examiners
Executive Hills West
Capitol Complex
Des Moines, Iowa 50319-0180

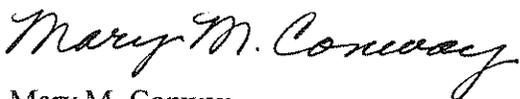
Dear Ms. Martino,

Thank you for your letter of July 25, 1995, regarding my inquiry on whether Licensed Mental Health Counselors and/or Licensed Marriage and Family Therapists are qualified to give a written diagnosis to third parties for reimbursement utilizing the DSM-IV Manual.

Enclosed you will find a Petition For Declaratory Ruling Before The Iowa State Board of Medical Examiners pursuant to the requirements of 653 IAC 10.10.

As a Public Member of The Iowa State Board of Behavioral Sciences Examiners, the question of who may make and use diagnoses seems to pose a significant public safety problem. Our Board is here to protect and benefit the public, therefore, I believe a Declaratory Ruling by the Board of Medical Examiners on this issue is appropriate.

Very truly yours,



Mary M. Conway
Vice-President
Iowa State Board of Behavioral Sciences Examiners
(712) 852-3712

RECEIVED
AUG 22 1995
STATE BOARD OF MEDICAL EXAMINERS

PETITION FOR DECLARATORY RULING
BEFORE THE
IOWA STATE BOARD OF MEDICAL EXAMINERS

Statement of Facts

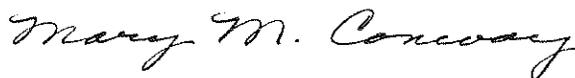
Mrs. A is a party to a dissolution proceeding. Without the knowledge of her legal counsel, Mrs. A visits a licensed mental health counselor who is not a licensed physician, specifically, not a psychiatrist. After conferring with Mrs. A and consulting the Diagnostic Statistics Manual IV (DSM-IV), the mental health counselor renders a "diagnosis" of clinical depression and enters the same in Mrs. A's permanent record. Later in the dissolution proceedings, the "diagnosis" of clinical depression becomes an issue for purposes of child placement and health insurance. Mrs. A's legal counsel objects to the introduction of such "diagnosis", maintaining that only psychiatrists, not licensed mental health counselors, may render a written "diagnosis" upon which third parties may rely.

Issues

- 1) Whether a licensed mental health counselor, who is not a licensed physician, may render a written "diagnosis" and whether third parties may rely upon such a "diagnosis"?
- 2) After an adverse outcome in the dissolution proceedings, Mrs. A is seen by a psychiatrist who ultimately determines that her mental health problems stem from situational, not biological, factors. What ramifications are there for the mental health counselor who made the incorrect initial "diagnosis"?

Submitted by: Mary M. Conway
Vice-President

Iowa State Board of Behavioral Sciences Examiners
P.O. Box 316
Emmetsburg, Iowa 50536
(712) 852-3712





TERRY E. BRANSTAD, GOVERNOR

BOARD OF MEDICAL EXAMINERS
ANN M. MARTINO, PH.D., EXECUTIVE DIRECTOR

July 25, 1995

Mary M. Conway
Board of Behavioral Sciences Examiners
P.O. Box 316
Emmetsburg, IA 50536

Dear Ms. Conway:

You have requested an opinion of the Board of Medical Examiners as to whether Mental Health counselors or marriage and family therapists would be practicing medicine without a license if they make psychiatric diagnoses from the DSM IV Manual.

The Board may only make legally-binding policy through issuance of a rule, a declaratory ruling, or a decision following a contested case proceeding. If you wish to request a declaratory ruling, which would be the most appropriate way to address your request, please submit that request pursuant to the requirements of 653 IAC 10.10, a copy of which is enclosed.

Please feel free to contact this office should you have any further questions. Thank-you.

Sincerely,

Ann M. Martino, PhD
Executive Director

cc: File
Enclosure

*huc
6/12/95*

P.O. Box 316
Emmetsburg, Iowa 50536
May 11, 1995

Chairman, Iowa State Board of Medical Examiners
State Capitol Complex
Executive Hills West
Des Moines, Iowa 50319-0180

Dear Chairman,

I am a Public Member of the Iowa State Board of Behavioral Sciences Examiners. Board licenses and oversees Mental Health Counselors and Marriage and Family Therapists. There are three Mental Health Counselors, three Marriage and Family Therapists and three Public Members on this Board.

An important question has been raised on the issue: Can Licensed Mental Health Counselors or Licensed Marriage and Family Therapists give a written diagnosis to third parties for reimbursement utilizing the DSM IV Manual? It is my opinion that they cannot, but I am definitely in the minority among the Board members.

My position is that (1) Physicians are the only ones who can make psychiatric diagnoses from the DSM IV Manual. (2) Mental Health Counselors or Marriage and Family Therapists would be practicing medicine without a license if they were allowed to make and use diagnoses for third party reimbursement. (3) Said Counselors/Therapists would be perpetrating fraud if they did, indeed, make and use diagnoses for third-party reimbursement. (4) Public safety would be compromised if they were allowed to do so.

This opinion is based on my belief that Mental Health Counselors and Marriage and Family Therapists would be operating outside the scope of their training if they were allowed to diagnosis illnesses that are clearly medical in nature.

Would you advise me on this issue? Our next meeting is June 15, 1995, at which time we will be voting on whether or not to allow Licensed Mental Health Counselors and Licensed Marriage and Family Therapists to diagnosis. If I am to be successful in preventing this from happening, I will need substantive evidence, such as an opinion from the Board of Medical Examiners, to accomplish my intention.

Thank you, in advance, for your assistance.

Very truly yours,

Mary M. Conway

Mary M. Conway

Board of Behavioral Sciences Examiners

95 MAY 15 PM 1:17
I.A. BOARD OF MEDICAL EXAMINERS

subject to interpretation.

5. The undersigned attorney, as a party to that hearing, recalls that the Court made no final determination regarding the authority of the Associate Director. Instead, the Court directed the Board's executive director to issue an order denying the continuance request under her signature, thus resolving in a simple manner the question of whether the associate director properly signed the order in question.

6. The district court further suggested that John Doe IV consider whether she would be willing, in support of her continuance request, to agree not to practice medicine pending the resolution of the contested case before the Board. The Court indicated that if the parties were not able to reach agreement regarding a continuance, it would likely dismiss the case for lack of jurisdiction under Iowa Code Section 17A.19(1).

7. John Doe IV subsequently agreed not to practice medicine pending resolution of the contested case. Upon receipt of this agreement and following a hearing, the Board's executive director entered an order granting an abbreviated continuance. The matter never returned to the district court for final ruling on the legal issues raised. The judicial review action remains open, presumably pending a decision in the pending contested case.

8. Accordingly, the questions raised in the request for declaratory ruling are not the proper subject of a declaratory ruling by the Board because they involve issues that have been

raised before the Board in a pending contested case and before the district court upon a petition for judicial review. John Doe IV may again raise these issues in the contested case proceeding, and may pursue them upon judicial review of any adverse decision. See 653 IAC 10.10(7)(c) (the Board may decline to issue a declaratory ruling if the issues presented are pending resolution by a court of Iowa); Uniform Rules on Agency Procedure, X.5 (a petition for declaratory ruling may be denied if "the questions presented by the petition are also presented in a current ... contested case, or ... judicial proceeding that may definitively resolve them.")

9. Questions regarding the Board's disciplinary procedures are most properly decided within the context of the disciplinary proceeding itself, rather than by declaratory ruling. For this reason, Petitioner's request should be denied. See Uniform Rules on Agency Procedure, X.5(5) (a declaratory ruling request may be denied if the questions presented by the petition "would more properly be resolved in a different type of proceeding.")

10. The questions raised in Petitioner's request are not the appropriate subject of a declaratory ruling. See Uniform Rules on Agency Procedure X.5(8) (a declaratory ruling request may be denied if the petition "is not based upon facts calculated to aid in the planning of future conduct but is instead based solely upon prior conduct in an effort to establish the effect of that conduct or to challenge an agency decision already made.")

WHEREFORE, for the reasons set forth above, the State of

Iowa requests that the request for declaratory ruling be denied.

Respectfully submitted,

THOMAS J. MILLER
ATTORNEY GENERAL OF IOWA



THERESA O'CONNELL WIEG
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319
(515) 281-6858

Copy to:

Michael Sellers
One Corporate Place, Suite 320
1501 42nd St.
West Des Moines, Iowa 50265-1005

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing instrument was served upon each of the attorneys of record of all parties in the above-entitled cause by enclosing the same in an envelope addressed to each such attorney at his respective address as disclosed by the pleadings of record herein, with postage fully paid and by depositing said envelope in a United States Post Office depository in Des Moines, Iowa, on the

11 day of JANUARY 1996
R. Dale

95 DEC -8 AM 11:57

FACT BACKGROUND

IA. BOARD OF MED. EXAMINERS

1. In a legal proceeding before the Iowa District Court in and for Polk County, in a case entitled John Doe, IV, v. The Board of Medical Examiners of the State of Iowa, the Judge of the Iowa District Court ordered that the Executive Director of the Board of Medical Examiners of the State of Iowa (hereinafter "Board") hold an immediate hearing, prior to 11:30 a.m. on Tuesday, December 5, 1995, for the purpose of having the Board's Executive Director rule upon a pending Motion for Continuance that had been filed shortly after service on Respondent of the original Complaint and Statement of Charges.

2. The Judge also ruled, during a hearing on a Petition for Judicial Review of an Order that had been issued by Dennis Carr, Associate Director/Director of Compliance of the Board, denying the Motion for Continuance, that the ruling on the Motion for Continuance was void and ruled that pursuant to Iowa statute and administrative rule the Associate Director/Director of Compliance does not have statutory or administrative rule authority to rule upon pending motions or legal matters in disciplinary proceedings.

3. The Judge also stated to the participants that it was the opinion of the Iowa District Court that anyone associated with the Board who has any direct participation, either in the investigation of a case or in the management of a case and preparation of investigative materials, should not participate, in any way, in decisions regarding the legal aspects of administrative proceedings and disciplinary proceedings, due to the obvious conflict of interest.

REQUEST FOR DECLARATORY RULING

4. The undersigned, as counsel for several respondents, hereby requests a declaratory ruling by the Board that:

a. All procedural matters involving pending disciplinary proceedings subsequent to the decision by the Board or disciplinary committees of the Board that a Complaint and Statement of Charges should be formally filed against a licensee will be considered and ruled upon either by the Executive Director of the Board, an Administrative Law Judge designated by the Executive Director of the Board, or by the Board itself or a panel of the Board.

b. All decisions as to whether or not motions or other legal proceedings should or should not be referred over to an Administrative Law Judge for determination shall be made only by the Executive Director of the Board or the Board itself or a panel of the Board.

c. The Associate Director/Director of Compliance, who is also the chief investigator participating in or directing the preparation of investigative files and other materials for presentation to the Board or a panel of the Board in disciplinary proceedings, shall not participate, in any way, in the consideration of or decision making process relating to any motions or any aspects of the handling of legal proceedings in disciplinary proceedings before the Board.

Respectfully submitted,



Michael M. Sellers, Attorney-at-Law (PK0004971)
One Corporate Place - Suite 320
1501 - 42nd Street
West Des Moines, Iowa 50266-1005
Telephone: (515) 221-0111
Telefax: (515) 221-2702

ATTORNEY FOR PETITIONER/APPELLANT

ORIGINAL FILED

Copy to:

Director
Iowa Department of Human Services
Hoover State Office Building
East 13th and Walnut Street
Des Moines, Iowa 50319

Tom Miller, Iowa Attorney General
Iowa Department of Justice
Hoover Building - Second Floor
East 13th and Walnut Streets
Des Moines, Iowa 50319

Theresa O'Connell Weeg
Counsel to the Board of Medical Examiners of the State of Iowa
Iowa Department of Justice
Hoover Building - Second Floor
East 13th and Walnut Streets
Des Moines, Iowa 50319

Ann Martino, Ph.D., Director
Board of Medical Examiners of the State of Iowa
Executive Hills West
1209 East Court Avenue
Des Moines, Iowa 50319-0180

declar

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record to rein at their respective addresses disclosed on the pleadings on 12-4 19 95

By: Personal Delivery FAX
 Overnight Courier
 Federal Express Other: Patricia A. Green
Signature Patricia A. Green



TERRY E. BRANSTAD, GOVERNOR

BOARD OF MEDICAL EXAMINERS
ANN M. MARTINO, PH.D., EXECUTIVE DIRECTOR

January 17, 1997

Eileen Marie Wayne, M.D.
2623 17th Street
Rock Island, Illinois 61201

Re: Petition for Declaratory Ruling

Dear Dr. Wayne:

Recently, the Iowa Board of Medical Examiners (IBME) considered your Petition for a Declaratory Ruling. After discussing the matter at length, the Board has determined that it does not have the jurisdiction to issue a Declaratory Ruling on this matter.

The informed consent provisions of Section 147.137 are located in a subsection of Chapter 147 titled "Malpractice." In addition to the provision pertaining to informed consent, the subsection contains provisions governing hospital peer review activities, scope of recovery in malpractice cases, and contingent fees for attorneys in civil malpractice actions. As you are aware, there is a well-developed body of judicial decisions involving these provisions and other medical malpractice issues. Thus, the area of medical malpractice is the province of the judiciary and, as such, outside the general scope of the Board's authority.

As to the specific issue of informed consent, it is the Board's opinion that the courts are, and should continue in the future to be, the entity primarily responsible for interpreting the meaning of Section 147.137. The informed consent issue arises far more frequently in the civil malpractice arena than it does in the Board disciplinary process. The Board has determined that when questions about informed consent do arise in a disciplinary case, they are best addressed on the basis of the particular facts before it in the case. As yet, the Board had not decided a case that considers informed consent in the manner in which it is discussed in your petition.

IBME rules provide that the Board may decline to issue a Declaratory Ruling if there is a lack of jurisdiction, a lack of clarity in the issue presented, or the issue present is pending resolution by a court of Iowa or by the Attorney General. (See 653 Iowa Administrative Code 10.10.) Based on the reasons set forth above, the Board has determined that it does not have the jurisdiction to decide the question raised in your request for a Declaratory Ruling. The Board believes the issue would be better resolved by the Iowa courts.

In sum, the Board is not the prevailing authority on the meaning of 147.137 even though it may take action against a physician who fails to meet the requirements for informed consent it establishes. Accordingly, the IBME voted to decline your Petition for a Declaratory Ruling. For further information or clarification of the legal basis for the Board's decision, please contact Theresa Weeg, AAG, the IBME's legal counsel, at 515-281-6858.

Sincerely,



Ann M. Martino, Ph.D.
Executive Director

AMM/me

cc: Dennis Carr, Associate Director
Theresa Weeg, AAG
Board Members

F:\Wlts\wayne.no



TERRY E. BRANSTAD, GOVERNOR

BOARD OF MEDICAL EXAMINERS
ANN M. MARTINO, PH.D., EXECUTIVE DIRECTOR

December 2, 1996

Eileen Marie Wayne, M.D.
2623 17th Street
Rock Island, Illinois 61201

Dear Dr. Wayne:

The Iowa Board of Medical Examiners (IBME) has received your Petition for a Declaratory Ruling. The Board will review the Petition at its December 12, 1996 meeting and make a determination about how to proceed at that time. You will notified of the Board's decision subsequent to the meeting.

Please do not hesitate to contact me if I can in anyway be of further assistance.

Sincerely,

Ann M. Martino, Ph.D.
Executive Director

AMM/me

cc: Dennis Carr, Associate Director
✓Theresa Weeg, AAG
Board Members

F:\lltrslwayne.dr

Eileen Marie Wayne MD

2623 17th Street
Rock Island, IL 61201
(309) 786-6800
Fax (309) 786-8586
Answering Service (319) 328-4936
E-Mail EileeWayne@aol.com

9000-2 PM 4:16
IA. EC
EXAMINERS

**PETITION FOR DECLARATORY RULING BEFORE THE IOWA STATE
BOARD OF MEDICAL EXAMINERS**

November 29, 1996

Iowa Board of Medical Examiners
Executive Hills West
1209 East Court
Des Moines, Ia 50319

Dear Board Members:

Please provide clarification of the phrase "presumption that informed consent was given." The phrase is found in the General Provisions, Health-Related Professions Consent in Writing §147.137. At issue is whether the word presumption refers to a presumption of consent or a presumption of being informed. Please provide written clarification that the phrase means the following:

"Presumption that informed consent was given" means that a signed legal consent for a procedure presumes the patient has been informed of the risks, benefits, and alternatives to that procedure. It means presumed informed. It does NOT mean PRESUMED CONSENT to a different, related, or additional procedure. If a different or additional procedure is performed because of an emergency, then "presumed informed" is impossible and unnecessary. In the absence of a well documented emergency, performing an additional or different procedure violates the Iowa Law governing informed consent.

I look forward to the Board's response.

Sincerely,


Eileen Marie Wayne, M.D.

96 NOV 22 PM 12: 03

IA. BOARD OF MED. EXAMINERS

Eileen Marie Wayne MD

2623 17th Street
Rock Island, IL 61201
(309) 786-6800
Fax (309) 786-8586
Answering Service (319) 328-4936
E-Mail EileeWayne@aol.com

November 19, 1996

Ann Martina, Executive Director
Iowa Board of Medical Examiners
Executive Hills West
1209 East Court
Des Moines, Ia 50319

Dear Ann Martina,

Thank you for taking my phone call Monday November 18, 1996. It is curious that a group of physicians, who are members of the Licensing Board, are unable to provide written clarification of informed consent. Perhaps a consumer group or journalist might be more suited to the task. I appreciate your help and await Counsel's response.

Sincerely,

Eileen Marie Wayne, M.D.
Eileen Marie Wayne, M.D.

Eileen Marie Wayne MD
BOARD CERTIFIED EYE SURGEON
LASER, CATARACT & IMPLANT SURGERY
2623 17TH STREET
ROCK ISLAND, ILLINOIS 61201
(309) 786-6800
(309) 786-8586 FAX

96 OCT 28 PM 12:00
IA. BOARD OF MED. EXAMINERS

October 25, 1996

Ann Martina, Executive Director
Iowa Board of Medical Examiners
Executive Hills West
1209 East Court
Des Moines, Ia 50319

Dear Ann Martina,

Thank you for taking my phone call and providing clarification of the Iowa Law governing informed consent. At issue is whether the word presumed refers to a presumption of consent or a presumption of being informed. Please provide written clarification that the phrase "presumed informed consent" means the following:

Presumed informed consent means that a signed legal consent for a procedure presumes the patient has been informed about the risks, benefits, and alternatives to that procedure. It means presumed informed. It does NOT mean PRESUMED CONSENT to a different, related, or additional procedure. If a different or additional procedure is performed because of an emergency, then "presumed informed" is impossible and unnecessary. In the absence of a well documented emergency, performing an additional or different procedure violates the Iowa Law governing informed consent.

Please present my request for written clarification of the phrase "presumed informed" to the Board at the October 31 meeting. I look forward to the Board's response.

Sincerely,

Eileen Marie Wayne, M.D.

Eileen Marie Wayne, M.D.

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF:)	
)	
Request for Declaratory)	DENIAL OF REQUEST FOR
Ruling re: Pharmacist)	DECLARATORY RULING
Immunizations)	

On this 4th day of May, 1998, the Iowa Board of Medical Examiners (Board), having considered the request of the Iowa Osteopathic Medical Association (IOMA), through its executive director Normal Pawlewski, in a letter to the Board dated March 2, 1998, that the Board issue a declaratory ruling on the question of whether pharmacists who administer immunizations are engaged in the unlicensed practice of medicine, hereby finds as follows:

1. In correspondence following submission of the request for declaratory ruling, the Board advised IOMA that additional time was needed to consider this request. No objection was made. The statutory time frames for responding to a request for declaratory ruling were therefore waived.

2. Following review of the request for declaratory ruling at a Board meeting held June 4, 1998, the Board determined it is not appropriate to issue a declaratory ruling on this issue. The request for declaratory ruling is therefore **DENIED** for the following reasons:

a. In IOMA's March 2, 1998, letter to the Board, IOMA simultaneously filed a complaint against a named pharmacist for practicing medicine without a license, and filed its request for declaratory ruling.

Accordingly, the request for declaratory ruling is not based upon facts calculated to aid in the planning of future conduct but is, instead, based solely or primarily upon prior conduct in an effort to establish the effect of that conduct. See Uniform Rule X.5(8). The Board concludes issuance of a declaratory ruling is therefore an inappropriate manner in which to resolve this complaint.

b. In its letter requesting a declaratory ruling, IOMA further asks the Board to overrule the opinion that has been issued by the Board of Pharmacy Examiners (Pharmacy Board) concluding that Iowa-licensed pharmacists are not prohibited from participating in immunization programs. The request for declaratory ruling is thus a challenge to an agency decision already made. See Uniform Rule X.5(8). The Board concludes that issuance of a declaratory ruling is therefore an inappropriate manner in which to resolve this issue.

c. Issuance of a declaratory ruling on the question of whether a pharmacist may administer immunizations would necessarily determine the legal rights of pharmacists, who have not joined in the petition or filed a similar petition. It may fairly be presumed that the position of many pharmacists on the question presented would be adverse to that of IOMA.

See Uniform Rule X.5(9). The Board concludes that issuance of a declaratory ruling is therefore an inappropriate manner by which to resolve this issue.

3. The Board notes that the Pharmacy Board has jurisdiction over the professional practices of Iowa-licensed pharmacists. The Board does not believe issuance of a declaratory ruling on the issue of pharmacist immunizations is an appropriate exercise of its authority given the statutory provisions and administrative rules upon which the Pharmacy Board relied to conclude in its letter dated January 17, 1996, that Iowa-licensed pharmacists are not prohibited from participating in immunization programs. See Uniform Rule X.5(5). The Board believes that any issues regarding the scope of pharmacy practice should be resolved not by the Board of Medical Examiners, but instead by the legislature, and/or referred to a scope of practice review committee pursuant to the provisions of 1997 Iowa Acts, H.F. 710, section 6, and 641 IAC 194.

WHEREFORE, IT IS HEREBY ORDERED that this request for declaratory ruling be denied for the reasons set forth above.

Teresa Mock, M.D., Chairperson
Iowa Board of Medical Examiners

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF IOWA

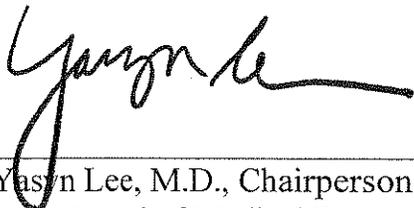
PETITION FOR)	FILE NO. <u>11</u>.
DECLARATORY ORDER)	
)	
LAWRENCE C. VALIN, M.D.,)	DENIAL OF PETITION FOR
PETITIONER)	DECLARATORY ORDER

On October 18, 2006, Petitioner filed a Petition for Declaratory Order with the Iowa Board of Medical Examiners (Board) pursuant to Iowa Code section 17A.9. Petitioner seeks the Board to declare the provisions of 653 Iowa Administrative Code subsection 13.7(3) unconstitutional on the ground that it prohibits the free exercise of his religion. 653 IAC 13.7(3) states, "Confidentiality. A physician shall maintain the confidentiality of all patient information obtained in the practice of medicine. Information shall be divulged by the physician when authorized by law or the patient or when required for patient care."

Petitioner's request was not submitted in the format specified by 653 IAC 1.9(3) for the filing of a petition for declaratory order. However, the Board has determined that it will waive the specific format requirements of this rule. The Board has reviewed Petitioner's request for declaratory order and concluded that the request should be denied on the ground that Petitioner has asked the Board to determine whether a statute is unconstitutional on its face. This is a ground for denial of a petition for declaratory order pursuant to 653 IAC 1.9(9)(a)(10).

THEREFORE IT IS HEREBY ORDERED: that Petitioner's request for declaratory order is hereby **DENIED**.

This Order is approved by the Board on November 9, 2006.



Yashin Lee, M.D., Chairperson
Iowa Board of Medical Examiners
400 SW 8th Street, Suite C
Des Moines, Iowa 50309-4686

BEFORE THE IOWA BOARD OF MEDICINE

IOWA ASSOCIATION OF) File No. 01-10-12
NURSE ANESTHETISTS,)
Petitioner-Applicant) PETITION-APPLICATION FOR
) DECLARATORY ORDER
) RE: ARC 8579B
)

NOTICE OF PETITION FOR DECLARATORY ORDER

On April 7, 2010, Petitioner filed a Petition-Application for Declaratory Order with the Iowa Board of Medicine (Board) pursuant to Iowa Code section 17A.9. Petitioner requests that the Board declare whether the Board will interpret proposed rule ARC 8579B to mean that the practice of chronic interventional pain management is “solely and exclusively the practice of medicine”.

Pursuant to Iowa Code section 17A.9 and 653 IAC 1.9(2) the Board files this Notice of Petition for Declaratory Order.

Attached, please find a copy of ARC 8579B.

Also attached, please find a copy of Petitioner’s Petition-Application for Declaratory Order.


Siroos S. Shirazi, M.D., Chairman
Iowa Board of Medicine
400 SW 8th Street, Suite C
Des Moines, Iowa 50309-4686

April 16, 2010
Date

<p>IOWA ASSOCIATION OF NURSE ANESTHETISTS</p> <p>Petitioner-Applicant</p>	<p>PETITION-APPLICATION FOR DECLARATORY ORDER</p> <p>RE: ARC 8579B</p>
---	--

COMES NOW your Petitioner-Applicant the Iowa Association of Nurse Anesthetists (IANA) and states in support of its Petition-Application for Declaratory Order the following:

1. That your Petitioner-Applicant is a professional association which represents approximately 275 Certified Registered Nurse Anesthetists (CRNAs) who are licensed under Iowa law as Advanced Registered Nurse Practitioners (ARNPs).
2. That numerous members of the IANA have, for in excess of 15 to 20 years, provided professional services to the public known as "pain management services" or what are referenced as "chronic interventional pain management services" in ARC 8579B.
3. That the Iowa Board of Medicine (IBOM) has had under consideration the issue of chronic interventional pain management services for the past year or more. The IBOM has issued from time to time various drafts of public policy statements and rules related to chronic interventional pain management services.
4. That attached hereto and made a part of the Petitioner-Applicant's petition is a copy of correspondence delivered to the IBOM at a public hearing on March 30, 2010 regarding ARC 8579B.

physician or osteopathic physician who is actively engaged in the practice”.

10. That members of the IANA have been providing chronic interventional pain management services throughout the state of Iowa during the regular course of their practice for more than 15 years on an independent basis without the supervision of physicians. If the IBOM's intent is to interpret ARC 8579(B) as interventional pain management services being “solely and exclusively within the practice of medicine” CRNAs would be deprived of their practice rights and suffer significant harm. An interpretation by the IBOM that chronic interventional pain management services is “solely and exclusively the practice of medicine” would be an arbitrary and capricious action by the Board.

11. That further, such a restrictive interpretation would be beyond the authority delegated to the IBOM by attempting to define the practice of medicine in a manner that would be in derogation of the Board of Nursing's power and authority to license nurses and to define the practice of nursing.

12. That further, such a restrictive interpretation would result in the unconstitutional deprivation of property rights without due process of law and the deprivation of the professional practice rights of nurses duly licensed as ARNPs under the Board of Nursing.

is properly made in order that aggrieved parties may seek appropriate legal remedy.

16. The question that Petitioner-Applicant wants answered for the record is as follows:

Is it the intention of the IBOM to interpret ARC 8579B in a manner to mean that chronic interventional pain management services are “solely and exclusively the practice of medicine” and to prohibit other practitioners, including CRNAs, from providing such services?

17. Your Petitioner-Applicant suggests that the appropriate answer to the above question is “NO”. The reasons for the desired answer being “no”, is that CRNAs as ARNPs have for in excess of 15 to 20 years provided chronic interventional pain management services as a part of their practice in a safe and efficacious manner. That interpreting the rule in a restrictive manner to exclude CRNAs will be a deprivation of the practice rights of CRNAs as set forth above.

18. That your Petitioner-Applicant is not a party to another proceeding involving the questions at issue, but is aware of the Board of Nursing and the Board of Health having taken action as set forth in the attached copy of “The Rules Digest” of April 2010. As stated in *The Rules Digest*, the portion of the rule in question is “ambiguous because it does not indicate whether chronic interventional pain management is **exclusive** to medical and osteopathic physicians”.

Administrative Rule 653-1.9(1). Specifically, whether the Board will interpret the proposed rule to mean that the practice of chronic interventional pain management is "solely and exclusively the practice of medicine".

CARNEY & APPLEBY P.L.C.



4/7/2010

James W. Carney (AT00001327)
303 Locust Street, Ste 400
Des Moines IA 50309-1770
Telephone: (515) 282-6803
Facsimile: (515) 282-4700
Email: carney@carneylawfirmiowa.com
Attorney for Petitioner-Applicant

DATE

Original Filed
Copies to:

James C. Larew, General Counsel
Office of Governor Chet Culver and Lt. Governor
Patty Judge
1007 E. Grand Avenue
Des Moines, Iowa 50319

Lorinda Inman, Executive Director
Iowa Board of Nursing
RiverPoint Business Park
400 S.W. 8th Street, Ste B
Des Moines, IA 50309

Joe Royce, Senior Legal Counsel
Iowa General Assembly
Statehouse
Des Moines, IA 50319

Tom Newton, Director
Iowa Dept. of Public Health-
Iowa Board of Health
321 E. 12th Street
Des Moines, Iowa, 50319

Kent Nebel, Director of Legal Affairs
Iowa Board of Medicine
400 SW 8th St, Ste C
Des Moines, IA 50309

Mark Odden, President
Iowa Association of Nurse Anesthetists
17893 - 224th St
Manchester, IA 52057

attachments: March 29, 2010 letter to the IBOM
The Rules Digest, April 2010

CARNEY & APPLEBY, P.L.C.
ATTORNEYS AT LAW

JAMES W. CARNEY
GEORGE W. APPLEBY
DIANE L. DORNBURG
SCOTT A. HALL

400 HOMESTEAD BUILDING
303 LOCUST STREET
DES MOINES, IOWA 50309-1770
www.carneylawfirmiowa.com

Telephone (515) 282-6803
Facsimile (515) 282-4700

JENNIFER A. TYLER

E-mail: carney@carneylawfirmiowa.com

March 29, 2010

Mark Bowden, Executive Director
Iowa Board of Medicine
400 SW 8th St, Ste C
Des Moines IA 50309-4685

RE: ARC 8579B Standards for Pain Management

Dear Mr. Bowden:

We represent the Iowa Association of Nurse Anesthetists in regard to ARC 8579B, the Iowa Board of Medicine's proposed rule establishing standards of practice for interventional chronic pain management. I request that you provide a copy of this communication to each member of the Board of Medicine.

The history of the pain management proposals considered by the Board of Medicine is long and represents a significant amount of time, energy and effort on the part of the Iowa Board of Medicine. The proposed rule is, in the opinion of IANA members, a significant improvement over prior proposals. There is, however, a continuing concern as to the intent of the Iowa Board of Medicine. Quite simply, is the intent of the proposed rule in ARC 8579B that the practice of interventional chronic pain management, as defined by the rule, is "solely and exclusively" the practice of medicine?

A short review of the history of this issue gives cause to raise this question to the Board of Medicine. As you may recall, the Board of Medicine originally adopted a policy statement on chronic interventional pain management and posted the policy statement on the Board's website. The policy statement in part stated "the board concludes that the practice of chronic interventional pain management, including the use of fluoroscopy, is the practice of medicine and is not within the scope of practice of other health care professionals, including CRNAs." The same policy statement went on to state that other professionals performing chronic interventional pain management procedures "should do so only under the supervision of a physician or osteopathic physician who is actively engaged in the practice". The position pronounced in the policy statement is a radical departure from the long existing practice here in Iowa of CRNAs providing chronic interventional pain management services as independent practitioners.

This issue was considered by the Iowa legislature during the 2010 legislative session. I am certain that the Board of Medicine is aware of the fact that HF 2136 and companion bill SSB 3085 were introduced in the legislature. We have enclosed a copy of HF 2136 for your ready reference. The proposed legislation prohibited a person from practicing

House File 2136 - Introduced

HOUSE FILE
BY T. OLSON

A BILL FOR

1 An Act regulating the practice of chronic interventional pain
2 medicine and providing penalties.
3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
4 TLSB 5839YH (3) 83
5 jr/nh

PAG LIN

1 1 Section 1. NEW SECTION. 148F.1 Definitions.
1 2 As used in this chapter, unless the context otherwise
1 3 requires:
1 4 1. "Chronic interventional pain medicine" means the diagnosis
1 5 and treatment of pain-related disorders primarily with the
1 6 application of interventional techniques in managing subacute,
1 7 chronic, persistent, and intractable pain.
1 8 2. "Fluoroscope" means a radiologic instrument equipped with
1 9 a fluorescent screen on which opaque internal structures can
1 10 be viewed as moving shadow images formed by the differential
1 11 transmission of X rays throughout the body.
1 12 3. "Interventional techniques" means percutaneous needle
1 13 placement through which drugs are then placed in targeted
1 14 areas, nerves are ablated, or certain surgical procedures
1 15 involving injection of steroids, analgesics, or anesthetics are
1 16 performed. "Interventional techniques" include the following:
1 17 a. Lumbar, thoracic, and cervical spine injections,
1 18 intra-articular injection, intrathecal injections, and epidural
1 19 injections, both interlaminar and transforaminal.
1 20 b. Facet injections.
1 21 c. Discography.
1 22 d. Nerve destruction.
1 23 e. Occipital nerve blocks.
1 24 f. Cervical, thoracic, or lumbar sympathetic blocks.
1 25 g. Intradiscal electrothermal therapy.
1 26 h. Spinal cord stimulation or peripheral nerve stimulation.
1 27 i. Intrathecal pump placement.
1 28 j. Ablation of targeted nerves.
1 29 k. Vertebroplasty.
1 30 l. Kyphoplasty.
1 31 m. Utilization of fluoroscopy, computerized tomography,
1 32 or ultrasound to assess the cause or location of a patient's
1 33 chronic pain or as a means of accurately directing needles,
1 34 catheters, or electrodes as part of a therapeutic modality for
1 35 chronic pain treatment.
2 1 Sec. 2. NEW SECTION. 148F.2 Prohibited practices ==
2 2 penalties.
2 3 A person shall not practice or offer to practice chronic
2 4 interventional pain medicine in this state unless such person
2 5 has been duly licensed under the provisions of chapter 148 to
2 6 engage in the practice of medicine and surgery or osteopathic
2 7 medicine and surgery, chapter 149 to engage in the practice
2 8 of podiatry, or chapter 153 to engage in the practice of

Senate Joint Resolution 2003 - Introduced

SENATE JOINT RESOLUTION
BY DOTZLER and COURTNEY

SENATE JOINT RESOLUTION

1 A Joint Resolution to nullify administrative rules of the
2 board of nursing concerning advanced registered nurse
3 practitioners and providing an effective date.
4 BE IT RESOLVED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
TLSB 5078XS (2) 83
jr/nh

PAG LIN

1 1 Section 1. 655 Iowa administrative code, rule 7.2, subrule
1 2 2, is nullified.
1 3 Sec. 2. EFFECTIVE DATE. This joint resolution, being deemed
1 4 of immediate importance, takes effect upon enactment.
1 5 EXPLANATION
1 6 This joint resolution nullifies an administrative rule
1 7 adopted by the board of nursing that allows an advanced
1 8 registered nurse practitioner to provide direct supervision in
1 9 the use of fluoroscopic equipment. The joint resolution takes
1 10 effect upon enactment.
LSB 5078XS (2) 83
jr/nh

The Board will discuss the policy statement and receive public comment about it on May 21. Written comments for the board are due by April 24 and should be mailed to Board Executive Director Mark Bowden, 400 S.W. Eighth Street, Suite C, Des Moines, IA 50309 or e-mailed to mark.bowden@iowa.gov

Iowa Board of Medicine

Policy on Chronic Interventional Pain Management

Approved _____

Definition

Chronic interventional pain management, as defined by the National Uniform Claims Committee, is the diagnosis and treatment of pain-related disorders primarily with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain.¹ Interventional pain techniques include percutaneous (through the skin) needle placement. Drugs are then placed in targeted areas, nerves are ablated (excised or amputated), or certain surgical procedures are performed. By way of example, procedures often involve injection of steroids, analgesics, and anesthetics and include: lumbar, thoracic, and cervical spine injections, intra-articular injection, intrathecal injections, epidural injections (both regular and transforaminal), facet injections, discography, vertebroplasty, kyphoplasty, nerve destruction, occipital nerve blocks, and lumbar sympathetic blocks. Interventional pain management may also include the use of fluoroscopy.

Diagnosis and Treatment

Chronic interventional pain management involves interactive procedures in which the physician is called upon to make continuing adjustments, noting that it is not the procedures themselves, but it's the "the purpose and manner in which such procedures are utilized" that demand the ongoing application of direct and immediate medical judgment that constitutes the practice of medicine. These procedures are used to assess the cause of a patient's chronic pain, as a therapeutic modality of treatment, and as a basis on which to recommend additional treatment, including the need for surgical intervention and repeated or additional treatments. Often times the pain physician will perform a different chronic interventional pain management procedure than prescribed by the referring physician based on the pathophysiology of the patient and the determination that a patient would be unable to withstand the prescribed procedure. In order to practice competent chronic interventional pain management the pain physician must understand the particular history of the patient, which includes a complete neurological, musculoskeletal and psychological assessment, as well as review of the available diagnostic studies (both pre-procedure images and those obtained during the actual performance of the procedure). Only then can the pain physician develop a proper treatment plan which may or may not differ from the

¹ Manchikanti, L. Medicare in interventional pain management: A critical analysis. *Pain Physician*. 2006;9: 171-197.

(15%), interventional techniques (15%), and other issues related to the practice of pain management.⁷

CRNAs do not possess the requisite education or training to practice medicine and, particularly, to perform chronic interventional pain management.

Lack of training. Nurse anesthetists are required to have a bachelor's degree which earns them an RN designation. They then undergo CRNA training which consists of 18-24 months of didactic and clinical training in administration of anesthetics. By way of example, CRNAs only receive a total of six to seven years of total education compared to a physician practicing chronic interventional pain management who is required to have a minimum education of twelve years, and several have up to sixteen years of documented education. CRNAs cannot document *any* formal education in performing chronic interventional pain management.⁸ In fact, the College of Accreditation's (COA) current standards, last revised in January 2006, do not require nurse anesthetist programs to provide any clinical case experience in pain management (acute or chronic).⁹ Additionally, the COA does not list pain management in the description of "full scope of practice" for a CRNA.¹⁰ This acknowledgment by the national accreditation body that the medical specialty of chronic interventional pain management is beyond the skills of a CRNA further supports the separation between nursing and medicine.

Since CRNAs cannot show any formal didactic or clinical training, many justify their competency to practice medicine by attending a weekend seminar. In a 2008 American Academy of Pain Management newsletter, it was reported that the American Association of Nurse Anesthetists was pursuing continuing education shortcuts to expertise in interventional pain-management techniques.

Through the Institute for Post Graduate Education, AANA is offering a 3-day Interventional Pain Management Cadaver Model Lab course for CRNAs. The course's learning objectives include epidural steroid injections, discography, facet injections, coding, and cervical, thoracic, and lumbar radiofrequency lesioning. Although a 3-day comprehensive course in interventional pain management may not seem adequate for providing comprehensive knowledge in the discipline, it is the amount of training that most CRNAs receive in the practice of pain management. The prevailing argument is that doing epidural and selective nerve blocks for acute pain in the operation room will naturally extend to performing interventional procedures for chronic pain.¹¹

⁷ Web. ABIPP Information Bulletin for Certification as Fellow for Interventional Pain Practice. <http://www.abipp.org/forms/diplomate/default.aspx>. Retrieved December 3, 2008.

⁸ Web. University of Iowa College of Nursing Anesthesia Nursing Course Sequence, (www.uiowa.edu). Retrieved November 24, 2008.

⁹ COA, *Standards for Accreditation of Nurse Anesthesia Education Programs*, 2004 edition, revised January 2006. p. 6-7.

¹⁰ Id. Glossary, p. 25. Note that this definition is attributed to "Scope and practice for nurse anesthesia practice," available from the AANA.

¹¹ Web. Francis, Michael. LSBN to Allow CRNAs to Practice Pain Management Procedures. *Pain Medicine Network*. Winter, 2008. 4. www.painmed.org/pdf/2008winter_newsletter.pdf.



IOWA GENERAL ASSEMBLY

Administrative Rules Review Committee

STATEHOUSE * ROOM 312 * DES MOINES, IOWA 50319 * (515) 281-3084/3355/4800
FAX (515) 281-4424 * E-MAIL jroyce@legis.state.ia.us; mduster@legis.state.ia.us

THE RULES DIGEST

April 2010

Scheduled for committee review
Tuesday, April 13th, 2010.
Senate Committee Room #116

Reference
XXXII IAB No. 19(03/10/10)
XXXII IAB No. 20(03/24/10)

HIGHLIGHTS IN THIS ISSUE:

OSHA: CONSULTATIVE SERVICES, Labor Services Division1
TRAINING EXTENSION BENEFITS, Workforce Development2
PRACTICE OF MEDICINE, Medical Board3
STREAM DESIGNATIONS, EPC4
NUTRITIONAL STANDARDS, Education Department4
SPECIAL HUNTING LICENSES, Natural Resources Commission7

LABOR SERVICES DIVISION

10:20

OSHA: consultative services, IAB Vol. XXXII, No. 19 ARC 8591B, ADOPTED.

Iowa's Division of Labor Services operates with close ties to the federal Occupational Health and Safety Administration. This rulemaking is an update of existing provisions relating to consultative services provided upon request to employers without charge. The purpose of the services is to help employers provide safe and healthy workplaces. Under this program, the division will provide a safety consultant who will review the workplace, without cost or penalty, for health and safety problems.

The consultant is independent of the enforcement staff. However, the employer must take immediate action to eliminate employee exposure to a hazard that, in the judgment of the consultant, presents an imminent danger to employees. The employer must also remediate other identified serious hazards.

The consultant will evaluate the employer's program for a safe and healthy workplace; identify specific hazards in the workplace; and provide appropriate advice and assistance in establishing or improving the employer's safety and health program and in correcting any hazardous conditions identified. Assistance may include education and training of

THE RULES DIGEST

-3-

A clinic may also participate in the program, with an agreement similar to that used for individual health care providers, identify the clinic site, the patient groups served, and the *free* services provided.

Similar to the process for denial, suspension or revocation of a professional license, these agreements can be denied, suspended, or revoked, following a due process hearing.

MEDICINE BOARD

1:00

Interventional chronic pain management, IAB XXXII No. 19 ARC 8579B, NOTICE.

This proposal is a continuation of a long-standing rulemaking issue. The Nursing Board has adopted rules allowing an advanced registered nurse practitioner (ARNP) (more specifically: a certified registered nurse anesthetist---CRNA) to provide direct supervision in the use of fluoroscopic x-ray equipment. The Department of Public Health has adopted a rule amendment that allows all CRNAs to supervise radiology technicians and students for the use of fluoroscopy. The public health rule complements the Board of Nursing's new rule that allows CRNAs to supervise fluoroscopy.

In 2009 the Committee referred this issue to the General Assembly, which took no legislative action. Senate Study Bill 3085 (Human Resources Committee) and House File 2136 (Judiciary Committee) both specifically defined the practice of chronic interventional pain medicine and the techniques used in that practice. Both bills limited the practice of interventional pain medicine to licensed physicians, podiatrists, or dentists; neither was passed out of sub-committee.

The Medicine Board now proposes standards of practice for the practice of interventional chronic pain management. It should be noted that unlike the proposed legislation, these rules do not contain language which specifically limits interventional pain medicine to a particular profession. The rule sets out a detailed definition of the term "*interventional chronic pain management*." In part, the definition states that:

"Interventional chronic pain management" means the diagnosis and treatment of pain-related disorders with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain.

The definition sets out the techniques used in pain management and provides examples of those techniques in use. The rule also describes the process of pain management: comprehensive patient assessment, pain diagnosis, evaluation and selection of treatment options, termination of treatment when appropriate, follow-up care, and collaboration with other health care providers.

BEFORE THE IOWA BOARD OF MEDICINE

)	File No. 01-10-12
)	
IOWA ASSOCIATION OF)	PETITION-APPLICATION FOR
NURSE ANESTHETISTS,)	DECLARATORY ORDER
Petitioner-Applicant)	RE: ARC 8579B
)	

NOTICE OF MEETING - PETITION FOR DECLARATORY ORDER

On April 7, 2010, Petitioner filed a Petition-Application for Declaratory Order with the Iowa Board of Medicine (Board) pursuant to Iowa Code section 17A.9. Petitioner requests that the Board declare whether the Board will interpret proposed rule ARC 8579B to mean that the practice of chronic interventional pain management is “solely and exclusively the practice of medicine”.

On April 16, 2010, the Board filed a Notice of Petition for Declaratory Order.

Meeting: The Board shall hold a brief and informal meeting between the original petitioner, all intervenors, and the Board. The original petitioner and intervenors shall attend in person at the Iowa Board of Medicine office, 400 SW 8th Street, Suite C, Des Moines, Iowa, to present to the Board members via speaker phone. The meeting is scheduled to begin at 7:45 a.m. on Thursday, May 6, 2010.

Siroos S. Shirazi, M.D.

Siroos S. Shirazi, M.D., Chairman
Iowa Board of Medicine
400 SW 8th Street, Suite C
Des Moines, Iowa 50309-4686

April 28, 2010

Date

BEFORE THE IOWA BOARD OF MEDICINE

PETITION BY IOWA)	FILE NO. 01-10-12
ASSOCIATION OF NURSE)	
ANESTHETISTS FOR)	IOWA DENTAL ASSOCIATION'S
DECLARATORY ORDER)	PETITION FOR INTERVENTION
RE: ARC 8579B)	
)	

COMES NOW the Iowa Dental Association ("IDA") and in support of its Petition for Intervention in the above-referenced Petition-Application for Declaratory Order hereby states as follows:

1. IDA represents nearly ninety percent of all dentists practicing in the state of Iowa. All dentists in the state of Iowa are regulated by the Iowa Dental Board.
2. The Proposed Rule found at ARC 8579B provides that "interventional chronic pain management is the practice of medicine." The Proposed Rule located at ARC 8579B defines "interventional chronic pain management" very broadly and such definition would include certain activities routinely performed by dentists.
3. Dentists often engage in interventional chronic pain management and such practices are within their scope of practice and are regulated by the Iowa Dental Board.
4. Representatives of the Board of Medicine have on two occasions publically stated that they do not intend the Proposed Rule found at ARC 8579B to preclude dentists from performing interventional chronic pain management within their scope of practice. However, "interventional chronic pain management is the practice of medicine" could be interpreted to mean that other professionals, such as dentists, cannot perform such services. This language makes the rule in question ambiguous because it does not specify whether interventional chronic pain management is exclusive to the practice of medicine. This ambiguity has been recognized

in the Rules Digest dated April, 2010, which was attached to the Petition by the Iowa Association of Nurse Anesthetists.

5. To the extent not already set forth herein, IDA joins in and fully supports the statements of the Petitioner-Applicant Iowa Association of Nurse Anesthetists regarding ARC 8579B.

6. IDA requests intervention in this matter and has an interest in the outcome because ARC 8579B, as currently written, creates ambiguity regarding whether the Board of Medicine's Proposed Rule asserts that only medical doctors may perform interventional chronic pain management as defined therein.

7. IDA is not a party to another proceeding involving the questions at issue herein and in the Iowa Association of Nurse Anesthetists' Petition-Application for Declaratory Order regarding ARC 8579B. However, IDA has participated and provided comment letters to the Board during the rulemaking process. A copy of the IDA's comment letter to the Board is attached hereto as Exhibit A.

8. In addition to the names and addresses of other associations identified in paragraph 19 as being interested in the questions raised in the Iowa Association of Nurse Anesthetists Petition-Application, IDA believes that the following persons or classes of persons may be interested in the questions presented:

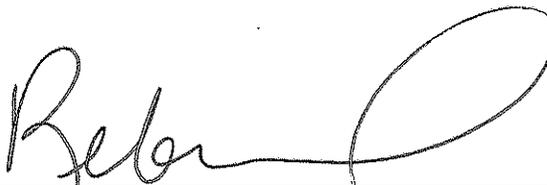
- a. Iowa Dental Board
400 SW 8th Street, Suite D
Des Moines, IA 50309
(515) 281-5157
- b. Iowa Hospital Association
100 E. Grand, Suite 100
Des Moines, IA 50309
(515) 288-1955

- c. Iowa Physician Assistant Society
525 SW 5th Street, Suite A
Des Moines, IA 50309
(515) 282-8192

9. Pursuant to Iowa Administrative Code section 1.9(3)(6), IDA consents to be bound by the determination of the matters presented in this proceeding to the extent it is allowed to participate in the proceeding(s).

10. IDA requests that all further communications concerning this Petition for Intervention be directed to Rebecca A. Brommel at the address and telephone number listed below.

WHEREFORE the Iowa Dental Association respectfully requests it be allowed to intervene in the Petition-Application for Declaratory Order regarding ARC 8579B filed by the Iowa Association of Nurse Anesthetists. The Iowa Dental Association further respectfully requests a declaratory order from the Board of Medicine declaring and clarifying the intent of the Board of Medicine in adopting ARC 8579B pursuant to Iowa Code Section 17A.9 and Iowa Administrative Code 653-1.9(1). The Iowa Dental Association specifically requests the Board enter an order indicating that the Proposed Rule does not mean that the practice of interventional chronic pain management is fully and exclusively the practice of medicine and thus, that interventional chronic pain management performed by dentists within their scope of practice is subject only to the regulations of the Iowa Dental Board.



Rebecca A. Brommel, AT0001235
BROWN, WINICK, GRAVES, GROSS,
BASKERVILLE AND SCHOENEBAUM, P.L.C.
666 Grand Avenue, Suite 2000
Des Moines, IA 50309-2510
Telephone: 515-242-2400
Facsimile: 515-283-0231
Email: brommel@brownwinick.com

ATTORNEYS FOR IOWA DENTAL
ASSOCIATION

Original to:

CERTIFICATE OF SERVICE

Mark Bowden
Executive Director
Iowa Board of Medicine
400 SW 8th Street, Suite C
Des Moines, IA 50309-4686

The undersigned hereby certifies that a true copy of the foregoing instrument was served upon each of the attorneys of record of all parties to the above-entitled cause by enclosing the same in an envelope addressed to each such attorney at such attorney's address as disclosed by the pleadings of record herein on the 23rd day of April, 2010.

Copy to:

James W. Carney
303 Locust Street, Suite 400
Des Moines, Iowa 50309-1770

By: U.S. Mail Facsimile
 Hand Delivered Overnight Courier
 Federal Express Other

Signature Brian Ramsey

ATTORNEY FOR PETITIONER-
APPLICANT IOWA ASSOCIATION OF
NURSE ANESTHETISTS

Kent Nebel
Director of Legal Affairs
Iowa Board of Medicine
400 SW 8th Street, Suite C
Des Moines, IA 50309

ATTORNEY FOR IOWA BOARD OF
MEDICINE

Theresa Weeg
Iowa Attorney General's Office
1305 E. Walnut Street
Des Moines, IA 50319

ATTORNEY FOR IOWA BOARD OF
MEDICINE



Brown Winick
ATTORNEYS AT LAW®

Brown, Winick, Graves, Gross,
Baskerville and Schoenebaum, P.L.C.

666 Grand Avenue, Suite 2000
Ruan Center, Des Moines, IA 50309-2510

March 30, 2010

direct phone: 515-242-2490

direct fax: 515-323-8590

email: cownie@brownwinick.com

Mark Bowden
Executive Director
Iowa Board of Medicine
400 SW 8th Street, Suite C
Des Moines, Iowa 503094686

Re: Proposed rule regarding chronic pain management

Dear Mr. Bowden:

This firm serves as counsel to the Iowa Dental Association (the "Association"). The Association represents nearly ninety percent of all dentists practicing in the state of Iowa. It has come to the attention of the Association that the Iowa Board of Medicine recently proposed a rule to establish standards of practice for interventional chronic pain management (the "Proposed Rule"). The Proposed Rule may interfere with the ability of dentists to treat patients by regulating certain practices that dentists routinely perform to treat chronic pain. The Association, therefore, opposes the Proposed Rule.

The Proposed Rule provides that "[i]nterventional chronic pain management is the practice of medicine." As a result, the Board of Medicine would regulate any activities that are included within the definition of "interventional chronic pain management," thereby prohibiting dentists from performing these activities. The Proposed Rule defines "interventional chronic pain management" very broadly, such that the definition includes certain activities that dentists perform on a routine basis.

Dental patients frequently require treatment for chronic pain. The Iowa Dental Board regulates such practices when performed by a dentist. For example, dentists engage in the diagnoses and treatment of disorders of the temporomandibular joint ("TMJ"). Treatment of TMJ disorders often requires intra-articular injections of corticosteroids. The Proposed Rule, however, would regulate intra-articular injection of steroids as interventional chronic pain management. In addition, for over 50 years, fluoroscopy has been a useful tool in dentistry for the diagnoses of the causes of chronic pain. Due to recent technological developments, many dentists expect fluoroscopy to become an increasingly important tool in future years. The Proposed Rule, however, would include in the definition of interventional chronic pain management fluoroscopy

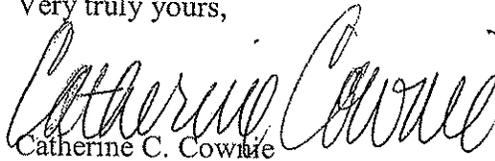
March 30, 2010

Page 2

used to assess the source of a patient's chronic pain. These are merely two specific examples in which the Proposed Rule inappropriately intrudes into the practice of dentistry. Dentists also must prescribe analgesics and anesthetics to dental patients, which are included within the scope of the Proposed Rules. These procedures, when employed by dentists, must remain exclusively within the regulation of the Iowa Dental Board, rather than the Board of Medicine.

For these reasons, the Association opposes the Proposed Rule. The Association requests that the Board of Medicine revise the Proposed Rule to exclude dentists and the services performed by dentists. Please do not hesitate to contact me if you have any questions.

Very truly yours,

A handwritten signature in cursive script that reads "Catherine C. Cowie". The signature is written in black ink and is positioned above the printed name.

Catherine C. Cowie

CCC:af

BOARD OF MEDICINE~~04-16907-919409ARWV~~

PETITION FOR INTERVENTION BY THE IOWA MEDICAL SOCIETY	RE: PETITION FOR DECLARATORY ORDER BY THE IOWA ASSOCIATION OF NURSE ANESTHETISTS ON PROPOSED RULE ARC 8579B File No. 01-10-12
--	--

COMES NOW the Iowa Medical Society (“IMS”), and in accordance with IAC 653-1.9(3), petitions the Iowa Board of Medicine (“IBM”) to intervene in the above-stated matter. In support of its Petition for Intervention, IMS states as follows:

1. The Iowa Medical Society (“IMS”), as a statewide professional organization of approximately 4600 MD and DO physician members who also are licensed by and under the jurisdiction of the Iowa Board of Medicine (“IBM” or “Board”), has standing to appear before the IBM as an intervenor in this matter. The issuance of a declaratory order by the IBM in this matter potentially impacts the delivery of health care by IMS member physicians in this state, practice relationships between IMS member physicians and other non-physician licensees, and the health and safety of patients served by IMS member physicians. 653-1.9(3)(c)(1).

2. IMS is qualified and entitled to intervene in this matter on behalf of itself and its member physicians who would be affected by action taken on the petition. The Petition for Declaratory Order flows from rulemaking proposed by the IBM defining interventional chronic pain management (ICPM) and declaring ICPM as the practice of medicine. IMS is the party that originally sought clarification and declaration from the IBM regarding interventional chronic

pain management, including fluoroscopy, as the practice of medicine. IMS has actively participated in all stages of study and debate of this matter before the IBM as well as before the Iowa Board of Nursing, the Iowa Department of Public Health, the Iowa Administrative Rules Committee, and the Iowa General Assembly. In addition, IMS physician members practice the medical subspecialty of ICPM. 653-1.9(3)(c)(1).

3. The Petitioner sets out a single question to be answered in Paragraph 16 of the Petition as follows: “Is it the intention of the IBOM to interpret ARC 8579B in a manner to mean that chronic interventional pain management services are ‘solely and exclusively the practice of medicine’ and to prohibit other practitioners, including CRNA’s, from providing such services?” ARC 8579B sets forth the IBM’s proposed rule defining ICPM, identifying functions associated with ICPM, and declaring that ICPM is the practice of medicine.

4. IMS urges the IBM to refuse to issue a declaratory order on the question presented based on IBM rule 653-1.9(9)(a)(4). Rulemaking on the subject matter of the petition is underway. To date, the IBM rule remains a noticed rule. As such, the question posed by Petitioner is premature as the question may be definitively resolved during the rulemaking process. Further, a ruling as requested by Petitioner could lead to confusion and, potentially, actions contrary to the intent of the rule, thereby hindering the application of the IBM’s proposed rule upon final adoption. 653-1.9(3)(c)(2).

5. IMS further urges the IBM to refuse to issue a declaratory order on the question presented based on IBM rule 653-1.9(9)(a)(5). Petitioner’s question is more appropriately addressed in a

different type of proceeding or by another body of jurisdiction. The IBM is fully authorized to declare that certain defined medical procedures are the practice of medicine requiring a duly-issued medical license. Parties who believe they also should be able to engage in a medical specialty practice without a medical license and absent mutually acceptable and nationally recognized standards of practice, education, and training to do so need to petition elsewhere. 653-1.9(3)(c)(2).

6. IMS further urges the IBM to refuse to issue a declaratory order on the question presented based on IBM rule 653-1.9(9)(a)(6). Petitioner's question is overly broad and inappropriate for a declaratory order. By defining ICPM and declaring ICPM as the practice of medicine, the IBM has, first and foremost, advised its physician licensees regarding ICPM, a highly skilled arena of medical specialty delivery. Too, this proposed rule, if adopted, fairly puts persons who are not licensed physicians on notice that engaging in ICPM without a medical license subjects them to potential legal scrutiny. The Petitioner asks the IBM to go further by generally declaring that this medical subspecialty is not exclusive to the practice of medicine, thereby generally open for practice by non-physicians. This the IBM cannot not do. A petition for a declaratory ruling must be supported by specified facts and circumstances. Iowa Code section 17A.9(1) and IBM rule 653.1.9(1). Here Petitioner fails to set out particular facts and circumstances on which a declaratory order might issue. Further, absent specified facts and circumstances, clarity of response is not possible and misunderstandings based on broad presumptions are likely to result. 653-1.9(3)(c)(2).

7. Petitioner's question, unsupported by a specific set of facts upon which to respond, cannot be answered with a simple "yes" or "no." To the extent that the IBM proceeds to answer Petitioner's question, the IBM's answer must be consistent with case law direction of the Iowa Supreme Court which holds that the practice of medicine encompasses the entire field of medicine while other health care professions are limited by the authority granted to them by the Iowa General Assembly. *State ex. rel. Iowa Dep't of Public Health v. Van Wyk*, 320 NW 2d 599 (Iowa 1982). Persons engaging in the practice of medicine, including ICPM, carry the burden of showing that they are authorized to do so. Facts and circumstances in each given situation are important to this legal analysis. 653-1.9(3)(c)(2).

8. Petitioner does **not** ask the question that has driven this debate for the past three years, namely: Are advanced registered nurse practitioners (ARNPs) permitted by law to hold themselves out to the public as capable of independently engaging in ICPM as defined by the IBM? The answer to that question at this point in time is unequivocally "no." All physicians engage in some form of pain management for patients consistent with their training and their fields of practice. Similarly, other licensed professionals, including ARNPs and certified registered nurse anesthetists (CRNAs), engage in some form of pain management for their patients consistent with their scopes of practice and training. Those acts do **not** rise to the level of ICPM practice and neither those physicians nor those other licensees can hold themselves out to the public as ICPM specialists capable of providing ICPM services. The practice of ICPM is a focused and comprehensive medical subspecialty. Efforts by the IBM to elicit specific information about nationally recognized education, training, certification, and practice standards

for ARNPs and/or CRNAs in the specialty field of ICPM have been met with silence. No such record has been made by Petitioners. 653-1.9(3)(c)(2).

9. A “no” answer to Petitioner’s question is not compelled by Petitioner’s allegations in Paragraph 10. Despite good faith efforts of the IBM to elicit field information from the nursing profession, *no* reliable evidence has been presented to establish that ARNPs have practiced ICPM for the past 15 years independently and without physician supervision. Survey information, compiled and relied upon by the Iowa Board of Nursing (BON) and now in the possession of the IBM as a result of the IBM’s freedom of information request, shows that in the past five (5) years, very few ARNPs (43 of 1459 surveyed ARNPs) have utilized certain fluoroscopic procedures for pain and that in nearly all cases those ARNPs have been certified registered nurse anesthetists (CRNAs). The circumstances surrounding such use (i.e., physician delegation, supervision and/or direction) are not known. More importantly, the fact that a very few persons claim or admit that they engage in the defined practice of medicine without having obtained a medical license does **not** compel a legal conclusion that now non-physician licensees may practice medicine without a medical license. Quite the contrary. The fact that non-physician licensees elect on their own to advance into the field of medical practice absent legal authority and clearly articulated and recognized national standards of practice, education and training to do so is anathema to the public health and safety interests underlying Iowa’s licensure laws. 653-1.9(3)(c)(2).

10. A “no” answer to Petitioner’s question is not compelled by Petitioners’ allegations in Paragraph 11. The authority of the BON is not impaired. At all times during the course this

protracted debate, the BON has never hesitated to express its views and to further its positions. The IBM should not be chilled or swayed away from exercising its lawful authority to address important issues of medical practice and public health and safety by claims such as these. In any event, the IBM states in ARC 8579B that the purpose of its proposed rule is to assist physicians who consider interventional techniques to treat patients with chronic pain. 653-1.9(3)(c)(2).

11. A “no” answer to Petitioner’s question is not compelled by Petitioner’s allegations in Paragraph 12. Defining ICPM and declaring ICPM as the practice of medicine in no way runs afoul of constitutional principles of due process. Iowa case law is clear on this point. *State v. Van Wyk*, 320 NW 2d at 605-06. Licensed nurses are not authorized by the constitution to practice medicine. In any event, constitutional issues are matters of law to be addressed by the courts. 653-1.9(3)(c)(2).

12. A “no” answer to Petitioner’s question is not compelled by Petitioner’s allegations in Paragraph 13. Medicare’s conditions of participation set forth requirements that hospitals must meet in order to participate in the Medicare program. Governor Vilsack’s “opt-out” letter (attached) was narrowly focused on an exemption from Medicare’s supervision requirements to allow Iowa CRNAs to provide anesthesia services within the scope of CRNA *nursing* practice in a Medicare participating hospital. The opt-out letter does not grant permission to CRNAs or ARNPs to practice medicine without a license and, as such, is irrelevant to the issue underlying this Petition. 653-1.9(3)(c)(2).

13. A “no” answer to Petitioner’s question is not compelled by Petitioner’s allegations in Paragraph 14. The Iowa General Assembly took *no* action on ICPM legislation in the 2010 session. Subcommittee hearings do not constitute action of the General Assembly and no legal assumptions or presumptions can be made from subcommittee action or inaction. More importantly and to the point, the General Assembly has not acted to alter Iowa case law. *State v. Van Wyk*, 320 NW 2d at 604. The Iowa General Assembly is presumed to know decisions of the Iowa Supreme Court and if unhappy with a decision, the General Assembly may act to change it. The legal standard articulated by the Iowa Supreme Court in *Van Wyk* remains intact. 653-1.9(3)(c)(2).

14. IMS seeks Intervention as a party of interest and expertise that has been actively engaged in all stages of the issues underlying Petitioner’s request. IMS’s core purpose is *to assure the highest quality health care in Iowa through our role as physician and patient advocate*. Patient health and safety is placed at risk when non-physician practitioners engage in the practice of medicine absent legal authority and clearly articulated and accepted standards of practice, education and training. ICPM as defined by the IBM is a field of advanced medical specialty practice recognized as such by the Centers for Medicare and Medicaid Services, the American College of Graduate Medical Education, and the American Medical Association. Most anesthesiologists do not and will not engage in ICPM because of its complexities, its continued findings and consequent changes in medical protocol, its demand for expertise, and its risks to patient health and safety. The fact that certain non-physician licensees now claim that they can, do and will engage in any form of ICPM upon their own election and absent articulated and

accepted national standards of practice, education and training is a threat to patient health and safety and a marked departure from the quality of care that all Iowans deserve. 653-1.9(3)(c)(3).

15. IMS remains a party of interest to the IBM's rulemaking re: ICPM and, further, remains a party of interest on the Iowa Department of Public Health's rulemaking re: ARNP supervision of fluoroscopy. IMS currently is involved in no other proceeding involving the question presented in this Petition. 653-1.9(3)(c)(4).

16. In addition to persons listed by Petitioner in Paragraph 19 of the Original Petition, IMS believes the following parties are interested in this matter: Iowa Osteopathic Medical Association (IOMA), Iowa Academy of Family Physicians (IAFP), and Iowa Radiological Society (IRS). The IBM sent notice of the Petition to IOMA and IAFP in its e-mail notice of April 21, 2010. The address for IRS is as follows: D. Lee Bennett, MD, President, Iowa Radiological Society, University of Iowa Hospitals and Clinics, Department of Radiology, 200 Hawkins Drive, Iowa City, IA 52242, lee-bennett@uiowa.edu. 653-1.9(3)(c)(5).

17. IMS respects the decision making authority of the IBM. In the event of an answer to Petitioner's question that IMS believes is legally incorrect or inconsistent with the public's health and safety, IMS cannot agree to be bound by it. Iowa Code section 17A.9(2). IMS reserves its right to fully pursue administrative and judicial remedies as may be appropriate. Petitioner's question is general in nature and simply not appropriate for or capable of answer through a declaratory order. 653-1.9(3)(c)(6).

Respectfully submitted,



4/27/10

Jeanine Freeman, JD

DATE

Senior Vice President of Legal Affairs
Iowa Medical Society
1001 Grand Avenue
West Des Moines, IA 50265-3502
Telephone: (515) 223-1401
Facsimile: (515) 223-0590
Email: jfreeman@iowamedical.org



4/27/10

Heidi Goodman, BSN, JD

DATE

Policy Counsel
Iowa Medical Society
1001 Grand Avenue
West Des Moines, IA 50265-3502
Telephone: (515) 223-1401
Facsimile: (515) 223-0590
Email: hgoodman@iowamedical.org

Please direct all correspondence as noted above.

Original Filed Copies to:

James W. Carney
Attorney for Petitioner
Carney & Appleby P.L.C.
303 Locust St. Suite 400
Des Moines, IA 50309-1770

D. Lee Bennett, MD, President
Iowa Radiological Society
UIHC Dept. of Radiology
200 Hawkins Drive
Iowa City, IA 52242

Joseph Cassady, Jr., MD, President
Iowa Society of Anesthesiologists
525 SW 5th St. Suite A
Des Moines, IA 50309

Nicholas J. Mauro, JD
Crawford, Quilty & Mauro Law Firm
666 Grand Ave. Suite 1701
Des Moines, IA 50309

Kevin Kruse, CAE
Iowa Society of Anesthesiologists
525 SW 5th St. Suite A
Des Moines, IA 50309

Leah McWilliams, Executive Director
Iowa Osteopathic Medical Association
950 12th Street
Des Moines, IA 50309-1001

Jen Harbison, Executive Director
Iowa Academy of Family Physicians
100 East Grand Avenue
Des Moines, IA 50309

Laura Delaney, President
Iowa Physician Assistant Society
525 SW 5th St., Suite A
Des Moines, IA 50309

Kent Nebel, Director of Legal Affairs
Iowa Board of Medicine
400 SW 8th St. Suite C
Des Moines, IA 50309

Laura Malone, BSN
Director of Nursing & Clinical Services
Iowa Hospital Association
100 East Grand Avenue
Des Moines, IA 50309

Lorinda Inman, RN, MSN
Executive Director
Iowa Board of Nursing
400 SW 8th St. Suite B
Des Moines, IA 50309

Linda Goeldner, Executive Director
Iowa Nurses Association
1501 Westown Pkwy. Suite 471
West Des Moines, IA 50266

Joe Kelly
Iowa Association of Nurse Practitioners
1400 Dean Avenue
Des Moines, IA 50316

Mark Odden, President
Iowa Association of Nurse Anesthetists
17893 224th Street
Manchester, IA 52057

Kevin Kruse, CAE
Iowa Podiatric Medical Society
525 SW 5th St. Suite A
Des Moines, IA 50309

Larry Carl, Executive Director
Iowa Dental Association
5530 West Parkway Suite 100
Johnston, IA 50131

Tom Newton, Director
Iowa Department of Public Health
321 E. 12th Street
Des Moines, IA 50319

Joe Royce, Senior Legal Counsel
Iowa Administrative Rules Committee
Statehouse/Iowa General Assembly
Des Moines, IA 50319

James C. Larew, General Counsel
Office of Governor Chet Culver
& Lt. Governor Patty Judge
1007 E. Grand Avenue
Des Moines, IA 50319



THOMAS J. VILSACK
GOVERNOR

OFFICE OF THE GOVERNOR

SALLY J. PEDERSON
LT. GOVERNOR

December 12, 2001

Via Fax #202-690-6833

The Honorable Thomas A. Scully, Administrator
Centers for Medicare and Medicaid Services
314G Hubert Humphrey Building
200 Independence Ave., S.W.
Washington, DC 20201

Dear Mr. Scully:

Pursuant to the recently filed rule regarding anesthesia services condition of participation for hospitals and as published in the Federal Register on November 13, I hereby notify you of the state of Iowa's election for state exemption from the requirement for physician supervision of CRNAs. Please consider this official notice of Iowa's election for state exemption.

Pursuant to the prerequisites of the rule, please be advised that I have consulted with the State Board of Medicine and the State Board of Nursing to ensure that the quality of care provided by nurse anesthetists in the state of Iowa is of the highest degree and that the opt-out ensures access to anesthesia care in Iowa's 118 hospitals that have surgical suites. In the state of Iowa, CRNAs are the exclusive provider of anesthesia services in 91 out of 118 Iowa hospitals.

In order to assure quality, Iowa will apply for an unsolicited proposal grant to scientifically measure the difference, severity and age corrected, for peri and post anesthetic outcomes, morbidity, mortality, and rescue rates, between the two groups providing unsupervised anesthesia in the state of Iowa. This comparison will be between board certified MD/DO anesthesiologists and CRNAs. Should there be a significant statistical difference, this waiver request would be reviewed for further action, if indicated.

By this letter we are seeking your support for such funding, and will, at your indication, file a formal request from the Iowa Department of Public Health for such funding.

Further, pursuant to the rules, you are advised that under Iowa law, CRNAs are independent practitioners who have prescriptive authority. Iowa was among the first states to grant full prescriptive authority during the peri-operative period to CRNAs. Should you need any additional information, please let me know immediately. As Governor of Iowa I have concluded it is in the best interest of the state of Iowa to opt-out of the current Physician Supervision Requirement, that the opt-out is consistent with state law and is requested on behalf of the citizens of the state of Iowa, hospitals, ambulatory surgical centers and critical access hospitals.

Sincerely,

Thomas J. Vilsack
Governor

IN RE: PETITION BY IOWA ASSOCIATION OF NURSE ANESTHETISTS FOR A DECLARATORY ORDER ON PROPOSED RULE 8579B	FILE NO. 01-10-12 IOWA SOCIETY OF ANESTHESIOLOGISTS' PETITION FOR INTERVENTION
---	---

COMES NOW the Iowa Society of Anesthesiologists pursuant to IAC 653-1.9(3), and hereby petitions the Iowa Board of Medicine (“IBM”) to intervene in the above-stated matter stating to the Board as follows:

1. The Iowa Society of Anesthesiologists (“ISA”) acts as a statewide association of anesthesiologist members licensed under the jurisdiction of the Iowa Board of Medicine (“Board”). ISA’s purpose includes elevating the standards of practice in the areas of anesthesiology and chronic interventional pain management, and to protect the unsuspecting public from unqualified providers.
2. On or about April 7, 2010, the Iowa Association of Nurse Anesthetists (IANA) filed a Petition for Declaratory Order with the Board regarding ARC 8579B. The IANA requests an Order stating the Board does not intend to “interpret ARC 8579B in a manner to mean that chronic interventional pain management services are ‘solely and exclusively the practice of medicine’ and to prohibit other practitioners, including CRNAs, from providing such services”.
3. Pursuant to IAC 653-1.9(3), ISA states the allegations of fact and law contained within the IANA Petition compel it to file this Petition for Intervention. ISA’s predominant interest in the outcome of this Petition centers on elevating the standards of

practice in the area of chronic interventional pain management and protecting the unsuspecting public from unqualified providers of this specialized area of medicine. It seeks intervention as a party in interest with expertise and specialized knowledge of the issue, including its involvement in all stages of the discussion relevant to IANA's request.

4. ISA maintains standing and qualification to intervene in this matter pursuant to IAC 653-1.9. The Petition for Declaratory Order at issue deals with the Board's noticed rule regarding interventional chronic pain management (ICPM). ISA participated in all stages of information gathering and discussion of this matter before the Board, as well as before the Iowa Board of Nursing, the Iowa Department of Public Health, the Iowa Administrative Rules Review Committee, and the Iowa General Assembly. In addition, ISA's members practice and teach the medical subspecialty of chronic interventional pain management.

5. ISA is not currently a party to any proceeding involving the questions at issue.

6. ISA urges the Board to refuse to issue a declaratory order on the question presented in the IANA Petition pursuant to IAC 653-1.9(9). The rule at issue and the question presented within the IANA Petition on its face deal with a matter currently in the rule making process which may definitively get resolved through this process. The IANA Petition is not yet ripe and, therefore, not appropriate for declaratory order as per the Board's rules.

7. In addition, the IANA Petition does not contain facts sufficient to demonstrate it will be aggrieved or adversely affected by the failure of the Board to issue an order pursuant to IAC 653-1.9(9)(a)(2). Likewise, the facts and questions presented within the Petition

are insufficient or otherwise inappropriate as a basis upon which to issue an order pursuant to IAC 653-1.9(9)(a)(6). Iowa Code section 152.1 and Iowa Administrative Code sections 655-7.1 and 655-7.2 set forth the scope of practice for CRNAs, which does not include the practice of chronic interventional pain management. Therefore, the rule at issue within the IANA Petition does not adversely affect a CRNAs' authority to practice in this area. In addition, the allegation that CRNAs have been engaged in this practice for any amount of time contrary to their scope as set forth in the Iowa Code does not provide an appropriate basis for the relief the IANA seeks in this Petition.

8. The questions presented within the IANA Petition may appropriately get resolved in a different type of proceeding or through another body with jurisdiction over the matter, thereby allowing the Board to refuse to issue the requested order pursuant to IAC 653-1.9(9)(a)(5). The Board of Medicine maintains complete authority to declare that certain defined medical procedures fall within the practice of medicine requiring a duly-issued medical license. CRNAs seeking to practice in this medical subspecialty beyond the scope of their practice as set forth within the Iowa Code and absent mutually acceptable and nationally recognized standards of practice, education and training must petition for such authority either to the legislature, the district court or some other venue.

9. To the extent the Board deems the IANA Petition ripe for a ruling, ISA urges the Board to issue an Order stating that chronic interventional pain management is the practice of medicine, thereby prohibiting other practitioners from engaging in this practice absent some other authority set forth within the Iowa Code.

10. The allegations contained in paragraph 8 of the IANA Petition incorrectly state the law with respect to the scope of CRNA practice as per Iowa Code section 152.1 and the Iowa Administrative Code.

11. The allegations contained in paragraph 10 of the IANA Petition simply assert conclusory statements not supported by any data, certification, licensure or oversight with respect to this area of medicine.

12. The allegations contained within paragraph 11 of the IANA Petition again incorrectly state the Iowa law with respect to the scope of nursing practice, which is set forth within the Iowa Code and not unilaterally by the Board of Nursing.

13. The allegations contained in paragraph 13 of the IANA Petition simply have nothing to do with a CRNA's independent practice of chronic interventional pain medicine.

Govern Vilsack's "opt-out" letter narrowly focuses on an exemption from Medicare's supervision requirements to allow CRNAs to provide anesthesia services within the scope of CRNA nursing practice. The opt-out letter does not grant permission to allow CRNAs to practice medicine without a license, including chronic interventional pain medicine.

14. The allegations contained with paragraph 14 of the IANA Petition are misguided at best and intentionally misleading at worst. The Iowa General Assembly took no action regarding chronic interventional pain management during the 2010 session. Rather, a subcommittee in each chamber (consisting of 3 people per each subcommittee simply declined to present the issue to the general assembly. This paragraph further ignores the Iowa law currently in force which does not grant authority for CRNAs to practice chronic interventional pain medicine.

15. As per the nurses accepted as “experts” in the area of chronic interventional pain medicine in the case of *Spine Diagnostics Center of Baton Rouge, Inc., v. Louisiana State Board of Nursing*, 4 So.3d 854 (La. App. 2008)(a copy of which is attached and made part of this Petition):

- a. No national guidelines or regulations applicable to institutions to assess competency, ability, credentials or skill sets of CRNAs with respect to interventional pain management currently exist.
- b. A distinct difference exists between acute pain treatment in a hospital or surgical setting and chronic interventional pain management.
- c. At the time a CRNA acquires his or her certificate, absent anything else, this person is not competent to perform interventional pain management procedures.
- d. No post-certification competency benchmarks exist for CRNAs related to interventional pain management procedures.
- e. To ISA’s knowledge the Iowa Board of Nursing does not maintain any system designed to verify or in any way assess whether a CRNA possesses the documented education, training, experience, knowledge, skills and abilities to safely perform interventional pain management procedures.
- f. As per the American Association of Nurse Anesthetists (the parent organization of the IANA), there are no guidelines for assessing the competency, skill set, abilities or training needed for CRNAs to be performing interventional pain management procedures.

g. Currently there is not licensing process or any type of regulatory process in place that would tell a member of the public whether a particular CRNA has met a threshold standard of competency.

16. Please direct all further communication on this matter to Nicholas J. Mauro at the address listed below

WHEREFORE, the ISA makes application to intervene in the IANA's Petition for Declaratory Order and requests that the Board to refuse issuing such an order pursuant to its authority under IAC 653-1.9(9).

Respectfully Submitted by:

CRAWFORD QUILTY & MAURO LAW FIRM

Nick Mauro 4/27/10

Nick Mauro AT0005007

1701 Ruan Center, 666 Grand Avenue

Des Moines, IA 50309

(515) 245-5420

(515) 245-5421 (FAX)

mauro@crowfordlawfirm.com

ATTORNEYS FOR ISA

Original filed.

Copies to:

Joe Royce, Senior Legal Counsel
Iowa General Assembly
Statehouse
Des Moines, IA 50319

Kent Nebel, Director of Legal Affairs
Iowa Board of Medicine
400 S.W. 8th St., Ste. C
Des Moines, Iowa 50309

Lorinda Inman, Executive Director
Iowa Board of Nursing

CERTIFICATE OF SERVICE			
The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the pleadings on			
<i>April 27</i> , 200 <i>9</i> 0			
By:	<input checked="" type="checkbox"/> U.S. Mail	<input type="checkbox"/> Fax	
	<input type="checkbox"/> Hand Delivered	<input type="checkbox"/> Overnight Courier	
	<input type="checkbox"/> Federal Express	<input type="checkbox"/> Other:	
Signature	<i>Nick Mauro</i>		

RiverPoint Business Park
400 S.W. 8th, Ste. B
Des Moines, Iowa 50309

Tom Newton, Director
Iowa Department of Public Health
Iowa Board of Health
321 E. 12th Street
Des Moines, Iowa 50319

Mark Odden, President
Iowa Association of Nurse Anesesthetists
17893 – 224th St.
Manchester, IA 52057

Jeanine Freeman
Heidi Goodman
Iowa Medical Society
1001 Grand Avenue
West Des Moines, Iowa 50265-3502

Joe Kelly
Iowa Association of Nurse Practitioners
1400 Dean Avenue
Des Moines, Iowa 50316

Iowa Podiatric Medical Society
525 S.W. 5th, Ste. A
Des Moines, Iowa 50309

Iowa Dental Association
5530 West Parkway, Ste. 100
Johnston, Iowa 50131

Julie Pottorf
Deputy Attorney General
Iowa Department of Justice
Hoover State Office Bldg.
1305 East Walnut Street
Des Moines, IA 50319

H

Court of Appeal of Louisiana,
 First Circuit.
**SPINE DIAGNOSTICS CENTER OF BATON
 ROUGE, INC.**
 v.
LOUISIANA STATE BOARD OF NURSING
 through **LOUISIANA DEPARTMENT OF
 HEALTH AND HOSPITALS**, and August J. Rantz,
 III.
No. 2008 CA 0813.

Dec. 23, 2008.

Background: Medical practice filed petition for injunctive relief and declaratory judgment after Louisiana State Board of Nursing (LSBN) adopted practice committee recommendation that it was within the scope of practice for a certified registered nurse anesthetist (CRNA) to perform, under the direction and supervision of a physician, pain management procedures involving the injection of local anesthetics, steroids and analgesics. The 19th Judicial District Court, East Baton Rouge Parish, No. 536,009, Janice Clark, J., denied the request for injunctive relief, medical practice filed application for writ review, and the Court of Appeal reversed and issued a preliminary injunction. Following a trial, the District Court entered judgment for medical practice and awarded costs and fees, and LSBN and nurse anesthetists association appealed.

Holdings: The Court of Appeal, Pettigrew, J., held that:

- (1) pursuant to the law of the case doctrine, Court of Appeal would decline to consider whether LSBN advisory opinion was a declaratory order rather than a rule;
- (2) as a matter of first impression, evidence supported finding that LSBN statement expanded the scope of practice for CRNAs into areas where they had not traditionally practiced and finding that the practice of interventional pain management is not within the scope of practice of a CRNA;
- (3) medical practice was a "small business" and thus could recover litigation expenses; and
- (4) medical practice was limited by statute to recovery of \$7500 in litigation expenses.

Affirmed in part; reversed in part.

West Headnotes

[1] Courts 106 ↪ 99(6)

106 Courts
106II Establishment, Organization, and Procedure
106II(G) Rules of Decision
106k99 Previous Decisions in Same Case
 as Law of the Case

106k99(6) k. Other Particular Matters, Rulings Relating To. Most Cited Cases
 Pursuant to the law of the case doctrine, Court of Appeal would decline to consider whether advisory opinion issued by Louisiana State Board of Nursing (LSBN), in response to certified registered nurse anesthetist's (CRNA's) petition asking whether it was within a CRNA's scope of practice to perform pain management procedures involving the injection of local anesthetics, steroids, and analgesics, was a "declaratory order" rather than a "rule" within the meaning of the Administrative Procedure Act, as arguments and issues on appeal from final judgment were indistinguishable from those previously presented to the Court of Appeal on application for writ relief and preliminary injunction; Court of Appeal had previously considered the authority to issue declaratory orders and advisory opinions, thoroughly reviewed the relevant arguments, and had concluded that the LSBN's statement, insofar as it related to chronic or interventional pain management, was a rule that required compliance with the Act's procedural requirements. LSA-R.S. 37:930(A), 49:962.

[2] Appeal and Error 30 ↪ 1097(1)

30 Appeal and Error
30XVI Review
30XVI(M) Subsequent Appeals
30k1097 Former Decision as Law of the Case in General

30k1097(1) k. In General. Most Cited Cases
 Pursuant to the law of the case doctrine, an appellate court generally will not, as part of a subsequent ap-

peal, reconsider its earlier ruling in the same case.

[3] Health 198H ↪192

198H Health

198HI Regulation in General

198HI(B) Professionals

198Hk191 Regulation of Professional Conduct; Boards and Officers

198Hk192 k. In General. Most Cited

Cases

Testimony from various medical experts was sufficient evidence to support finding that Louisiana State Board of Nursing (LSBN) statement that it was within the scope of practice for a certified registered nurse anesthetist (CRNA) to perform, under the direction and supervision of a physician, pain management procedures involving the injection of local anesthetics expanded the scope of practice for CRNAs into areas where they had not traditionally practiced, and finding that the practice of interventional pain management is not within the scope of practice of a CRNA, but rather is solely the practice of medicine, such that medical practice was entitled to permanent and mandatory injunctive relief preventing CRNAs from performing such pain management procedures. LSA-R.S. 37:930(A, G).

[4] Injunction 212 ↪128(1)

212 Injunction

212III Actions for Injunctions

212k124 Evidence

212k128 Weight and Sufficiency

212k128(1) k. In General. Most Cited

Cases

Injunction 212 ↪130

212 Injunction

212III Actions for Injunctions

212k130 k. Trial or Hearing. Most Cited

Cases

The issuance of a permanent injunction takes place only after a trial on the merits, in which the burden of proof must be founded on a preponderance of the evidence.

[5] Injunction 212 ↪5

212 Injunction

212I Nature and Grounds in General

212I(A) Nature and Form of Remedy

212k5 k. Mandatory Injunction. Most Cited

Cases

Injunction 212 ↪130

212 Injunction

212III Actions for Injunctions

212k130 k. Trial or Hearing. Most Cited

Cases

A mandatory injunction, so named because it commands the doing of some action, cannot be issued without a hearing on the merits.

[6] Injunction 212 ↪147

212 Injunction

212IV Preliminary and Interlocutory Injunctions

212IV(A) Grounds and Proceedings to Procure

212IV(A)4 Proceedings

212k147 k. Evidence and Affidavits.

Most Cited Cases

A mandatory preliminary injunction has the same basic effect as a permanent injunction, and therefore may not be issued on merely a prima facie showing that the party seeking the injunction can prove the necessary elements; instead, the party must show by a preponderance of the evidence at an evidentiary hearing that he is entitled to the preliminary injunction.

[7] Health 198H ↪192

198H Health

198HI Regulation in General

198HI(B) Professionals

198Hk191 Regulation of Professional Conduct; Boards and Officers

198Hk192 k. In General. Most Cited

Cases

Uncontradicted testimony indicated that medical practice had annual receipts of less than \$9 million per year such that practice was a "small business" and could recover up to \$7,500 in total litigation expenses in connection with petition for injunctive relief after Louisiana State Board of Nursing (LSBN) issued statement that it was within the scope of practice for a certified registered nurse anesthetist

(CRNA) to perform pain management procedures involving the injection of local anesthetics, steroids and analgesics. LSA-R.S. 49:965.1(A, D); LSA-C.C.P. art. 1920; 13 C.F.R. § 121.201.

[8] Statutes 361 ↪ 241(1)

361 Statutes

361VI Construction and Operation

361VI(B) Particular Classes of Statutes

361k241 Penal Statutes

361k241(1) k. In General. Most Cited

Cases

Penal statutes must be strictly construed and their provisions shall be given a genuine construction according to the fair import of their words, taken in their usual sense, in connection with the context and with reference to the purpose of the provision.

[9] Health 198H ↪ 192

198H Health

198HI Regulation in General

198HI(B) Professionals

198Hk191 Regulation of Professional Conduct; Boards and Officers

198Hk192 k. In General. Most Cited

Cases

Medical practice which brought petition for injunctive relief after Louisiana State Board of Nursing (LSBN) issued statement that it was within the scope of practice for a certified registered nurse anesthetist (CRNA) to perform pain management procedures involving the injection of local anesthetics, steroids and analgesics was limited under rule to recovery of \$7,500 in litigation expenses. LSA-R.S. 49:965.1(A, D); LSA-C.C.P. art. 1920; 13 C.F.R. § 121.201.

*856 John P. Wolfe, III, Chad A. Sullivan, Tiffany N. Thornton, Michael M. Thompson, Rebecca H. Klar, Baton Rouge, LA, for Plaintiffs-Appellees, Spine Diagnostics Center of Baton Rouge, Inc. and The American Society of International Pain Physicians.

Nicholas Gachassin, III, Lafayette, LA, for Defendant-Appellee, August J. Rantz, III.

Christopher L. Whittington, Baton Rouge, LA, for Intervenor-Appellee, Louisiana Society of Anesthesiologists.

E. Wade Shows, Jeffrey K. Cody, Baton Rouge, LA, for Defendant-2nd Appellant, Louisiana State Board of Nursing.

Sheri M. Morris, Larry M. Roedel, Edward J. Walters, Jr., Michael A. Patterson, Baton Rouge, LA, for Intervenor-1st Appellant, Louisiana Association of Nurse Anesthetists.

Dominic J. Gianna, New Orleans, LA, for American Association of Nurse Anesthetists, Amicus curiae.

Stephen M. Pizzo, Guice A. Giambone, III, Kelly A. Dugas, Metairie, LA, for Louisiana Association of Nurse Practitioners, Amicus Curiae.

Rodney C. Braxton, Baton Rouge, LA, Alice L. Bodley Silver Spring, MD, for American Nurses Association, Louisiana State Nurses Association, and Louisiana Alliance of Nursing Organizations, Amici Curiae.

Clark R. Cosse', III Baton Rouge, LA, for Louisiana Hospital Association, Amicus Curiae.

Thomas G. Abram Chicago, IL, for National Council of State Boards of Nursing, Inc., Amicus Curiae.

Before PETTIGREW, McDONALD, and HUGHES, JJ.

*857 PETTIGREW, J.

**3 In the instant case, appellants challenge the trial court's judgment granting injunctive relief in favor of plaintiffs. Following this court's review of the record and relevant law, we affirm in part and reverse in part.

FACTS AND PROCEDURAL HISTORY

On March 24, 2005, August J. Rantz, III, a certified registered nurse anesthetist ("CRNA"), submitted a petition for an advisory opinion to the Louisiana State Board of Nursing ("the LSBN"), which requested a response to the following query:

Whether it is within the scope of practice for a CRNA to perform procedures involving the injec-

tion of local anesthetics, steroids and analgesics for pain management purposes, including, but not limited to, peripheral nerve blocks, epidural injections (62310), and spinal facet joint injections (64470 & 64472) when the CRNA can document education, training and experience in performing such procedures.

After considering Rantz's petition, the LSBN's practice committee submitted a recommendation to the LSBN that it was within the scope of practice for CRNAs to perform such procedures under the direction and supervision of a physician.

Prior to the LSBN's consideration of the practice committee's recommendation, Spine Diagnostics Center of Baton Rouge, Inc. ("Spine Diagnostics") filed a "Petition For Injunctive Relief And For Declaratory Judgment," seeking to enjoin the LSBN from adopting the committee's recommendation, to prevent Rantz from practicing interventional pain management, and to prevent Rantz from performing anesthesia-related management unless by physician order and under the direct and immediate supervision of a physician. Additionally, Spine Diagnostics prayed that the trial court issue a declaratory judgment finding that the practice of "pain management" constitutes the "practice of medicine."^{FN1} At its December 7, 2005 board meeting, the LSBN amended the recommendation of the practice committee, and adopted the following statement:

^{FN1}. The Louisiana Society of Anesthesiologists has intervened in the litigation praying for the same relief sought by Spine Diagnostics.

That it is within the scope of practice for the CRNA to perform procedures under the direction and supervision of the physician involving the injection **4 of local anesthetics, steroids and analgesics for pain management purposes, peripheral nerve blocks, epidural injections, and spinal facet joint injections when the CRNA can document education, training and experience in performing such procedures and has the knowledge, skills, and abilities to safely perform the procedures based on an order from the physician.

The statement was subsequently published on the LSBN's web site as well as in its quarterly publication, *The Examiner*.

Following the LSBN's adoption of the above statement, **Spine Diagnostics** filed a first supplemental and amending petition, contending the LSBN was attempting to promulgate a "rule" within the meaning of the Louisiana Administrative Procedure Act ("LAPA") that "has not been properly adopted and promulgated and should be declared invalid."^{FN2} Thereafter, at **Spine*858 Diagnostics'** request, the Louisiana State Board of Medical Examiners ("the LSBME") issued an Advisory Opinion regarding interventional pain management by CRNAs. In its opinion, the LSBME indicated that CRNAs could provide anesthetics for acute pain associated with surgery, but opined that the procedures at issue for interventional pain management purposes constituted the practice of medicine that could only be performed by a physician.^{FN3}

^{FN2}. We note it was not necessary that Spine Diagnostics exhaust all administrative remedies prior to seeking injunctive relief in connection with its action for declaratory judgment. See La. R.S. 49:963(E).

^{FN3}. In the opinion, the LSBME noted, in pertinent part, as follows:

... the injection of local anesthetics, steroids and analgesics, peripheral nerve blocks, epidural injections and spinal facet joint injections, when used for interventional pain management of patients suffering from chronic pain, constitute the practice of medicine, are not delegable by a physician to a non-physician by physician prescription, direction or supervision, and may only be performed in this state by a physician licensed to practice medicine in Louisiana.

After a two-day hearing on Spine Diagnostics' request for injunctive relief, the trial court took the matter under advisement. The court subsequently rendered judgment denying the request for injunctive relief, but noted that the request for declaratory judgment would proceed via ordinaria in accordance with the case management order. Thereafter, Spine Diagnostics filed a writ application with this court seeking review of that judgment. We granted certiorari for the limited purpose of reviewing the judg-

ment denying Spine Diagnostics' request for injunctive relief, insofar **5 as that request alleged the LSBN had promulgated a "rule" within the intendment of the LAPA without following the procedural requirements therein.

In an unpublished decision rendered on December 28, 2006, this court reversed the trial court's judgment and issued a preliminary injunction in favor of **Spine Diagnostics**.
<http://www.westlaw.com/Find/Default.wl?rs=dfa1.0&vr=2.0&DB=4361&FindType=Y&SerialNum=2011550836>*Spine Diagnostics Center of Baton Rouge, Inc. v. Louisiana State Bd. of Nursing ex rel. Louisiana Dept. of Health and Hospitals*, 2006-0554 (La.App. 1 Cir. 12/28/06) (unpublished opinion), *writs denied*, 2007-0183, 2007-0217 (La.3/16/07), 952 So.2d 702, 703 ("Spine Diagnostics I"). In so doing, we noted, in pertinent part, as follows:

Thus, **Spine Diagnostics** has made a *prima facie* showing that the LSBN statement substantively expands the scope of practice for CRNAs into an area where they have not traditionally practiced, i.e., chronic or interventional pain management. Such a substantive expansion of the scope of practice clearly constitutes a rule within the meaning of La. R.S. 49:951(6). Further, although the LSBN contends the statement is limited in scope, the actual language of the statement approved by the LSBN does not limit its application to Rantz alone, and is capable of being applied to every CRNA who has the requisite knowledge, skills, and abilities to perform the procedures at issue. CRNAs are able to freely access the statement insofar as it was published in *The Examiner* and on the LSBN's website.

Given these circumstances, we find Spine Diagnostics has made a *prima facie* showing that the statement adopted by the LSBN insofar as it relates to chronic or interventional pain management is a rule within the meaning of the LAPA. Since it is undisputed that the requirements of the LAPA were not met, Spine Diagnostics is entitled to a preliminary injunction enjoining enforcement of the statement adopted by the LSBN at its December 7, 2005, board meeting, and enjoining Rantz from practicing chronic or interventional *859 pain management procedures pursuant to the authority of that

statement.

On June 29, 2007, Spine Diagnostics filed a second supplemental and amending petition, adding Raymond R. Smith, Jr., a CRNA who had admitted to performing interventional pain management procedures in violation of the Medical Practice Act, the Nurse Practice Act, and other general and equitable laws.^{FN4} Spine Diagnostics also alleged that the LSBN attempted to circumvent this court's December 28, 2006 ruling by **6 urging House Bill 684 and Senate Bill 322.^{FN5} On July 9, 2007, the Louisiana Association of Nurse Anesthetists ("LANA") sought to intervene in this matter as of right. On October 15, 2007, LANA was permitted to intervene in the proceedings.

^{FN4}. Spine Diagnostics subsequently moved to voluntarily dismiss Mr. Smith from this action, without prejudice. Judgment granting said dismissal was signed by the trial court on October 25, 2007.

^{FN5}. According to the record, Senate Bill 322 was proposed as an attempt to amend La. R.S. 37:930(A)(3) relative to the practice of nursing to provide that it is within the scope of practice of a CRNA to perform certain pain management procedures, including peripheral nerve blocks, epidural injections, and spinal facet joint injections, when the CRNA can document education, training, and experience in performing such procedures.

The trial on Spine Diagnostics' request for declaratory judgment, permanent injunction, and contempt was held on November 29 and 30, 2007, and December 3, 2007. Thereafter, the trial court took the matter under advisement and, on January 10, 2008, rendered judgment in favor of Spine Diagnostics as follows:^{FN6}

^{FN6}. On January 17, 2008, the trial court signed an amended judgment, which was identical in substance to the judgment rendered on January 10, 2008. According to the record, the amended judgment was necessary only to correct a clerical error because the original judgment indicated it had been signed on January 10, 2007, when in fact the

judgment had been rendered on January 10, 2008.

The Court ORDERS, ADJUDGES and DECREES, the following in connection with the declaratory judgment:

1. The statement issued by the LSBN substantively expands the scope of practice for CRNAs into an area where they have not traditionally practiced, i.e. chronic or interventional pain management.
2. The practice of interventional pain management is not within a CRNAs scope of practice.
3. The practice of interventional pain management is solely the practice of medicine.
4. The opinion issued by the LSBN is an effort to substantively expand CRNA scope of practice and is an improper attempt at rule making.

IT IS FURTHER ORDERED, ADJUDGED and DECREED that in connection with the permanent injunction:

1. A permanent injunction issue prohibiting the LSBN from enforcing the statement.
2. A permanent injunction issue prohibiting August Rantz, III from performing chronic interventional pain procedures in connection with the LSBN statement.
3. The LSBN shall remove the advisory opinion from its website.
4. The LSBN shall post the judgment of this Court on its website and publish it in the LSBN publication, *The Examiner*.

IT IS FURTHER ORDERED, ADJUDGED and DECREED that

1. LSBN is taxed with all costs associated with these proceedings;

*860 2. LSBN is taxed with all expert costs and fees;

3. LSBN is taxed \$7,500.00 in litigation costs pursuant to LA R.S. 49:965.1(A);

4. LSBN is taxed with costs of all deposition transcripts.

**7 It is from this judgment that the LSBN and LANA have appealed.^{FN7}

FN7. Both the LSBN and LANA originally sought to suspensively appeal the trial courts judgment. However, the trial court denied the requests for suspensive appeals, and instead granted both parties devolutive appeals. *Amici Curiae* briefs on behalf of the American Association of Nurse Anesthetists, the Louisiana Association of Nurse Practitioners, the American Nurses Association, the Louisiana Alliance of Nursing Organizations, the Louisiana Hospital Association, and the National Council of State Boards of Nursing, Inc. have also been filed for this court's review.

In its appeal, the LSBN assigns the following specification of errors:

1. The Trial Court erred in ruling that Spine Diagnostics met its burden of proof to obtain a permanent injunction enjoining the Nursing Board's Advisory Opinion on the basis that it constituted a "rule" which should have been promulgated in accordance with the LAPA.
2. The Trial Court erred in ruling that Spine Diagnostics had met its burden of proof to obtain a permanent injunction enjoining the Nursing Board's Advisory Opinion on the basis that it substantively expands the scope of practice for CRNAs into an area where CRNAs have not traditionally practiced, i.e., chronic or interventional pain management.
3. The Trial Court erred in ruling that Spine Diagnostics had met its burden of proof to obtain a mandatory injunction requiring the removal of the Advisory Opinion from its website and ordering publication of the judgment on the Nursing Board's website and in its quarterly publication, *The Examiner*.

4. The Trial Court erred in declaring the practice of injecting local anesthetics, steroids and analgesics for chronic pain management under the direction and supervision of a physician to be beyond the traditional scope of practice for CRNAs.
5. The Trial Court erred in declaring the practice of injecting local anesthetics, steroids and analgesics for chronic pain management under the direction and supervision of a physician to be solely the practice of medicine.
6. The Trial Court erred in awarding Spine Diagnostics up to \$7,500 in reasonable litigation expenses pursuant to La. R.S. 49:965.1 and other fees/costs for its expert witnesses and the taking of depositions.

Similarly, LANA sets forth the following on appeal for our review:

1. The trial court committed legal error in declaring the practice of injecting local anesthetics, steroids and analgesics for chronic pain management pursuant to a physician's order beyond the scope of CRNA practice.
2. The trial court committed legal error in declaring the practice of injecting local anesthetics, steroids and analgesics for chronic pain management pursuant to a physician's order to be solely the practice of medicine.
3. The trial court erred in finding the Nursing Board's advisory opinion is an improper attempt at rule-making.
- **8 4. The trial court erred in finding that the Nursing Board advisory opinion substantively*861 expands the scope of practice for CRNAs into an area where CRNAs have not traditionally practiced, i.e. chronic or interventional pain management.

LAW OF THE CASE DOCTRINE

[1] On appeal, the LSBN and LAIMA both argue that the advisory opinion issued by the LSBN in response to Rantz's petition was nothing more than a declaratory order, which is provided for in La. R.S. 49:962, not a rule within the meaning of the LAPA.^{EN8} Thus,

they assert, the trial court erred in finding that the LSBN's advisory opinion was an improper attempt at rule-making. In response, Spine Diagnostics contends that the LSBN and LANA are attempting to relitigate issues previously decided by this court. Spine Diagnostics maintains that these arguments are precluded by the law of the case doctrine as they have been briefed, argued, and decided by this court.

FN8. Louisiana Revised Statutes 49:962 provides as follows:

Each agency shall provide by rule for the filing and prompt disposition of petitions for declaratory orders and rulings as to the applicability of any statutory provision or of any rule or order of the agency. Declaratory orders and rulings shall have the same status as agency decisions or orders in adjudicated cases.

[2] Pursuant to the law of the case doctrine, an appellate court generally will not, as part of a subsequent appeal, reconsider its earlier ruling in the same case. Spruell v. Dudley, 2006-0015, p. 4 (La.App. 1 Cir. 12/28/06), 951 So.2d 339, 342, writ denied, 2007-0196 (La.3/23/07), 951 So.2d 1106.

In Louisiana Land and Exploration Company v. Verdin, 95-2579, pp. 3-4 (La.App. 1 Cir. 9/27/96), 681 So.2d 63, 65, writ denied, 96-2629 (La.12/13/96), 692 So.2d 1067, cert. denied, 520 U.S. 1212, 117 S.Ct. 1696, 137 L.Ed.2d 822 (1997), this court discussed the law of the case doctrine and its application as follows:

The law of the case principle is a discretionary guide which relates to (a) the binding force of a trial judge's ruling during the later stages of trial, (b) the conclusive effects of appellate rulings at trial on remand, and (c) the rule that an appellate court ordinarily will not reconsider its own rulings of law on a subsequent appeal in the same case. It applies to all prior rulings or decisions of an appellate court or the supreme court in the same case, not merely those arising from the full appeal process. Re-argument in the same case of a previously decided point will be barred where there is simply a doubt as to the correctness of the earlier ruling. However, the law of the case principle is not applied in cases of palpable **9 error or where, if the

law of the case were applied, manifest injustice would occur.

The reasons for the law of the case doctrine is to avoid relitigation of the same issue; to promote consistency of result in the same litigation; and to promote efficiency and fairness to both parties by affording a single opportunity for the argument and decision of the matter at issue.

When an appellate court considers arguments made in supervisory writ applications or responses to such applications, the court's disposition on the issue considered usually becomes the law of the case, foreclosing relitigation of that issue either at the trial court on remand or in the appellate court on a later appeal. However, where a prior disposition is clearly erroneous and will create a grave injustice, it should be reconsidered. [Citations omitted.]

*862 In considering this doctrine and its applicability herein, we note that the arguments and issues raised by the LSBN and LANA in this regard appear to be indistinguishable from those presented to the trial court in the original request for injunctive relief and again to this court in the writ application in *Spine Diagnostics I*. In fact, a review of our opinion in *Spine Diagnostics I* reveals this court previously considered the ISBN's authority to issue declaratory orders and advisory opinions pursuant to La. R.S. 49:962, thoroughly reviewed arguments concerning La. R.S. 37:930 as it relates to this issue, and concluded that the LSBN's statement, insofar as it relates to chronic or interventional pain management, was a rule that required compliance with the procedural requirements of the LAPA. Although ably argued on appeal, a review of the instant record reveals that this court's previous ruling was without error. Thus, by operation of the law of the case doctrine, we decline review of these issues on appeal.

SCOPE OF PRACTICE ISSUE

[3] The central issue to be decided in this appeal is whether procedures involving the injection of local anesthetics, steroids and analgesics for pain management purposes, peripheral nerve blocks, epidural injections, and spinal facet joint injections are within the scope of practice of CRNAs or whether these procedures are considered the practice of medicine

and can only be performed by a physician licensed to practice medicine in Louisiana. The issue before us is *res nova*.

**10 The statutory provisions governing practice by a CRNA are found in La. R.S. 37:390. Louisiana Revised Statutes 37:930(A) provides that CRNAs are authorized to administer local anesthetics under the direction and supervision of a physician.^{FN9} In 2004, the Louisiana Legislature statutorily recognized the importance of CRNAs in providing anesthetics to Louisiana residents when it added paragraph (G) to La. R.S. 37:930. This provision provides, in pertinent part, as follows:

FN9. Louisiana Revised Statutes 37:930(A) provides as follows:

A. No registered professional nurse shall administer any form of anesthetic to any person under their care unless the following conditions are met:

(1) The registered nurse has successfully completed the prescribed educational program in a school of anesthesia which is accredited by a nationally recognized accrediting agency approved by the United States Department of Health, Education, and Welfare.

(2) Is a registered nurse anesthetist certified by a nationally recognized certifying agency for nurse anesthetists following completion of the educational program referred to in Paragraph (1) of this Subsection and participates in a continuing education program of a nationally approved accreditation agency as from time to time required which program shall be recognized as the Continuing Education Program for Certified Registered Nurse Anesthetists; and

(3) Administers anesthetics and ancillary services **under the direction and supervision** of a physician or dentist who is licensed to practice under the laws of the state of Louisiana. [Emphasis added.]

G. (1) The Louisiana Legislature hereby finds that:

(a) Certified Registered Nurse Anesthetists (CRNAs) have been selecting and administering anesthesia in Louisiana and the United States for over one hundred years.

....

(e) Nurse anesthetists receive rigorous clinical and academic training, requiring a bachelor's degree from an accredited school of nursing and one year of professional nursing experience in an acute care setting prior to being considered for entrance to an accredited twenty-four*863 to thirty-six month nurse anesthesia educational program.

(f) CRNAs administer the majority of anesthetics in Louisiana and all of the anesthetics in many parts of the state.

(g) Multiple studies have demonstrated that CRNAs are safe, accessible, and cost-effective providers of anesthetics.

(h) CRNAs are critical providers of quality anesthesia services in the health care delivery system in this state.

(i) An adequate supply of CRNAs in Louisiana is vital to continued access to safe, cost-effective health care for the citizens of Louisiana.

....

**11 (n) CRNAs are trained and legally authorized to administer all types of anesthetics in all settings while AAs [Anesthesiologist assistants] are limited by the type of anesthetics they can administer and the settings in which they are authorized to perform their services.

On appeal, the LSBN and LANA argue that Spine Diagnostics failed to prove by a preponderance of the evidence that the LSBN's statement expands the scope of practice for CRNAs into areas where CRNAs have not traditionally practiced. Noting an overlap between various practitioners, including nurses, and the practice of medicine, the LSBN and LANA contend that interventional pain management

is not solely the practice of medicine. Moreover, they maintain that had the legislature intended to exclude CRNAs from performing interventional pain management procedures, language concerning the restriction could have simply been added to La. R.S. 37:930 to accomplish same.

To the contrary, Spine Diagnostics asserts that the evidence presented at the trial on the merits supports the trial court's ruling that the LSBN's statement expands the scope of practice for CRNAs into an area not traditionally practiced. Spine Diagnostics argues that (1) CRNAs do not have an established history of performing interventional pain management procedures; (2) CRNAs do not have the education, training, or accreditation to safely and effectively perform these procedures; (3) studies demonstrate decreased safety, competency, and efficacy when these procedures are performed by CRNAs; (4) CRNAs have no regulatory mechanism or process to assess their competency, training, or education; (5) no verifiable need exists for CRNAs in this area of practice; and (6) CRNA practice in this area will negatively impact public health and safety.

As previously mentioned, this matter was tried over three days before the trial court. After hearing from the witnesses and considering the documentary evidence presented by the parties, the trial court entered a declaratory judgment finding that the statement issued by the LSBN expanded the scope of practice for CRNAs into an area where they have not traditionally practiced, i.e., chronic or **12 interventional pain management. The trial court further declared that the practice of chronic or interventional pain management is not within the scope of practice of a CRNA, but rather is solely the practice of medicine.

Appellate courts review a trial court's decision to grant or deny a declaratory judgment using the abuse of discretion standard. Mai v. Floyd, 2005-2301, p. 4 (La.App. 1 Cir. 12/6/06), 951 So.2d 244, 245. Factual findings made by the trial court are reviewed using the manifest error or clearly wrong standard. Rosell v. ESCO, 549 So.2d 840, 844 (La.1989).

The trial court also issued a permanent injunction prohibiting the LSBN from enforcing its statement and prohibiting Mr. Rantz from performing chronic interventional*864 pain procedures in connection with the LSBN statement and a mandatory injunction

ordering the LSBN to remove the statement from its website, post the judgment of the trial court on its website, and publish the judgment in its publication, *The Examiner*.

[4][5][6] The issuance of a permanent injunction takes place only after a trial on the merits, in which the burden of proof must be founded on a preponderance of the evidence. *State Machinery & Equipment Sales, Inc. v. Iberville Parish Council*, 2005-2240, p. 4 (La.App. 1 Cir. 12/28/06), 952 So.2d 77, 81. A mandatory injunction, so named because it commands the doing of some action, similarly cannot be issued without a hearing on the merits. The jurisprudence has established that a mandatory preliminary injunction has the same basic effect as a permanent injunction, and therefore may not be issued on merely a prima facie showing that the party seeking the injunction can prove the necessary elements; instead, the party must show by a preponderance of the evidence at an evidentiary hearing that he is entitled to the preliminary injunction. *Concerned Citizens for Proper Planning, LLC v. Parish of Tangipahoa*, 2004-0270, p. 7 (La.App. 1 Cir. 3/24/05), 906 So.2d 660, 664. The standard of review for the issuance of a permanent injunction is the manifest error standard. *Cathcart v. Magruder*, 2006-0986, p. 18 (La.App. 1 Cir. 5/4/07), 960 So.2d 1032, 1041. Under this standard, the issue to be resolved by a reviewing court is not whether the trier of fact was right or wrong, but whether the fact finder's conclusion was a reasonable one. ***13Stobart v. State through Dept. of Transp.*

and
[http://www.westlaw.com/Find/Default.wl?rs=dfa1.0&vr=2.0&DB=735&FindType=Y&ReferencePosition-Type=S&SerialNum=1993085793&ReferencePosition=882Development, 617 So.2d 880, 882 \(La.1993\).](http://www.westlaw.com/Find/Default.wl?rs=dfa1.0&vr=2.0&DB=735&FindType=Y&ReferencePosition-Type=S&SerialNum=1993085793&ReferencePosition=882Development, 617 So.2d 880, 882 (La.1993).) Thus, if the trial court's findings are reasonable in light of the record reviewed in its entirety, this court may not reverse, even if convinced that had it been sitting as trier of fact, it would have weighed the evidence differently. *Parish of East Feliciana ex rel. East Feliciana Parish Police Jury v. Guidry*, 2004-1197, p. 15 (La.App. 1 Cir. 8/10/05), 923 So.2d 45, 53, writ denied, 2005-2288 (La.3/10/06), 925 So.2d 515.

The trial court heard from many medical experts regarding the scope of practice issue. Dr. Laxmaiah

Manchikanti, the single most published author in the United States on interventional pain management techniques, was accepted by the court as an expert in interventional pain management with special expertise in credentialing, education, training, research, access, and scope of practice. Dr. Manchikanti developed the definition of interventional pain management that is accepted by the United States Congress today. He testified at length concerning the level of training needed to perform interventional pain management procedures, indicating that the health and safety of the patients warrants the enhanced skills of a duly licensed and trained medical physician. Dr. Manchikanti opined that interventional pain management procedures are not traditionally within the scope of practice for a CRNA.

Dr. John Dombroski testified as an expert in the field of anesthesiology, internal medicine, and pain medicine, and was allowed to express an opinion with respect to the scope and practice of medicine in those areas of medicine as they interface with other health-care professionals such as CRNAs. Dr. Dombroski stated unequivocally that CRNAs should not be allowed to be performing interventional pain management procedures as they have never had the proper training required to do so. He indicated that the patients deserve the best care possible, including a proper medical diagnosis and the correct assessment ***865* by a duly licensed and trained medical physician.

The trial court also was provided testimony from Dr. Gabor Racz via deposition. Dr. Racz is an anesthesiologist who is currently working as a professor. He has taught both physicians and CRNAs. Dr. Racz is a highly decorated physician, having been listed in the "Best Doctors in America" and receiving the lifetime achievement award ***14* from the American Society of Interventional Pain Physicians. He is also the President of the World Institute of Pain. Dr. Racz testified that under no circumstances should a CRNA be allowed to perform interventional pain management procedures. He added that if CRNAs wish to do these procedures, they have every right to "avail themselves to the training, and whatever it takes to be an interventional pain physician." Dr. Racz opined that nurses do not practice to a physician level and that a medical diagnosis differs from a nursing diagnosis.

Dr. Frank Falco was accepted as an expert in the field of physical medicine. He is also board certified in rehabilitation, pain medicine, and sports medicine. Dr. Falco testified regarding the requirements of a pain medicine fellowship training program. He explained that the assessment of a chronic pain patient is very complex and is not “simply putting a needle in someplace and injecting some solution in that area.” Dr. Falco noted further:

The pain fellow must understand based on a history tailored towards the pain patient and the physical examination, that is, a complete examination involving the neurological assessment, a musculoskeletal assessment, a psychological assessment, reviewing of all of the diagnostic data, the CT, the xray, the MRI, the electrodiagnostic studies, and then making a diagnosis based upon the evaluation and then laying out a treatment plan. We have three fellows in our ACGME Accredited Pain Medicine Fellowship. They are constantly supervised for the entire twelve months. They get four months of in-patient training.

When asked if CRNAs had any role to play in the chronic pain management arena, Dr. Falco responded that although CRNAs are excellently trained in providing anesthesia services for surgery under the direction of an anesthesiologist, “[t]hey do not have the training that allows them to include in their scope of practice the management of chronic complex pain.” Dr. Falco opined that it would be “practicing medicine with a license, without the proper training,” which could lead to significant complications not only from the procedures themselves, but also from the patients being mismanaged. Dr. Falco concluded that without going to medical school, CRNAs cannot receive the training needed to be able to competently perform these procedures.

Jack Neary, a CRNA from New Hampshire, testified that he performs interventional pain management procedures unsupervised. He acknowledged that he **15 has no training in radiology or neurology. Mr. Neary noted further that he knows of no regulations or guidelines of any sort that apply nationally to institutions to assess the competency, ability, credentials or skill sets of CRNAs with respect to interventional pain management procedures. From his perspective, once a CRNA gets their certificate and the proper training, and feels comfortable with a procedure, they

can do it. With regard to the scope of practice for CRNAs in New Hampshire, Mr. Neary testified that the New Hampshire Board of Nursing has found that certain interventional pain management procedures are within the scope of practice of a CRNA licensed in New Hampshire.

*866 Christine Langer testified regarding the educational requirements of a CRNA. Ms. Langer is an instructor who trains CRNAs at the Louisiana State University School of Nursing. She indicated she does not teach a section called “interventional pain management,” noting that the majority of her teaching focuses on training CRNAs for the hospital setting. Ms. Langer agreed that there is a distinct difference between acute pain treatment in a hospital or surgical setting and chronic interventional pain management. She also acknowledged that at the time a student acquires a CRNA certificate, absent anything else, no student in Louisiana is competent to perform interventional pain management procedures. Ms. Langer testified that she is not aware of any post-certification competency benchmarks for CRNAs related to interventional pain management procedures. She agreed that CRNAs cannot make medical diagnoses.

Barbara Morvant, the Executive Director for the LSBN, testified concerning the licensing and credentialing of CRNAs in Louisiana. She explained that in its role as a licensing agency, the LSBN credentials CRNAs for entry level practice, and provides for re-certification requirements in their field of nurse anesthesia practice. The LSBN also investigates any complaints that may be filed against CRNAs. When asked specifically about the LSBN statement in question and whether the LSBN had any mechanism or system designed to verify or in any way assess whether a CRNA has the documented education, training, experience, knowledge, skills, and abilities to safely perform **16 interventional pain management procedures, Ms. Morvant acknowledged that it has no such system in place.

Jackie Rowles is the President-Elect of the American Association of Nurse Anesthetists and is a practicing CRNA in Indiana. She has been performing interventional pain management procedures for almost five years. Ms. Rowles agreed that she cannot make a medical diagnosis, only a nursing diagnosis. She explained, however, that when her patients come to her for treatment, they have already been seen by a phy-

sician and have a diagnosis. Ms. Rowles acknowledged that there are no guidelines for assessing the competency, skill set, abilities, or training needed for CRNAs to begin performing interventional pain management procedures. Rather, she opined that a CRNA should be allowed to perform these procedures once the CRNA has had the “necessary education, training, and feels like they have the necessary skills.”

Kathleen Wren, a CRNA with a Master of Science in nursing, testified regarding her twenty-three years of experience as CRNA, practicing in eight different states including Louisiana. During her career as a CRNA, she established three pain clinics and three rural hospitals, in Nebraska and Iowa. Her pain clinics provided anesthetic blocks for chronic pain patients. Ms. Wren stated that in her experience as a CRNA, the injection of steroids and analgesics for pain management purposes, including peripheral nerve blocks, epidural injections, and spinal facet joint injections, have always been a part of the practice of CRNAs in the states she practiced in, including Louisiana. However, Ms. Wren later admitted that she never practiced interventional pain management in Louisiana. In her opinion, it is within the scope of practice of a properly trained nurse anesthetist to perform interventional pain management procedures outside of the hospital setting. When asked whether she was aware of any certification beyond the CRNA licensing process or any type of regulatory process in place that would tell the public whether a particular CRNA has met a threshold standard of competency, *867 Ms. Wren stated that she believed that was a function of the LSBN.

Rusty Smith, a CRNA in Louisiana, testified that he performs interventional pain management in Louisiana and has done so for several years. Mr. Smith indicated that **17 while he has been performing epidural injections for chronic pain relief for approximately twenty years, it is just in the last four years of his practice that he has begun offering spinal facet joint injections related to chronic pain management. He does these procedures exclusively at an ambulatory surgery center in Vidalia, Louisiana. His largest referring physician for interventional pain management procedures is Dr. Russ Fairbanks. When a patient comes to him from Dr. Fairbanks, the patient has been examined and diagnosed. Mr. Smith indicated that when submitting codes to Medicare

and Medicaid, he uses the diagnosis submitted by Dr. Fairbanks. When asked if he continued with these interventional pain management procedures even after learning of the preliminary injunction that was in place concerning the LSBN's statement, Mr. Smith stated that to his knowledge, the injunction was only against Mr. Rantz. In fact, Mr. Smith indicated that even after the preliminary injunction had been ordered, Ms. Morvant, the Executive Director of the LSBN, told him that there was nothing that would prevent him from continuing in his practice.

Dr. Fairbanks, accepted by the trial court as an expert in the field of orthopedics, testified regarding his relationship with Mr. Smith. According to Dr. Fairbanks, over the last five years he has referred approximately three or four patients a week to Mr. Smith for interventional pain management procedures.^{FN10} Dr. Fairbanks testified that after he sees the patient and makes a diagnosis, he refers the patient to Mr. Smith who then works under his direction. However, Dr. Fairbanks admitted that he is not in the operating suite when Mr. Smith performs these procedures. In fact, Dr. Fairbanks indicated that there may even be times when he is not in the facility when the procedures are being performed. Dr. Fairbanks stated that he has never had any complaints from his patients regarding the treatment they have received from Mr. Smith. Although Dr. Fairbanks denied having any direct financial ties with Mr. Smith, he **18 did acknowledge that he owns a percentage of the surgery center in Vidalia where Mr. Smith performs the procedures. Dr. Fairbanks also noted that there is an interventional pain medicine physician in Natchez, Mississippi, which is only five miles from his surgery center in Vidalia.

^{FN10.} We note that Mr. Smith did not testify during trial as to the number of interventional pain management procedures he performed. However, after the trial on the merits, there was a contempt hearing concerning a subpoena duces tecum that Mr. Smith had failed to respond to prior to trial. The motion for contempt against Mr. Smith was ultimately dismissed, and the parties entered into a stipulation that from 2004 to 2007, Mr. Smith performed a total of twelve interventional pain management procedures at the ambulatory surgical center in Vidalia.

We have thoroughly reviewed the record before us and find no abuse of discretion by the trial court in its declaratory judgment in favor of Spine Diagnostics finding that the statement issued by the LSBN expanded the scope of practice for CRNAs into an area where they have not traditionally practiced and finding that the practice of interventional pain management is not within the scope of practice of a CRNA, but rather is solely the practice of medicine. Moreover, with the foregoing legal precepts in mind, and having reviewed*868 the evidence considered by the trial court below, we are satisfied that Spine Diagnostics met its burden of proof on the permanent injunction and the mandatory injunction. The trial courts judgment regarding same is reasonable, supported by the record, and not manifestly erroneous.

AWARD OF REASONABLE LITIGATION EXPENSES AND OTHER COSTS TO SPINE DIAGNOSTICS

[7] The LSBN argues on appeal that the trial court erred in awarding Spine Diagnostics \$7,500.00 in reasonable litigation expenses pursuant to La. R.S. 49:965.1 plus an award for other fees/costs associated with expert witnesses and depositions. Spine Diagnostics argues that pursuant to La. Code Civ. P. art.1920,^{FN11} the trial judge has great discretion in awarding costs and its judgment should not be disturbed absent an abuse of discretion. See MCI Telecommunications Corp. v. Kennedy, 2004-0458, p. 11 (La.App. 1 Cir. 3/24/05), 899 So.2d 674, 681. Based on applicable law and jurisprudence, we reverse that portion of the judgment that awarded Spine Diagnostics any fees/costs in excess of the \$7,500.00 provided for in La. R.S. 49:965.1.

FN11. Article 1920 provides as follows:

Unless the judgment provides otherwise, costs shall be paid by the party cast, and may be taxed by a rule to show cause.

Except as otherwise provided by law, the court may render judgment for costs, or any part thereof, against any party, as it may consider equitable.

**19 Spine Diagnostics' request for litigation expenses and the trial court's award were based on La. R.S. 49:965.1(A). It provides, in pertinent part, as

follows:

When a small business files a petition seeking: ... (2) judicial review of the validity or applicability of an agency rule, ... the petition may include a claim against the agency for the recovery of reasonable litigation expenses. If the small business prevails and the court determines that the agency acted without substantial justification, the court may award such expenses, in addition to granting any other appropriate relief.

“Reasonable litigation expenses” are defined as “any expenses, not exceeding seven thousand five hundred dollars in connection with any one claim, reasonably incurred in opposing or contesting the agency action, including costs and expenses incurred in both the administrative proceeding and the judicial proceeding, fees and expenses of expert or other witnesses, and attorney fees.” La. R.S. 49:965.1(D)(1) (Emphasis added.); State ex rel. Louisiana Riverboat Gaming Com'n v. Louisiana State Police Riverboat Gaming Enforcement Div., 99-2038, p. 4 (La.App. 1 Cir. 9/22/00), 768 So.2d 284, 286, writ denied, 2000-2926 (La.1/5/01), 778 So.2d 598. To qualify for this relief, a “small business” must meet the criteria defined by the Small Business Administration in Section 13 of the Code of Federal Regulations, Part 121. La. R.S. 49:965.1(D)(2). A physician's office with annual receipts of less than \$9 million is considered a “small business” under the applicable regulation. 13 C.F.R. § 121.201.^{FN12} At the hearing on the preliminary injunction, Dr. John Burdine, owner of Spine Diagnostics, testified that Spine Diagnostics' annual receipts total less than \$9 million per year. A review of the record before us reveals that this testimony was not contradicted. Thus, *869 Spine Diagnostics meets the eligibility requirements set forth in the statute.

FN12. Effective August 26, 2008, 13 C.F.R. 121.201 was amended to provide that a physician's office must now have annual receipts of less than \$10 million to be considered a “small business.”

[8][9] Because La. R.S. 49:965.1 provides for an award for reasonable litigation expenses, it is penal in nature. It is a well-settled rule of statutory construction that penal statutes must be strictly construed and their provisions shall be given a genuine construction according to the fair import of their words, taken in

their usual sense, in **20 connection with the context and with reference to the purpose of the provision. Doc's Clinic, APMC v. State ex rel. Dept. of Health and Hospitals, 2007-0480, p. 32 (La.App. 1 Cir. 11/2/07), 984 So.2d 711, 732, writ denied, 2007-2302 (La.2/15/08), 974 So.2d 665. Pursuant to the clear language of this statute, any award for reasonable litigation expenses is limited to \$7,500.00 and is inclusive of any and all costs, fees, and expenses associated with opposing or contesting the agency action. Thus, there can be no award over and above the \$7,500.00 for other expert fees and deposition costs such as those awarded by the trial court in this matter. Accordingly, we affirm the \$7,500.00 award for litigation expenses and reverse that portion of the judgment awarding "all costs associated with these proceedings;" "all expert costs and fees;" and "costs of all deposition transcripts."

CONCLUSION

For the above and foregoing reasons, we reverse that portion of the trial court's judgment awarding "all costs associated with these proceedings;" "all expert costs and fees;" and "costs of all deposition transcripts." In all other respects, we affirm. All costs associated with this appeal are assessed equally against the Louisiana State Board of Nursing and the Louisiana Association of Nurse Anesthetists.

AFFIRMED IN PART; REVERSED IN PART.

La.App. 1 Cir.,2008.
Spine Diagnostics Center of Baton Rouge, Inc. v.
Louisiana State Bd. of Nursing ex rel. Louisiana
Dept. of Health and Hospitals
4 So.3d 854, 2008-0813 (La.App. 1 Cir. 12/23/08)

END OF DOCUMENT

BEFORE THE IOWA BOARD OF MEDICINE.

Re:)
)
PETITION BY JILL CIRIVELLO)
FOR AMENDMENT OF 653 IAC 13.7(4)) **ORDER DENYING PETITION**
RELATING TO SEXUAL MISCONDUCT) **FOR RULEMAKING**
)
)

I. SUMMARY

On July 10, 2015, Jill Cirivello (Petitioner), presented a petition (**EXHIBIT A**) to the Iowa Board of Medicine (Board), pursuant to Iowa Code Chapter 17A.7 and Iowa Administrative Code 653–1.7, to amend Iowa Administrative Code 653–13.7(4), which describes inappropriate sexual conduct with a patient, a patient’s parent or guardian if the patient is a minor, or with a former patient. The Petitioner requested that the following provisions of Section 1285.240, Title 68, Professions and Occupations, Illinois Administrative Code, Standards on Dishonorable, Unethical or Unprofessional conduct, be included in the Iowa Administrative Code:

Immoral Conduct (by a physician occurs when a physician) abuses the physician/patient relationship by taking unfair advantage of a patient’s vulnerability.

In determining immoral conduct in the commission of any act related to the licensee’s practice the Disciplinary Board shall consider, but not be limited to, the following standards:

- A) Taking advantage of a patient’s vulnerability by committing an act that violates established codes of professional behavior expected on a the part of a physician;
- B) Unethical conduct with a patient that results in the patient engaging in unwanted personal, financial or sexual relationships with the physician.

In addition, the Petitioner requested the Board to adopt a rule to prohibit polygraph testing of physicians in any type of investigation.

The Petitioner met with Board Executive Director Mark Bowden and Board Legal Director Kent Nebel on July 30, 2015, to discuss her petition. On August 5, 2015, the Petitioner amended her petition (**EXHIBIT B**), requesting the Board adopt the following amendment to Iowa Administrative Code 653–13.7:

~~Iowa law also prohibits~~ *A physician is expected to maintain a professional relationship and boundaries with a patient or a patient’s guardian in the course of providing professional medical services. If a personal or sexual relationship develops between a patient or a patient’s guardian in the course of the*

physician's personal life, the physician must terminate the physician-patient relationship.

~~any sexual act or encounter with a patient or the patient's guardian, which may lead to disciplinary action and is~~

Conduct towards a patient by a physician that could result in criminal or civil liability would be considered unprofessional and unethical conduct and the physician would be subject to disciplinary action.

Investigations conducted by the Board as a result of this provision shall be limited to the allegations in the complaint. In addition, alleged actions that occurred over three years prior to the complaint will not be considered due to the difficulty in obtaining accurate information. Any outside vendor utilized by the Board to assist with an investigation shall not subject a physician to polygraph testing.

~~There are also certain provisions stating that a physician may engage in sexual contact with a former patient once the physician-patient relationship was completely terminated. However, the board of medicine may examine the specific circumstances surrounding the relationship to determine whether it was completely terminated. A psychiatrist may never engage in sexual contact with a current or former patient or the patient's guardian, even if the patient consents. A physician is also prohibited from engaging in sexual harassment.~~

The Petitioner appeared before the Board on August 28, 2015, and presented statements. In support of the petition, the Petitioner referenced action taken by the Board in 2005 concerning the Petitioner's husband, a physician, who was investigated for allegations of sexual misconduct and ordered to submit to sexual misconduct evaluation. The physician refused to submit to the evaluation because it included polygraph testing, which the physician contended has little to no scientific validity. The Board suspended the physician's medical license for failure to submit to the sexual misconduct evaluation. The Petitioner asserted that the Board's action "led to an abandonment of the life we had lived before the investigation."

II. DENIAL OF PETITION

The Board, having reviewed the Petitioner's petition to adopt, amend, or repeal a rule, and considering statements she provided on July 10, 2014, and August 28, 2015, voted in open session on August 28, 2015, to deny the petition. Pursuant to Iowa Code 17A.7 and Iowa Administrative Code 653-1.7, the Board provides the following reasons for denial of the petition:

1. Petitioner asserts Iowa Administrative Code 653-13.7 (4) is overly broad and overreaching.

The Board's rule, which has been effective since January 28, 2004, has worked well over time and is consistent with ethical standards on physician-patient relationships established by American Medical Association and the American Osteopathic Association:

13.7(4) *Sexual conduct.* It is unprofessional and unethical conduct, and is grounds for disciplinary action, for a physician to engage in conduct which violates the following prohibitions:

a. In the course of providing medical care, a physician shall not engage in contact, touching, or comments of a sexual nature with a patient, or with the patient's parent or guardian if the patient is a minor.

b. A physician shall not engage in any sexual conduct with a patient when that conduct occurs concurrent with the physician-patient relationship, regardless of whether the patient consents to that conduct.

c. A physician shall not engage in any sexual conduct with a former patient unless the physician-patient relationship was completely terminated before the sexual conduct occurred. In considering whether that relationship was completely terminated, the board will consider the duration of the physician-patient relationship, the nature of the medical services provided, the lapse of time since the physician-patient relationship ended, the degree of dependence in the physician-patient relationship, and the extent to which the physician used or exploited the trust, knowledge, emotions, or influence derived from the physician-patient relationship.

d. A psychiatrist, or a physician who provides mental health counseling to a patient, shall never engage in any sexual conduct with a current or former patient, or with that patient's parent or guardian if the patient was a minor, regardless of whether the patient consents to that conduct.

The American Medical Association Council on Ethical and Judicial Affairs states categorically that "[s]exual contact that occurs concurrent with the physician-patient relationship constitutes sexual misconduct."¹ The Board, in applying this rule in sexual misconduct cases, believes such conduct may compromise patient care. The Board's rule is based on trust the patient must have in the physician and gives rise to physicians' ethical obligations to place patients' welfare above their own self-interest. The Board believes the proposed rule does not set forth the current standard of care regarding sexual misconduct and is too narrow in its prohibitions. Further, the proposed rule's limitation on investigations would prohibit the Board from taking action on serious conduct uncovered during an investigation simply because it was not on the "face of the complaint" or because it was not discovered within three years. Such a limitation is contrary to the Board's mission to protect the health, safety, and welfare of Iowans and contrary to the Court's interpretation of the Board's jurisdiction.

2. Petitioner asserts the Board is not able to provide substantial evidence that its current rule is necessary for the protection of patients.

The Board's rule recognizes that physicians have a superior position of power in the relationship between patient and physician, and the relative position of the patient within the professional relationship is such that

¹ Council on Ethical and Judicial Affairs, American Medical Association, <http://www.ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-ethical-judicial-affairs.page>

it is difficult for the patient to give meaningful consent to a sexual relationship with the patient's physician. Furthermore, Iowa Code 709.15, in prohibiting sexual exploitation by a physician, recognizes the vulnerability of a patient or a former patient.

3. Petitioner requests Board to prohibit polygraph testing of physicians in any type of investigation.

The Board does not utilize polygraph testing as an investigative tool. The Board does not order polygraph testing, but utilizes nationally recognized evaluation programs to assist in its investigations of sexual misconduct cases. These programs choose to utilize polygraph testing as a part of their comprehensive psychiatric evaluation process. The Board relies on their expertise to determine what testing is appropriate. National studies suggest that the polygraph appears to be a useful component of an independent, comprehensive evaluation for sexual misconduct, as it may provide additional information to better understand what happened and more accurately determine a strategy for possible rehabilitation of the physician.²

In conclusion, the Board believes Iowa Administrative Code 653-13.7 (4) is superior to the Petitioner's proposal, which is vague and lacks specific detail about potential violations, making it more difficult to prosecute cases of sexual misconduct.

THEREFORE, IT IS HEREBY ORDERED that the Petition for Rulemaking filed by Jill Cirivello is hereby **DENIED**.

10th day of September, 2015.



Hamed Tewfik, M.D., Chairman
Iowa Board of Medicine

Judicial review of the Board's action may be sought in accordance with the terms of the Iowa Administrative Procedure Act, from and after the date of this Order.³

² A.J. Reid Finlayson, Kimberly P. Brown, Richard J. Iannelli, Ron Neufeld, Kendall Shull, Diaielle P. Marganoff, Peter R. Martin, "Professional Sexual Misconduct: The Role of The Polygraph in Independent Comprehensive Evaluation," *Journal of Medical Regulation*, Volume 101, Number 2, 2015: 23-34.

³ Iowa Code Chapter 17A.

Statement and Petition for Rule Change to the Iowa Board of Medical Examiners

Submitted to Executive Director Mark Bowden and the Directors of the Iowa Board of Medicine

Submitted by Jill Cirivello

July 10, 2015

This statement and petition is filed pursuant to Iowa Code 17A.7. When consulted, the Executive Director's Assistant informed me that there were no formal procedures of the Iowa Board of Medicine to petition for rule change as prescribed by that Code.

Statement

In, 2005, this Board received a complaint from a disgruntled physician who my husband supervised that alleged he had a sexual relationship with a patient. The patient was questioned by this Board and denied it.

This Board did not receive even one complaint from a patient, medical resident, student or staff member alleging any wrong doing or sexual misconduct by my husband. And yet, that is what this Board reported to the media.

Then, following the allegation, this Board launched a year-long investigation of my husband that was filled with rumor and innuendo. The decision was made to require him to attend a sexual misconduct evaluation.

My husband dutifully called and made the appointment to attend the evaluation as required in Atlanta. While on the call, they explained the parts of this evaluation and one of those was to administer polygraph testing.

My husband led residents and other physicians in Journal Watch for most of his career and also chaired the hospital ethics committee. He knew that polygraph testing had little to no scientific validity and certainly not evidence-based as this Board requires of its' physicians. That, coupled with the fact that he knew he hadn't done anything wrong, started his path of civil disobedience.

That path led to an abandonment of the life we had lived before the investigation. He lost his license, his job and now his life. Many who knew my husband, including colleagues and family, would attribute some of the cause of his early death to the actions of this Board.

My husband was an amazing physician. He was kind and thoughtful to his patients. Many learned from his gentle and understanding ways. He accepted people as they were and did what he could to provide the best possible care.

Today I am proposing a change to your administrative rules so that another great physician will not be impacted by an antiquated rule of this Board. Your current rule regarding sexual misconduct is too overreaching and broad. So broad in fact that this Board actually alleged during the investigative process that I needed your protection!

Imagine my disbelief when the Board questioned me and asked how I met my husband. I was a nurse in the emergency room and my husband was a part-time emergency room doctor. He was not my supervisor. We were co-workers and we started dating. This Board alleged that he used his position to lure me into dating him. How absurd! I did not need this Board's protection from my husband! We were together for 29 years!

This Board should adopt a rule that provides protection from misconduct that is not overly broad and overreaching. This Board would not be able to provide substantial evidence that its current rule is necessary for the protection of patients. Our sister state of Illinois has a rule that provides the necessary amount of protection for patients without such a burden on physicians.

Please let's face some facts. Doctors are going to meet people in a variety of settings and sometimes they are going to date. They might date nurses, other doctors, staff and yes maybe even patients. That's how some people have met their spouse. It's just reality. We need to protect patients from unwanted conduct or a physician taking advantage of a vulnerable patient as addressed by the Illinois rules. But that should be the extent of the protection. Nothing more.

Again, when this Board's investigator questioned the patient who my husband allegedly had an affair with, she denied it. She didn't file a complaint with the Board even though she was contacted by the investigator on three different occasions. She admitted in her statement that she sent my husband e-mails, brought him gifts and called him frequently. Does this sound like unwanted contact or that he was trying to take advantage of a vulnerable patient? This was a woman who was invited to my home by me on many occasions for dinner. She was dating our good friend. My husband had only treated her for two minor ailments when her own physician from the same clinic was unavailable. For this you ruined our life.

I urge you not to let this happen to another family by changing your rules. Your current rule reads as follows:

653—23.1 (272C) Grounds for discipline.

23.1(5) Sexual misconduct. Engaging in sexual misconduct includes, but is not limited to, engaging in conduct set out at 653—subrule 13.7(4) or 13.7(6) as interpreted by the board.

Iowa law also prohibits any sexual act or encounter with a patient or the patient's guardian, which may lead to disciplinary action and is considered unprofessional and unethical conduct. There are also certain provisions stating that a physician may engage in sexual contact with a former patient once the physician-patient relationship was completely terminated. However, the board of medicine may examine the specific circumstances surrounding the relationship to determine whether it was completely terminated. A psychiatrist may never engage in sexual contact with a current or former patient or the

patient's guardian, even if the patient consents. A physician is also prohibited from engaging in sexual harassment.

Petition for Rule Change

Again, pursuant to Iowa Code Chapter 17A, I petition to amend your rules on sexual misconduct to mirror the State of Illinois's rules which read as follows: (I have inserted the entire rule for clarity but am referring specifically to the highlighted portions in red dealing with sexual misconduct)

**TITLE 68: PROFESSIONS AND OCCUPATIONS
CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL
REGULATION
SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS
PART 1285 MEDICAL PRACTICE ACT OF 1987
SECTION 1285.240 STANDARDS**

Section 1285.240 Standards

- a) Dishonorable, Unethical or Unprofessional Conduct
 - 1) In determining what constitutes dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public, the Disciplinary Board shall consider whether the questioned activities:
 - A) Are violative of ethical standards of the profession (such as safeguard patient confidence and records within the constraints of law; respect the rights of patients, colleagues and other health professionals; observe laws under the Act and pertaining to any relevant specialty; to provide service with compassion and respect for human dignity);
 - B) Constitute a breach of the physician's responsibility to a patient;
 - C) Resulted in assumption by the physician of responsibility for delivery of patient care that the physician was not properly qualified or competent to render;
 - D) Resulted in a delegation of responsibility for delivery of patient care to persons who were not properly supervised or who were not competent to assume such responsibility;

- E) Caused actual harm to any member of the public; or
 - F) Are reasonably likely to cause harm to any member of the public in the future.
- 2) Questionable activities include, but are not limited to:
- A) Being convicted of any crime an essential element of which is larceny, embezzlement, obtaining money, property or credit by false pretenses or by means of a confidence game, dishonesty, fraud, misstatement or moral turpitude;
 - B) Delegating patient care responsibility to any individual when the physician has reason to believe that the person may not be competent;
 - C) Misrepresenting educational background, training, credentials, competence, or medical staff memberships;
 - D) Failing to properly supervise subordinate health professional and paraprofessional staff under the licensee's supervision and control in patient care responsibilities; or
 - E) Committing of any other act or omission that breaches the physician's responsibility to a patient according to accepted medical standards of practice.
- b) Immoral Conduct
- 1) Immoral conduct in the commission of any act related to the licensee's practice means conduct that:
 - A) Demonstrates moral indifference to the opinions of the good and respectable members of the profession;
 - B) Is inimical to the public welfare;
 - C) **Abuses the physician/patient relationship by taking unfair advantage of a patient's vulnerability; and**
 - D) Is committed in the course of the practice of medicine.
 - 2) **In determining immoral conduct in the commission of any act related to the licensee's practice, the Disciplinary Board shall consider, but not be limited to, the following standards:**

- A) Taking advantage of a patient's vulnerability by committing an act that violates established codes of professional behavior expected on the part of a physician;
 - B) Unethical conduct with a patient that results in the patient engaging in unwanted personal, financial or sexual relationships with the physician;
 - C) Conducting human experimentation or utilizing unproven drugs, medicine, surgery or equipment to treat patients, except as authorized for use in an approved research program pursuant to rules of the Illinois Department of Public Health authorizing research programs (77 Ill. Adm. Code 250.130) or as otherwise expressly authorized by law;
 - D) Committing an act, in the practice of persons licensed under the Act, of a flagrant, glaringly obvious nature, that constitutes conduct of such a distasteful nature that accepted codes of behavior or codes of ethics are breached;
 - E) Committing an act in a relationship with a patient so as to violate common standards of decency or propriety; or
 - F) Any other behavior that violates established codes of physician behavior or that violates established ethical principles commonly associated with the practice of medicine.
- c) In determining what constitutes gross negligence, the Disciplinary Board shall consider gross negligence to be an act or omission that is evidence of recklessness or carelessness toward or a disregard for the safety or well-being of the patient, and that results in injury to the patient.

(Source: Amended at 29 Ill. Reg. 18823, effective November 4, 2005)

In addition, I request that you amend your rules to prohibit polygraph testing of physicians in any type of investigation. You require your physicians to practice evidence-based medicine. Please practice the same principles in these investigations as well. See quote below.

**Scientific Validity of Polygraph Testing:
A Research Review and Evaluation**

A Technical Memorandum

Washington, D. C.: U.S. Congress
Office of Technology Assessment
OTA-TM-H-15
November 1983

“In sum, OTA concluded that there is at **present only limited scientific evidence** for establishing the validity of polygraph testing. Even where the evidence seems to indicate that polygraph testing detects deceptive subjects better than chance (when using the control question technique in specific-incident criminal investigations), **significant error rates are possible**, and examiner and examinee differences and the use of countermeasures may further affect validity.”

I am not aware of any new evidence that would support the continuation of this practice.

Thank you for your time and consideration.

From: Jill [<mailto:jillcirivello@hotmail.com>]
Sent: Wednesday, August 05, 2015 3:02 PM
To: Nebel, Kent [IBM]
Subject: Changes to Language

Kent,

Here are my changes to the language of 13.7 based on our conversation last Thursday where it was suggested that I modify the Board's current language rather than look at the Illinois language. I plan to attend the next Board meeting to state why I think this language would be even better than the Illinois language. Please let me know which date and at what time I should arrive.

Thank you,

Jill

Iowa Administrative Code 13.7

~~Iowa law also prohibits~~ *A physician is expected to maintain a professional relationship and boundaries with a patient or a patient's guardian in the course of providing professional medical services. If a personal or sexual relationship develops between a patient or a patient's guardian in the course of the physician's personal life, the physician must terminate the physician-patient relationship.*

~~any sexual act or encounter with a patient or the patient's guardian, which may lead to disciplinary action and is~~

Conduct towards a patient by a physician that could result in criminal or civil liability would be considered unprofessional

and unethical conduct *and the physician would be subject to disciplinary action.*

Investigations conducted by the Board as a result of this provision shall be limited to the allegations in the complaint. In addition, alleged actions that occurred over three years prior to the complaint will not be considered due to the difficulty in obtaining accurate information. Any outside vendor utilized by the Board to assist with an investigation shall not subject a physician to polygraph testing.

~~There are also certain provisions stating that a physician may engage in sexual contact with a former patient once the physician-patient relationship was completely terminated. However, the board of medicine may examine the specific circumstances surrounding the relationship to determine whether it was completely terminated. A psychiatrist may never engage in sexual contact with a current or former patient or the patient's guardian, even if the patient consents. A physician is also prohibited from engaging in sexual harassment.~~

BEFORE THE IOWA BOARD OF MEDICINE.

Re:)
)
PETITION BY TIMOTHY FOLEY,)
ADITI RAO, ALEX BARE, ET AL. FOR)
AMENDMENT OF 653 IAC CHAPTER 13) **ORDER DENYING PETITION**
RELATING TO SEXUAL ORIENTATION) **FOR RULEMAKING**
CHANGE PRACTICES)

I. SUMMARY

On February 23, 2016, Timothy Foley, Aditi Rao, Alex Bare, et al. (Petitioners) submitted a petition (EXHIBIT A) to the Iowa Board of Medicine (Board), pursuant to Iowa Code § 17A.7 and Iowa Administrative Code 653-1.7, to amend 653 IAC 13, which establishes standards of practice and principles of medical ethics for administrative medicine physicians, medical physicians and surgeons, and osteopathic physicians and surgeons. Petitioners requested the adoption of a new rule, 653 IAC 13.13, with the following language to prohibit physicians from engaging in sexual orientation change efforts with any individual less than 18 years of age:

13.13(1) *Definitions. For the purpose of this rule:*

“Sexual Orientation Change Efforts” include any practice by a licensed physician that seeks to change an individual’s sexual orientation, including but not limited to the efforts to change behaviors or gender expressions or gender identity, or to eliminate or reduce sexual or romantic attractions or feelings toward individuals of the same sex. “Sexual orientation change efforts” does not include any of the following:

(a) Counseling or therapy that provides acceptance, support, and understanding of the individual or the facilitation of an individual’s coping, social support, and identity exploration and development, including sexual orientation-neutral interventions to prevent or address unlawful conduct or unsafe sexual practices.

(b) Psychotherapies that do not seek to change sexual orientation.

(c) Counseling for an individual seeking to transition from one gender to another.

“Physician” is any individual licensed to practice medicine pursuant to Iowa Code Chapter 148 or any physician that has the capability to prescribe or prescribe and furnish medication for human ailments

13.13(2) Notwithstanding any law to the contrary, physicians shall not engage in Sexual Orientation Change Efforts as defined in this section with any individual less than eighteen years of age

13.13(3) The Iowa Board of Medicine shall enforced this rule through appropriate disciplinary proceedings established pursuant to Iowa Code §

148.6(2)(g) and all other administrative or disciplinary proceedings within the Board's statutory jurisdiction. All disciplinary proceedings shall be in done in accordance to Iowa Code § 148.7

On April 8, 2016, the Board held a public hearing on the petition for rulemaking to hear from interested parties. See 653 IAC 1.7(4)(c) (allowing the Board to schedule oral presentation of Petitioners' views). The Board heard from parties both for and against the petition. Following the public hearing, the Board deliberated the action to be taken on the petition.

II. DENIAL OF PETITION

Upon receipt of a Petition for Rulemaking, "within sixty days after submission of the petition, the agency either shall deny the petition in writing on the merits, stating its reasons for the denial, or initiate rulemaking proceedings in accordance with section 17A.4..." Iowa Code § 17A.7(1); 653 IAC 1.7(4)(d). The Board on April 8, 2016, determined it did not have sufficient facts to initiate rulemaking at this time. 653 IAC 1.7(2)(b) requires "facts in sufficient detail to show the reasons for the proposed action." The petition cited numerous authorities supporting its request although no studies or evidence were provided to the Board. Accordingly, the Board lacked the ability to evaluate the facts and evidence cited. The Board voted 9-0 to deny the petition and to issue a formal order by April 22, 2016. The Board then voted 8-1 to establish a subcommittee and engage stakeholders to study sexual orientation change efforts and to consider rulemaking at a later date. The Board recognized that other professions such as mental health therapists, marital and family therapists and psychologists may be interested in participating in the subcommittee's study and review of this matter. The subcommittee's activities will allow the Board to gather and evaluate evidence regarding sexual orientation change efforts and to bring all interested professions to the discussion. Further, it will give the Board the time and opportunity to consider whether the language and definitions contained within the rule presented in the petition are appropriate or whether the proposed rule needs revised. The Board noted that evidence presented at the hearing indicated physicians in Iowa are not currently engaged in sexual orientation change efforts so there is no evidence that immediate action is necessary to protect the citizens of Iowa at this time. Consequently, the Board has time to conduct a thoughtful and careful consideration of the practice and the proposed language in the petition.

THEREFORE, IT IS HEREBY ORDERED that the Petition for Rulemaking filed by Timothy Foley, Aditi Rao, Alex Bare, et al. is hereby **DENIED**.

22nd day of April, 2016.



Hamed Tewfik, M.D., Chairman
Iowa Board of Medicine

Judicial review of the Board's action may be sought in accordance with the terms of the Iowa Administrative Procedure Act, from and after the date of this Order, pursuant to Iowa Code § 17A

EXHIBIT A

Before Iowa Board of Medicine

02-23-16P12:51 RCVD

Petition by Timothy Foley, Aditi Rao,
Alex Bare et al for the adoption of rules
relating to Sexual Orientation Change
Practices



PETITION FOR
RULE MAKING

1. Text of Proposed Rule Amendment

IAC 653—13.13 is amended to read as follows:

13.13(1) Definitions. For the purpose of this rule:

“Sexual Orientation Change Efforts” include any practice by a licensed physician that seeks to change an individual’s sexual orientation, including but not limited to efforts to change behaviors or gender expressions or gender identity, or to eliminate or reduce sexual or romantic attractions or feelings toward individuals of the same sex. “Sexual orientation change efforts” do not include any of the following:

(a) Counseling or therapy that provides acceptance, support, and understanding of the individual or the facilitation of an individual’s coping, social support, and identity exploration and development, including sexual orientation-neutral interventions to prevent or address unlawful conduct or unsafe sexual practices.

(b) Psychotherapies that do not seek to change sexual orientation.

(c) Counseling for an individual seeking to transition from one gender to another.

“Physician” is any individual licensed to practice medicine pursuant to Iowa Code Chapter 148 or any physician that has the capability to prescribe or prescribe and furnish medication for human ailments

13.13(2) Notwithstanding any law to the contrary, physicians shall not engage in Sexual Orientation Change Efforts as defined in this section with any individual less than eighteen years of age

13.13(3) The Iowa Board of Medicine shall enforce this rule through appropriate disciplinary proceedings established pursuant to Iowa Code §148.6(2)(g) and all other administrative or disciplinary proceedings within the Board’s statutory jurisdiction. All disciplinary proceedings shall be done in accordance with Iowa Code §148.7.

2. Statutory Jurisdiction of the Iowa Board of Medicine

Pursuant to IAC 653—1.3(1) the Iowa Board of Medicine “makes policy relative to matters involving medical and acupuncture education, licensure, practice, and discipline.” This rulemaking power vested in the Board grants it the jurisdiction to promulgate standards of practice which this petition seeks to amend.

This section also gives the Board standing to pursue disciplinary proceedings against those under its purview that violates this rule. Pursuant IAC 653—1.3(5)(d) the Board may “initiate and prosecute disciplinary proceedings” for those granted a license to practice if a licensee violates a standard of practice.

The legal precedent also exists because the Iowa Board of Medicine has adopted its standard of practice rules before, specifically in 653-13.5-13.15. This previous regulation of practices related to the execution of duties incumbent upon a doctor establishes sufficient legal grounds for which the board may pursue discipline.

3. Arguments in Favor of Adoption

Sexual Orientation Change Efforts (SOCE) have been rejected as valid medical procedure and has little to no scientific backing among professionals. A professional task force established by the American Psychological Association has concluded that “Recent studies provide no sound scientific basis for determining the impact of SOCE on decreasing same-sex sexual attraction” This conclusion has been corroborated by multiple professional organizations.

Despite its scientific absurdity this process continues to operate throughout the United States, and has been found in some jurisdictions to be a form of consumer fraud in New Jersey (See *King v. Christie*). Further, a similar law passed in California was upheld as the court concluded that such a law does not violate the first amendment nor does it breach any kind of professional-client relationship. This decision was not appealed and as of the drafting of this petition this is the only litigation on the question of gay conversion therapy.

Although its support has been scientifically and legally rejected SOCE continues to exist in Iowa and the United States at large. It is estimated that one third of lesbian, gay, bisexual, transgender, or question young people will be subjected to these practices at some point during their teenage years. The same study by the American Psychological Association that declared these efforts lacked sufficient scientific foundation concluded that those who have been subjected to this form of pseudo therapy have “report experiencing serious distress, including depression, identity, confusion, and fear due to the strong prohibitions of their faith regarding same- sex sexual orientation, behaviors, and relationships.” This depression is empirically linked to higher suicide rates later in life.

4. Underlying Statistics in Favor of Adoption

34% of LGBTQ individuals report having been sent outside the home to a therapist or religious leader to “cure, treat, or change their sexual orientation” during their teenage years. This correlates to suicidal thoughts and actions that are approximately four times higher than gay youth’s heterosexual counterparts. According to a survey of 55 transgender young people 40% of

young people have either attempted or seriously considered suicide compared with the national average of 17%.

5. Names and Addresses of Parties Favoring Adoption, including relevant groups

695 Signatories to an online petition urging action on the question of Sexual Orientation Change Efforts, whose names and postal codes are provided in Appendix I.

The interest of Iowa's young people, whose representatives have endorsed this legislation by a unanimous 22-0 vote who recognize the severity of the issue and prevent the course of action contained in this petition.

The Iowa LGBTQ community, specifically the young people, who have been subjected to this heinous practice oftentimes against their will and who seek to be accepted as full members of their society.

The following individuals who strongly urge the Board of Medicine to take action in the form of adopting the text of the rule written in part one of this petition.

Timothy Foley
1793 NW 122nd Ct.
Clive, IA 50325

Aditi Rao
141 Sandahlwood Circle
Cedar Falls, IA, 50613

Navaneetha Rao
141 Sandahlwood Circle
Cedar Falls, IA, 50613

Gita Rao
141 Sandahlwood Circle
Cedar Falls, IA, 50613

Alexander Bare
10135 210th St.
Walcott, IA 52773

Tara Djukanovic
9023 Cowden Drive
Johnston, Iowa

David A. Graham
4824 Lorraine Avenue
Sioux City, IA 51106-4115

Jean A. Graham
4824 Lorraine Avenue
Sioux City, IA 51106-4115

Aastha Chandra
3109 Stratford Ct
Cedar Falls, IA 50613

Alyson Brooke Sorensen
58 Cottner Drive
Council Bluffs IA, 51503.

Christopher Sorensen
58 Cottner Drive
Council Bluffs IA, 51503.

Megan Sorensen
58 Cottner Drive
Council Bluffs IA, 51503.

Xiao Liu
9016 Telford Circle
Johnston IA, 50131.

Katarina Walther
4606 Hudson Road
Cedar Falls, IA 50613

Elise Margulies

3863 Timberline Drive
West Des Moines, IA 50265

Kate Jaros
2863 260th Street
St. Charles, IA

Jack Jaros
2863 260th Street
St. Charles, IA

Andrew Dunn
1620 16th
St. Milford, IA 51351

Parker Day
5835 Wistful Vista Dr.
West Des Moines, IA 50266

Manasi Singh
355 S 84th St
West Des Moines, IA 50266

Annie Zhang
1107 65th St
West Des Moines, IA 50266

Evan McKinney
2135 Country Club Blvd.
Clive, IA 50325

Meta Miller
1480 Country Club Blvd.
Clive, IA 50325

Madison VanSickel
509 7th Ct.
West Des Moines, IA 50266

Ilsa Knivslund
414 West 11th St.
Cedar Falls, IA 50613

Danielle Templeton
416 Alvarado Ave,
Cedar Falls, IA 50613

Denise E. Hagerla
6000 University Ave., Suite 200
West Des Moines, IA 50266

Donna Redwing
3839 Merle Hay Rd #274
Des Moines, IA 50310

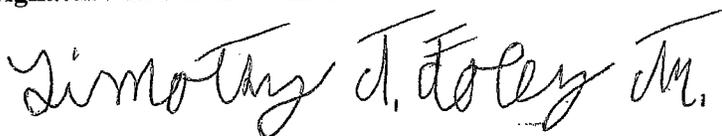
Keenan Crow
3839 Merle Hay Rd #274
Des Moines, IA 50310

Erica Barz
3839 Merle Hay Rd #274
Des Moines, IA 50310

Linda Foster
3839 Merle Hay Rd #274
Des Moines, IA 50310

Terri Bailey
125 S. 3rd St
Ames, IA 50010

Signature and Contact Information



Timothy J. Foley
Petitioner
(515) 537-4078

References

"Appropriate Therapeutic Responses to Sexual Orientation." American Psychological Association. Print.

California. Hearings on the Declaration of Caitlin Ryan. Testimony of Caitlin Ryan. 2012 Leg. ECF-41. N.p.: n.p., n.d. Print.

Centers for Disease Control and Prevention. "LGBT Youth." Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, 12 Nov. 2014. Web. 18 Apr. 2015.

Centers for Disease Control and Prevention. "Suicide Facts at a Glance 2015." N.p. Web. Accessed 14 February 14, 2016.

Bagley, Christopher and Pierre Tremblay. *Elevated rates of suicidal behavior in gay, lesbian, and bisexual youth*. Crisis: The Journal of Crisis Intervention and Suicide Prevention, Vol 21(3), 2000, 111-117.

King v. Christie, 2013 U.S. Dist. LEXIS 160035 (D.N.J. 2013)

Pickup v. Brown, 728 F.3d 1042 (9th Cir. 2013)

Appendix I: Online Signatories