



COLORADO

Department of
Regulatory Agencies

Division of Professions and Occupations
Healthcare Branch
Colorado Medical Board



NOTICE OF RULE MAKING HEARING

Pursuant to Section 24-4-103, C.R.S., and Section 12-36-104(1)(a), C.R.S., you are hereby advised that the Colorado Medical Board (“Board”) will hold a public rule making hearing on Thursday, April 20, 2017, at 1:30 p.m., 1560 Broadway, Conference Room 1250C, Denver, Colorado 80202, for consideration of the following:

Amending existing rules:

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.

The Board encourages interested parties to submit written comments regarding the proposed revisions to Rule 800 to the following address: Karen McGovern- Program Director, Colorado Medical Board, 1560 Broadway, Suite 1300, Denver, CO 80202, or via electronic mail to Jamie.groen@state.co.us regarding any of the above-listed rulemaking matters no later than Friday, March 31, 2017. In addition, at the time and place designated in this notice, the Board will afford interested parties an opportunity to submit written information, data, views or arguments. The Board also will afford interested parties an opportunity to make brief oral presentations unless the Board in its discretion determines that such oral presentations are unnecessary. All submissions will be considered. The rules under consideration may be changed or modified after public comment and hearing.

BY ORDER OF THE COLORADO STATE MEDICAL BOARD

Karen M. McGovern, Program Director

Dated this 15th day of March, 2017



**RULES REGARDING THE DELEGATION AND SUPERVISION OF MEDICAL SERVICES
TO UNLICENSED PERSONS ~~HEALTH CARE PROVIDERS~~ PURSUANT TO SECTION
12-36-106(3)(I), C.R.S.**

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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)(l), 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. Additionally, these Rules clarify particular requirements applicable to the delegation of medical services pursuant to section 12-36-106(3)(l), C.R.S. when the delegatee is performing Medical-Aesthetic Services as defined in Section VI(B) of these Rules.

Statutory provision.—~~These Rules interpret and clarify the requirements of section 12-36-106(3)(l), C.R.S., which provides as follows:~~

~~Under the personal and responsible direction and supervision of a person licensed under the laws of this State to practice medicine, a license to practice medicine is not required for the rendering of services, other than the prescribing of drugs, by persons qualified by experience, education, or training. Nothing in this exemption, however, shall be deemed to extend or limit the scope of any license, and this exemption shall not apply to persons otherwise qualified to practice medicine but not licensed to so practice in this State.~~

RULES

I. Scope of Rules. These Rules apply to the delegation of ~~medical~~ services constituting the practice of medicine to a person who is not licensed to practice medicine, is not qualified for licensure as a physician, or

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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-

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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 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

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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)(l), 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:

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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)(l), C.R.S., and these Rules.

~~A. Exemption from these Rules: Licensed providers practicing within their scope of practice.~~

~~1. 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. By way of example and not by way of limitation, these Rules do not apply to:~~

~~a. a licensed dentist practicing dentistry as defined by article 35 of title 12, C.R.S.,~~

~~b. a licensed pharmacist practicing pharmacy as defined by article 22 of title 12, C.R.S.,~~

~~c. a licensed physical therapist practicing physical therapy as defined by article 41 of title 12, C.R.S.~~

~~2. 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.~~

~~3. 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~~

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~~practice medicine and who is acting within the scope of the specific statutory exemption.~~

- ~~4. These Rules do apply to a licensed, registered or certified health care provider (other than a registered nurse) who acts outside his or her scope of practice. See section III(C) of these Rules. Additionally, these Rules do apply to individuals who are certified by a national or private body but who do not have Colorado state licensure, registration or certification.~~

~~B. Exemption from these Rules: Acts that do not constitute “medical services” as defined by the Medical Practice Act.~~

- ~~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. of the Medical Practice Act.~~
- ~~2. In part, “medical services” are defined by the Medical Practice Act 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. “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. 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.~~
- ~~4. 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, and 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.~~

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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.

B. Who May Not Delegate

1. Delegated services cannot be re-delegated to another party by the delegatee.

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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. 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.

4. Persons with a limited medical license may not delegate pursuant to these rules any medical services for which the licensee is prohibited from performing.

~~C. Limitations: Persons not eligible to serve as delegates under these Rules.~~

~~1. A physician shall not delegate medical services to any person who is otherwise qualified to be licensed by the Board as a physician or physician assistant but who is not so licensed, including, but not limited to:~~

~~a. Any physician or physician assistant with an inactive, lapsed, revoked, restricted, limited, suspended or surrendered license;~~

~~b. Any physician or physician assistant who meets all qualifications for licensure but who is not licensed in Colorado; and~~

~~c. Any physician or physician 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. Section 12-36-106(3)(l), C.R.S. shall not be deemed to extend or limit the scope of any license and may not be used to circumvent the revocation, suspension, surrender, restriction, limitation, inactivation, non-renewal or denial of a license to practice any~~

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~~field of the healing arts in the State of Colorado.~~

- ~~3. 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. Limitations: Physicians not eligible to delegate medical services under these Rules.~~

- ~~1. 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.~~

~~E. Limitations: Delegation by the delegatee prohibited.~~

- ~~1. Delegated services cannot be subsequently delegated to another party by the delegatee.~~

~~II. What "medical services" may be delegated under these Rules.~~

~~A. The prescribing of drugs may not be delegated under section 12-36-106(3)(l), C.R.S. and these Rules. The ordering of a prescription refill by a delegatee, however, 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.~~

~~B. In addition to other requirements set forth in these Rules, Medical Aesthetic Services performed by a delegatee must comply with the particular requirements set forth in Section VI of these Rules.~~

~~C. To delegate a medical service, the physician must be:~~

- ~~1. Qualified by education, training and experience to perform the medical service;~~

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~~2. Actively performing the medical service as part of his or her medical practice and not exclusively by delegating the service to a delegatee;~~

~~3. Insured to perform the medical service; and~~

~~4. Actively practicing medicine and available in the community where the delegated medical services occur.~~

~~D. Delegated medical 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 services should be routine, technical services, the performance of which do not require the special skills of a licensed physician.~~

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

~~III. Determination that a delegatee is “qualified by education, training or experience” to perform delegated medical services under these Rules.~~

~~a. The delegating physician must evaluate and determine It is the responsibility of the physician to ensure 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:~~

~~A. Upon request, the delegating physician must provide written documentation of the delegatee’s qualifications to the Board. Such documentation may include, but not be limited to:~~

~~1. Copies of diplomas, certificates or professional degrees from bona fide training program(s) appropriate to the specific services delegated; and~~

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~~2. Documentation of direct observation of the repeated and successful performance of the delegated services; and/or~~

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).

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)(l),

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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 the 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 delegates 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. If a physician wishes to delegate medical services to a person holding a license, certification or registration and the services are beyond the scope of that person's license, certification, or registration, the following requirements apply:~~

~~1. The person must have education, training or experience qualifying the person to perform the medical service in question, and this education, training or experience must be in addition to the education, training or experience related to the license, certification or registration. As an illustration, if consistent with these Rules, a physician may delegate a medical service that is beyond the scope of the practice of respiratory therapy to a respiratory therapist. It is insufficient, however, to rely solely on that respiratory therapist's education, training or experience as a respiratory therapist when evaluating qualifications to perform the delegated medical service. Instead, the physician must assure that the respiratory therapist has sufficient additional education, training or experience to qualify that person to perform the delegated medical service at issue.~~

~~2. Additionally, the delegation of the medical service must~~

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~~otherwise be in compliance with these Rules.~~

- ~~3. This section III(C) does not apply to delegation of medical services to a registered nurse. Instead, such delegation would be governed by the Nurse Practice Act.~~

B. The delegating physician and the delegatee shall take appropriate measures to ensure that delegates are identified in a manner that prevents confusion as to the delegates' qualifications and legal authority to provide medical services. Following are examples of situations in which confusion as to the delegates' 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.

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

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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

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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;

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

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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 delegatees 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.

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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).

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

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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 delegatees 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 delegatees 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

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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

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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.

~~IV. "Personal and responsible direction and supervision" required under these Rules.~~

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- ~~A. One or more physicians shall have explicitly agreed to provide the necessary direction and supervision of the delegatee(s). The agreement need not be written.~~
- ~~B. The delegating physician is accountable for the acts of the delegatee(s).~~
- ~~C. The physician's direction and supervision of the delegatee shall be sufficient to limit the need for the exercise of the judgment required of a physician.~~
- ~~D. 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;~~
 - ~~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.~~~~
- ~~E. Delegated services must be provided in the context of an appropriate physician/patient relationship.
 - ~~1. Section VI of these Rules sets forth the requirements for a physician/patient relationship when delegating Medical-Aesthetic Services.~~
 - ~~2. For all other delegations, ongoing care of a particular patient without direct physician involvement is inappropriate and demonstrates insufficient personal and responsible direction and supervision of a delegatee. 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~~~~

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~~physician of delegated services rendered by the delegatee, review by the physician of care rendered to the patient by the delegatee, review by the physician 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.~~

- ~~F. In the event of an adverse outcome resulting from a delegated medical service, the delegating physician must provide appropriate follow-up care and/or referrals.~~
 - ~~G. Any medical service rendered by the delegatee must conform to the same standard applicable if the delegating physician performed the service personally.~~
 - ~~H. 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.~~
 - ~~I. 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 available to attend to the patient.~~
 - ~~J. A delegating physician shall assure that there is a timely chart note for all patient contacts with the delegatee and with the delegating physician.~~
- ~~V. Identification of authority to act:~~

- ~~A. The delegating physician must provide information to patients regarding delegates performing medical services pursuant to the physician's delegation.~~
- ~~B. The delegating physician and the delegatee shall take appropriate measures to assure that delegates are identified in a manner that prevents confusion as to the delegates' qualifications and legal authority to provide medical services. Following are examples of situations in which confusion as to the delegates'~~

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~~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.~~

~~5. A delegatee uses a title such as “nurse” or “LPN”. Note that even a delegatee who is licensed as a practical nurse may not use the title “nurse” or “LPN” when performing acts as a delegatee that are beyond the scope of the practice of practical nursing;~~

~~6. A delegatee acting as an EMT or paramedic uses the title EMT or paramedic outside of the pre-hospital care setting, such as in the emergency room;~~

~~7. 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;~~

~~8. A delegatee uses the word “licensed” as part of a title when the delegatee does not possess a Colorado license to perform the medical services at issue; or~~

~~9. A delegatee uses the word “doctor” or the abbreviation “Dr.” when acting as a delegatee.~~

~~VI. Special provisions applicable to the delegation of Medical-Aesthetic Services.~~

~~A. Purpose of the section. The Board finds that the delegation of medical services in the area of Medical-Aesthetic Services involves a broad range of changing technologies and practices, and is an area in which insufficient personal and responsible delegation and supervision of medical services has led to public safety concerns in Colorado and nationwide. Such public safety concerns have also been identified by the Colorado Office of Barber and Cosmetology Licensure, which has referred numerous cases of concern to the Board. Representatives of the Colorado Office of Barber and Cosmetology Licensure have appeared before the Board on more than one occasion to address public safety concerns stemming from improper or inadequate~~

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~~physician delegation of Medical-Aesthetic Services, poor outcomes and the difficulty in identifying whether appropriate equipment is used in this field under appropriate supervision. These representatives have also reported that many practitioners in this field use devices that are not approved by the Food and Drug Administration, or devices that have been altered from their approved form. Additionally, the Board is concerned about fraudulent practices in this field, including the sham or inadequate supervision provided to too many delegates rendering Medical-Aesthetic Services.~~

~~B. Definition of “Medical-Aesthetic Services.” “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 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 injections of Botox, Collagen, Restylane, or any other substance injected for a primarily cosmetic purpose.~~

~~1. 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.~~

~~2. Off-label use of medications or devices when performing delegated Medical-Aesthetic Services is generally prohibited unless:~~

~~c. the delegating physician has specifically authorized and delegated the off-label use, and~~

~~d. the off-label use is within generally accepted standards of medical practice.~~

~~C. General applicability of other sections. Except as explicitly provided in this Section VI of these Rules, all requirements set forth~~

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~~in other Sections of these Rules apply to delegation of Medical-Aesthetic Services.~~

~~D. **Additional requirements.**—In addition to the other provisions of these Rules, the personal and responsible direction and supervision of delegates performing Medical-Aesthetic Services must include the following:~~

~~2. The delegating physician and the delegate 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.~~

~~3. The delegating physician must maintain a list of all delegates to whom the physician has delegated Medical-Aesthetic Services. The list must include a comprehensive and specific list of the delegated Medical-Aesthetic Services the physician has authorized the delegatee to perform. The list shall be maintained with documentation of the delegatee's qualifications to perform the Medical-Aesthetic Services as described in paragraph III(B) of these Rules. Upon request, all documentation maintained by the physician in accordance with this paragraph shall be provided to the Board.~~

~~4. The delegating physician is responsible for assuring the qualifications and competence of the delegatee to perform the delegated Medical-Aesthetic Services as follows:~~

~~a. Prior to authorizing a delegatee to perform any Medical-Aesthetic Services, the delegating physician must personally assess the qualifications and competence of the delegatee to perform the Medical-Aesthetic Services. This assessment must include a review the delegatee's education and training as relevant to performance of the delegated medical service(s). Additionally, this assessment must include, but must not be limited to, initial over-the-shoulder monitoring of the delegatee's performance of each delegated Medical-Aesthetic~~

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~~Service.~~

- ~~b. On at least an annual basis, the delegating physician must personally reassess the qualifications and competence of the delegatee to perform the Medical-Aesthetic Services. This reassessment must include, but must not be limited to, over-the-shoulder monitoring of the delegatee's performance of each delegated Medical-Aesthetic Service.~~
 - ~~c. The delegating physician must document the initial assessment and follow-up reassessments of the delegatee's performance of the delegated Medical-Aesthetic Services. Upon request, the delegating physician must provide such documentation to the Board.~~
- ~~5. 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.~~

~~E. **Physician-patient relationship for delegated Medical-Aesthetic Services.** The delegating physician's physician-patient relationship with a patient receiving delegated Medical-Aesthetic Services pursuant to these Rules need not comply with Section IV(E) of these Rules, but must include the following:~~

- ~~1. The delegating physician must ensure that each patient receives all information necessary to give appropriate informed consent for any Medical-Aesthetic Service and that such informed consent is timely documented in the patient's chart.~~
- ~~2. All patients receiving a delegated Medical-Aesthetic Service must 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-Aesthetic Services. Upon request, the delegating physician must timely and personally provide such consultation, evaluation or treatment.~~
- ~~3. The delegating physician must assure that the delegatee maintains appropriate patient charts for each patient receiving Medical-Aesthetic Services.~~

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- ~~4. At least weekly, 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 weekly monitoring must occur at the site where the delegated services are performed.~~

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

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the delegating physician has committed unprofessional conduct pursuant to Section 12-36-117(1)(gg), C.R.S.

SECTION 8. UNLICENSED PRACTICE OF MEDICINE

~~VII. 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 ~~subject of a cease and desist~~ 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.

~~VIII. Unprofessional conduct.~~

~~A. It shall be unprofessional conduct pursuant to section 12-36-117(1)(u), C.R.S. for any licensee to have delegated medical services or to have performed delegated medical services pursuant to section 12-36-106(3)(l), C.R.S. without complying with the provisions of these Rules.~~

~~B. It shall also be unprofessional conduct pursuant to section 12-36-117(1)(u), C.R.S. for any person who is not licensed by this Board but who 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.~~

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;

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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; Revised 4/___/17, Effective 4/___/17

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BOARD RULE 800, APPENDIX A

**Agreement Between Delegating Physician and Delegatee Performing
Medical-Aesthetic 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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BOARD RULE 800, APPENDIX A, PAGE 2

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-Aesthetic 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-Aesthetic 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-Aesthetic 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-Aesthetic 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-Aesthetic Services and that such informed consent is timely documented in the patient's chart.

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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)