

DEPARTMENT OF REGULATORY AGENCIES

Colorado Medical Board

RULE 800 - RULES REGARDING THE DELEGATION AND SUPERVISION OF MEDICAL SERVICES TO UNLICENSED PERSONS PURSUANT TO SECTION 12-36-106(3)(I), C.R.S.

3 CCR 713-30

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

INTRODUCTION

Basis. The general authority for promulgation of these Rules by the Colorado Medical Board ("Board") is set forth in sections 12-36-104(1)(a) and 24-4-103, C.R.S.

Purpose. The following Rules have been adopted by the Board to clarify the requirements of section 12-36-106(3)(I), C.R.S. (the "Delegation Statute"). The Delegation Statute governs the delegation of medical services to, and personal and responsible direction and supervision over, a person who is **not** licensed to practice medicine or otherwise licensed to perform the delegated medical services. This Rule does not govern delegation of medical services to physician assistants, anesthesiologist assistants or those individuals regulated by the Board of Nursing. Such delegation is governed by Rules 400 and 510, and the Nurse Practice Act, section 12-38-101 *et seq.*, C.R.S., respectively.

Scope of Rules. These Rules apply to the delegation of services constituting the practice of medicine to a person who is not licensed to practice medicine, is not qualified for licensure as a physician, physician assistant or anesthesiologist assistant, and is not otherwise exempt pursuant to section 12-36-106, C.R.S. from holding a license to practice medicine.

SECTION 1. MEDICAL SERVICES THAT MAY BE DELEGATED UNDER THESE RULES

A. Medical Services

1. "Medical services" are defined by the Medical Practice Act, section 12-36-106, C.R.S., to include suggesting, recommending, prescribing, or administering any form of treatment, operation, or healing for the intended palliation, relief, or cure of any physical or mental disease, ailment, injury, condition or defect of any person.
2. "Medical services" also include holding oneself out to the public as being able to diagnose, treat, prescribe for, palliate or prevent any human disease, ailment, pain, injury, deformity, or physical or mental condition. "Medical services" are further defined by section 12-36-106(1), C.R.S.
3. "Medical Services" includes those acts, other than those acts excluded by subsection (D) of this Section, performed pursuant to physician delegation by unlicensed persons or licensed healthcare professionals.

B. Medical-Aesthetic Services

1. "Medical-Aesthetic Services" are medical services in the cosmetic or aesthetic field that constitute the practice of medicine. Such Medical-Aesthetic Services include, but are not limited to: (a) the use of a Class IIIb or higher laser, radio-frequency device, intense pulsed light, or other technique that results in the revision, destruction, incision or other structural alteration of human tissue and/or for hair removal; and (b) the performance of injection(s) of any substance into the human body except as may be permitted pursuant to section D.
2. As with all delegated medical services, delegated Medical- Aesthetic Services must be of the type that a reasonable and prudent physician would find within the scope of sound medical judgment to delegate. Consequently, delegated Medical-Aesthetic Services should be routine, technical services, the performance of which do not require the special skills of a licensed physician.
3. Off-label use of medications or devices when performing delegated Medical-Aesthetic Services is generally prohibited unless:
 - a. the delegating physician has specifically authorized and delegated the off-label use, and,
 - b. the off-label use is within generally accepted standards of medical practice.
4. Medical-Aesthetic Services must be delivered within a facility appropriate to the delegated service provided and listed on the written agreement as set forth in Appendix A.

C. Use of Lasers

1. The revision, destruction, incision, or other structural alteration of human tissue using laser technology is a medical service and constitutes the practice of medicine, as defined in Section 12-36-106, C.R.S.
2. Use of Class IIIb or higher lasers or pulse light devices as constitutes the practice of medicine.

D. Acts That Do Not Constitute Medical Services

1. The definition of medical services under the Medical Practice Act does not include acting as an intermediary by communicating a physician's message or order to another person, or otherwise carrying out education activities as directed by the physician. Therefore a person who merely acts as an intermediary to communicate a physician's message or order to another person is not subject to these Rules.
2. The definition of medical services under the Medical Practice Act does not include gathering data. A person who merely gathers data is not subject to these Rules. For example, performing phlebotomy, measuring vital signs, and gathering historical patient information is not subject to these Rules.
3. Tattooing, application of permanent makeup, superficial exfoliative therapies, such as microdermabrasion, other superficial skin treatments, and those services regulated by the Barber and Cosmetologist Practice Act, section 12-8-101, *et. seq.*, C.R.S., are not medical services.

4. The use of Class I, II, and IIIa medical devices, including Class I,II, and IIIa lasers, does not constitute a medical service.
 5. Monitoring of medication compliance is not a medical service.
 6. Medication administration by Qualified Medication Administration Personnel (QMAP) who are regulated by the Colorado Department of Public Health and Environment is not included within the definition of medical services for purposes of this Rule.
- E. Delegated Medical Services Should Not Require Exercise of Medical Judgment
1. A physician should not delegate a medical service requiring the exercise of medical judgment by the delegatee.
 2. Delegated medical services should be limited to routine, technical services that do not require the special skills of a licensed physician.
- F. Medical Services that May Not Be Delegated
1. Prescription Medications
 - a. Prescribing of drugs may not be delegated under section 12-36-106(3)(I), C.R.S. and these Rules.
 - b. The ordering of a prescription refill by a delegatee does not constitute “the prescribing of drugs” provided that:
 1. The prescription refill is ordered at the same dose and for the same medication as the original prescription for that patient; and
 2. The prescription refill is ordered pursuant to a written refill protocol developed and authorized by one or more delegating physicians.
 2. Non-Prescription Medications
 - a. The recommendation of marijuana as a therapeutic option may not be delegated under section 12-36-106(3)(I), C.R.S., and these Rules.

SECTION 2. RULES GOVERNING INDIVIDUALS WHO CHOOSE TO DELEGATE MEDICAL SERVICES

- A. Who May Delegate
1. Licensed physicians may delegate the performance of medical services to delegates, in conformance with these Rules.
 2. To delegate a medical service, an eligible delegating physician must be:
 - a. Qualified by education, training and experience to perform the medical service;
 - b. Actively performing the medical service as part of his or her medical practice and not exclusively by delegating the service to a delegatee;
 - c. Insured to perform the medical service; and

- d. Actively practicing medicine and available in the community where the delegated medical services occur.
 1. To be “available in the community,” a physician must be physically present in the State and able to promptly, personally consult with or otherwise provide follow up care to the patient.
 2. A delegating physician may utilize telehealth technologies, where appropriate, to satisfy the requirements for prompt personal consultation or follow-up care, but should not rely exclusively on such telehealth technologies to perform those services.
 3. Physician assistants or anesthesiologist assistants may delegate medical services to unlicensed healthcare providers who are acting under the direct supervision of the licensed physician assistant or anesthesiologist assistant, where appropriate, within the scope of the physician assistant's or anesthesiologist assistant's delegated medical services.

B. Who May Not Delegate

1. Delegated services cannot be re-delegated to another party by the delegatee.
2. A person who holds a physician training license pursuant to section 12-36-122, C.R.S. is not authorized to delegate medical services pursuant to section 12-36-106(3)(l), C.R.S. and these Rules.
3. Persons with a limited medical license may not delegate pursuant to these rules any medical services for which the licensee is prohibited from performing.

SECTION 3. RULES GOVERNING INDIVIDUALS TO WHOM MEDICAL SERVICES ARE DELEGATED (“DELEGATEES”)

A. Persons Who May Serve as Delegates

1. Qualified by Education, Training or Experience
 - a. The delegating physician must evaluate and determine that the delegatee has the necessary education, training or experience to perform each delegated medical service.
 - b. As part of his or her evaluation, the delegating physician shall personally assess and review:
 1. Copies of diplomas, certificates or professional degrees from bona fide training program(s) appropriate to the specific services delegated; and,
 2. Appropriate credentialing by a bona fide agency, Board or institution, if applicable.
 3. In any practice which utilizes a credentialing committee or a human resources department for verification of credentials, a delegating physician may rely on a credentialing committee or a human resources department for verification of Section 3(A)(1)(b)(1) and (2).

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- c. The delegating physician shall perform over-the-shoulder direct observation of the delegatee's performance of any medical service prior to authorizing the delegatee to perform the medical service outside of the delegating physician's physical presence. A delegating physician may rely on another Colorado Medical Board licensee's evaluation of the delegatee's skill to perform medical services.
 2. In the event that a delegating physician chooses to delegate medical services to a person holding a license, certificate or registration, and the delegated services are beyond the scope of that person's license, certificate or registration, the delegating physician must ensure that the delegatee is qualified by additional education, training or experience beyond that required for the delegatee's license, certificate or registration. Any delegation described in this paragraph must comply with the requirements of this Rule 800.
 3. These Rules apply to individuals who are certified by a national or private body but who do not have Colorado state licensure, registration or certification.
 4. Graduates of physician assistant and anesthesiologist assistant programs who have not yet taken the certification examination, and thus, are not qualified for licensure, may perform delegated medical services pursuant to section 12-36-106(3)(I), C.R.S., until such time as they have been notified that they have passed the certification exam and are eligible for a Colorado license. The delegating physician and the unlicensed physician assistant graduate or unlicensed anesthesiologist assistant graduate shall comply with the requirements of these Rules until the physician assistant or anesthesiologist assistant is licensed and subject to Board Rule 400 or 510.
 5. Medical aesthetic service instructors at institutions accredited/certified by the Department of Higher Education may serve as delegatees provided the instructor possesses the necessary education, training or experience to perform each delegated medical service.
 - a. The physician may delegate the medical service to such Instructor and students at the aforementioned institution to be performed by the student under the direct supervision of the instructor.
 - B. The delegating physician and the delegatee shall take appropriate measures to ensure that delegatees are identified in a manner that prevents confusion as to the delegatees' qualifications and legal authority to provide medical services. Following are examples of situations in which confusion as to the delegatees' qualifications and legal authority to provide medical services is likely and in which the physician and the delegatee shall be responsible for taking effective measures to prevent such confusion. This list is illustrative and not exhaustive.
 1. A delegatee who is a "radiology practitioner assistant" uses the acronym "RPA", which is easily confused with the title of a licensed physician assistant or PA;
 2. A delegatee uses the word "licensed" as part of a title when the delegatee is not licensed, registered, or certified by the state of Colorado to perform the medical services at issue;
 3. A delegatee uses the word "doctor" or the abbreviation "Dr." when acting as a delegatee; or
 4. A delegatee who is an "aesthetician" uses the word "medical" as part of a title, such as "medical aesthetician", when the delegatee is not licensed, registered or certified by the state of Colorado to perform medical services.
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- C. Persons Not Eligible to Serve as Delegates
1. A physician shall not delegate medical services to any person who is otherwise qualified to be licensed by the Board as a physician, physician assistant or anesthesiologist assistant but who is not so licensed, including, but not limited to:
 - a. Any physician, physician assistant or anesthesiologist assistant with an inactive, expired, revoked, restricted, limited, suspended or surrendered license;
 - b. Any physician, physician assistant or anesthesiologist assistant (other than those physician assistants or anesthesiologist assistants authorized pursuant to Section 3(A)(4) of these Rules) who meets all qualifications for licensure but who is not licensed in Colorado; and
 - c. Any physician, physician assistant or anesthesiologist assistant whose application for licensure in the State of Colorado has been denied unless the denial is pursuant to section 12-36-116(1)(a), C.R.S.
 2. Medical services shall not be delegated to any person who holds a physician training license pursuant to section 12-36-122, C.R.S.
- D. Exceptions
1. These Rules do not apply to a person performing acts that do not constitute the practice of medicine as defined by section 12-36-106(1), C.R.S.
 2. These Rules do not apply to health care providers who are licensed, registered or certified by the state of Colorado and who are acting within their scope of practice.
 3. These Rules do not apply to a registered nurse (also known as a professional nurse or an RN). Services provided by a registered nurse, either as an independent nursing function or a delegated medical function, are governed by the Nurse Practice Act.
 4. These Rules do not apply to any person who is otherwise exempt pursuant to section 12-36-106, C.R.S. from holding a license to practice medicine and who is acting within the scope of the specific statutory exemption.

SECTION 4. RULES GOVERNING THE DELEGATING PHYSICIAN'S DELEGATION OF AUTHORITY TO PROVIDE MEDICAL SERVICES.

- A. Any medical service rendered by the delegatee must conform to the same standard applicable if the delegating physician performed the service personally.

SECTION 5. RULES GOVERNING THE DELEGATING PHYSICIAN'S REQUIREMENTS FOR SUPERVISION OF DELEGATEES

- A. The delegating physician must:
1. Provide ongoing inspection, evaluation, advice and control;
 2. Make decisions as to the necessity, type, effectiveness and method of treatment;
 3. Provide sufficient on-the-spot inspection to determine that the physician's directions are regularly being followed;

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4. Monitor the quality of the services provided by the delegatee; and,
 5. Provide personal and responsible direction and supervision that is consistent with generally accepted standards of medical practice.
- B. The physician's direction and supervision of the delegatee shall be sufficient to limit the need for a delegatee to exercise the judgment required of a physician.
 - C. Delegated services must be provided in the context of an appropriate physician/patient relationship.
 - D. Ongoing care of a particular patient without direct physician involvement is inappropriate and demonstrates insufficient personal and responsible direction and supervision of a delegatee.
 1. Factors establishing the presence of an appropriate physician/patient relationship include, but are not limited to, some or all of the following: physician performance of an initial consultation with the patient, direct observation by the physician of delegated services rendered by the delegatee, physician review of care rendered to the patient by the delegatee, physician review of outcomes following the performance of delegated services, and other active physician involvement in the provision, review and documentation of services provided by the delegatee.
 - E. Except as otherwise provided in these Rules, a physician must be on the premises and readily available to provide adequate personal and responsible direction and supervision.
 - F. Where a delegatee is acting pursuant to specific and detailed written protocols and where adequate written emergency protocols are in place, the presence of the delegating physician on the premises may not be necessary. However, a delegating physician must be physically present in the State and available to promptly, personally attend to the patient. At any time when a delegating physician is not physically present within the State, the delegating physician must identify and provide the contact information to delegates of a covering physician who is physically present in the State and available to promptly, personally attend to the patient.
 - G. At least every two weeks, the delegating physician must monitor the quality of the services provided by the delegatee through such means as direct observation, review of care, review of outcomes, review of equipment, review of protocols and procedures and review of charts. The monitoring must occur at the site where the delegated services are performed.
 - H. On at least an annual basis, the delegating physician must personally reassess the qualifications and competence of the delegatee to perform the medical services. This reassessment must include, but must not be limited to, over-the-shoulder monitoring of the delegatee's performance of each delegated medical service.
 - I. The delegating physician must document the initial assessment and follow-up reassessments of the delegatee's performance of the delegated medical services. Upon request, the delegating physician must provide such documentation to the Board.
 1. In a hospital or medical practice, a delegating physician may rely on a credentialing committee, human resources, or other documented institutional process/es for verification of this Section 5(F),(G),(H) and(I).
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SECTION 6. DOCUMENTATION REQUIREMENTS

A. Written Procedure Protocols

1. Written procedure protocols are required to be in place at any time that a delegating physician will not be physically located on the premises where medical services are provided by a delegatee.
2. The delegating physician shall create a comprehensive written protocol for use by the delegatee for each procedure that the physician delegates to the delegatee. The delegating physician may not rely upon a written protocol created by the delegatee to satisfy this requirement.

B. Written Emergency Protocols

1. Written emergency protocols are required to be in place at any time that a delegating physician will not be physically located on the premises where medical services are provided by a delegatee.
2. The delegating physician shall create a comprehensive written emergency protocol for use by the delegatee when medical services result in adverse events. The delegating physician may not rely upon a written protocol created by the delegatee to satisfy this requirement.
3. As part of a written emergency protocol, the delegatee shall be required to notify the delegating physician of all adverse events.

C. Medical Records

1. A delegating physician shall assure that there is a timely medical record for all patient contacts with either the delegatee or with the delegating physician. The medical record prepared by a delegatee shall conform to generally accepted standards of medical practice for recordkeeping.
2. A delegating physician shall review the care provided to every patient who is treated by the delegatee. The delegating physician shall demonstrate that he or she has reviewed the care provided to the patient by reviewing each entry in the patient's medical record. The delegating physician shall initial and date the medical record at the time he or she reviews the record.
3. A delegating physician shall review the care provided to patients pursuant to his or her delegated authority within fourteen days of the date that the care was provided.
4. When the delegated medical services by delegates occur in the context of a same-day encounter with the delegating physician and the delegating physician has been personally involved in the care of the patient, the delegating physician's own documentation of the encounter shall be adequate to meet the requirements for chart review, and the delegating physician need not co-sign any entries made by the delegatee.

D. Written Agreement between Delegating Physician and Delegatee

1. The delegating physician and the delegatee must have a written agreement documenting and detailing the relationship. This written agreement is attached in Appendix A of these Rules. The written agreement as set forth in Appendix A must be available to the public at the site where the delegated medical services are performed.

2. The delegating physician must maintain a list of all delegates to whom the physician has delegated medical services. The list must include a comprehensive and specific list of the delegated medical services that the physician has authorized the delegatee to perform.
 3. Where the delegating physician is on-site and able to personally direct the delegatee at least 60% of the time, the requirement for a written agreement may be satisfied through job descriptions, personnel records or other documents that identify the relationship between the delegating physician and delegatee.
- E. Documentation that the Delegating Physician or Healthcare Facility Must Maintain
1. The delegating physician or healthcare facility shall maintain a copy of all documentation required by these Rules, including but not limited to:
 - a. Appendix A written agreement;
 - b. Any agreement that the delegating physician enters into, in order to serve as a medical director.
 2. The delegating physician or healthcare facility is required to maintain all documentation required by these Rules.
 3. Upon request, the delegating physician is responsible to provide all documentation maintained by the physician or healthcare facility in accordance with these Rules to the Board. The delegating physician may not rely solely on a medical office or other entity to provide the requested documents.
- F. Disclosure Requirements to Patients
1. Delegating physicians shall ensure that delegates adequately disclose that a medical service will be performed by a delegatee, rather than by the delegating physician. When the delegating physician is not actively involved in the patient encounter, the disclosure shall include: the service the patient is receiving is a medical service; the delegatee of the service is not licensed by the state of Colorado or is acting beyond the scope of his or her Colorado license, certification or registration; the delegatee is providing the service pursuant to the delegated authority of a physician; and, the delegating physician is available personally to consult with them or provide appropriate evaluation or treatment in relation to the delegated medical services. Upon request, the delegating physician must timely and personally provide such consultation, evaluation or treatment, or provide appropriate follow-up care and/or referrals.
 - a. The disclosure requirements may be made in writing as part of a signed disclosure agreement, an Informed Consent agreement, or a Consent or Agreement to Treat form.
 2. For all delegated medical services occurring in the context of a bona fide physician-patient relationship, the delegating physician and the delegatee shall document the disclosure made to the patient, at the time each medical service is performed.
 3. For all offices at which delegated medical-aesthetic services are provided, the delegating physician shall ensure that each office conspicuously posts, in the office's reception area, a notice with the name and contact information for each delegating physician.

4. For all offices at which delegated medical-aesthetic services are provided, the delegating physician shall create a written disclosure, identifying the service to be performed, that the performance of the medical service is delegated to an unlicensed person, the name of the unlicensed person/delegatee, and the name and contact information for the delegating physician. The written disclosure shall be signed by the patient prior to receiving the medical service. The patient shall be given a copy of each disclosure and a copy shall be retained within the patient's medical record.
5. The delegating physician must ensure that each patient receives all information necessary to give appropriate informed consent or consent or agreement for treatment for any medical service and that such informed consent or consent or agreement for treatment is timely documented in the patient's chart.

SECTION 7. UNPROFESSIONAL CONDUCT

- A. It is a violation of these Rules for any physician to have delegated medical services without complying with the provisions of these Rules.
- B. It is a violation of these Rules for a licensee to perform delegated medical services pursuant to these Rules, when such licensee is otherwise restricted from performing such acts.
- C. It is a violation of these Rules for any person qualified for licensure by this Board and who later applies for licensure by this Board, to have performed delegated medical services or to have delegated medical services pursuant to section 12-36-106(3)(l), C.R.S. prior to licensure in Colorado.
- D. Any violation of these Rules may be determined to be unprofessional conduct pursuant to Section 12-36-117(1)(u), C.R.S.
- E. To the extent that delegates do not provide delegated medical services within generally accepted standards of medical practice, the delegating physician may be determined to have committed unprofessional conduct pursuant to Section 12-36-117(1)(p), C.R.S.
- F. To the extent that delegates falsify or repeatedly make incorrect essential entries on patient records, or repeatedly fail to make essential entries on patient records, the delegating physician may be determined to have committed unprofessional conduct pursuant to Section 12-36-117(1)(cc), C.R.S.
- G. In the event that a delegating physician fails to produce to the Board, upon its request through a 30-day letter, a copy of any document required to be maintained by these Rules, the Board may determine that the delegating physician has committed unprofessional conduct pursuant to Section 12-36-117(1)(gg), C.R.S.

SECTION 8. UNLICENSED PRACTICE OF MEDICINE

- A. Pursuant to section 12-36-106(2), C.R.S., any person who performs any of the acts constituting the practice of medicine as defined by section 12-36-106(1), C.R.S. and who is not licensed by the Board to practice medicine or exempt from licensure requirements by some provision of section 12-36-106, C.R.S. shall be deemed to be practicing medicine without a license. No person shall be exempt from medical licensure requirements pursuant to section 12-36-106(3)(l), C.R.S., unless such person is acting in conformance with these Rules.

- B. A person who practices medicine without a license may be the subject of a cease and desist order pursuant to section 12-36-118, C.R.S. Such person may also be the subject of injunctive proceedings by the Board in the name of the People of the State of Colorado pursuant to section 12-36-129(6), C.R.S. Such person may also be held criminally liable pursuant to section 12-36-129(1), C.R.S. Finally, such person may be subject to any other enforcement allowed under the law.

Adopted 11/15/02, Effective 1/30/03; Revised 04/14/05, Effective 06/30/05; Revised 10/13/05, Effective 11/30/05, Revised 5/11/06, Effective 7/2/06; Repealed and Readopted 5/22/08, Effective 6/30/08; Revised 08/19/10; Effective 10/15/10; Revised 11/18/2010; Effective 01/14/2011; Emergency-Revised 4/20/17, Effective 4/20/17; Permanent-Revised 4/20/17, Effective 6/14/17

BOARD RULE 800, APPENDIX A

**Agreement Between Delegating Physician and Delegatee Performing
Medical Services
Under Colorado Medical Board Rule 800**

_____ and
(Print Name & Title of Delegating Physician)

_____,
attest that: (Print Name & Title of Delegatee)

The delegating physician is licensed in the state of Colorado to practice medicine.

The delegating physician is qualified to perform each delegated medical service listed below, and actively performs each listed medical service as part of his or her medical practice and not exclusively by delegating the medical service to a delegatee.

The delegated services listed below are routine, technical services, the performance of which does not require the special skills of a licensed physician.

The delegating physician is insured to delegate the delegated services listed below.

The delegating physician is not legally restricted from performing the delegated services listed below.

The delegating physician is providing personal and responsible direction and supervision to the delegatee by complying with Colorado Medical Board Rule 800 ("Rule 800").

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The delegating physician is delegating the following services and understands that (s)he is fully accountable for the performance of these services by the delegatee. (Note: the description of the delegated medical services must be specific and detailed.)

The delegated medical services will be performed at the following facilities.
(Note: please include the name and address of each facility.)

The delegating physician has personally assessed the qualifications and competence of the delegatee to perform the Medical Services listed above. The assessment included, but was not limited to, initial over-the-shoulder monitoring of the delegatee's performance of each delegated Medical Service. The delegating physician will reassess the competence and performance of the delegatee on at least an annual basis as set forth in Rule 800.

It is agreed that all patients receiving a delegated Medical Service will be informed that the delegating physician is available personally to consult with them or provide appropriate evaluation or treatment in relation to the delegated Medical Services. The delegating physician shall timely and personally provide such consultation, evaluation or treatment to the patient upon request. The delegating physician will ensure that each patient receives all information to give appropriate informed consent for any Medical Services and that such informed consent is timely documented in the patient's chart.

In the event of an adverse outcome resulting from a delegated medical service, the delegating physician will provide appropriate follow-up care and/or referrals.

It is expressly agreed that the delegatee will only provide the delegated services listed in this document, unless the delegatee is separately licensed or otherwise legally authorized to provide other services not listed in this document.

This agreement shall remain in effect until formally rescinded in writing by either party.

(Signature & Title of Delegating Physician)

(Signature of Delegatee)

(Date)

(Date)

Editor's Notes

History

Entire rule eff. 06/30/2008.

Entire emer. rule eff. 07/01/2010.

Entire rule eff. 10/15/2010.

Entire rule eff. 01/14/2011.

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