

COLORADO MEDICAL BOARD
RULES REGARDING THE DELEGATION AND SUPERVISION OF MEDICAL
SERVICES TO UNLICENSED 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)(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. Additionally, these Rules clarify particular requirements applicable to the delegation of medical services pursuant to section 12-36-106(3)(I), 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)(I), 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 physician assistant, and is not otherwise exempt pursuant to section 12-36-106, C.R.S. from holding a license to practice medicine.
 - 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 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.

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 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;
 - 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.

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

- A. 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. 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;
 - 2. Documentation of direct observation of the repeated and successful performance of the delegated services; and/or
 - 3. Appropriate credentialing by a bona fide agency or institution, if applicable.
- C. 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 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.

IV. **“Personal and responsible direction and supervision” required under these Rules.**

- 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 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' 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 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;
2. A delegatee acting as an EMT or paramedic uses the title EMT or paramedic outside of the prehospital care setting, such as in the emergency room;
3. 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;
4. 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
5. 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 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 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:
 - 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.
- C. **General applicability of other sections.** Except as explicitly provided in this Section VI of these Rules, all requirements set forth 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:
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-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.

3. 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 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.
 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.
- 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.
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.

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 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; 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

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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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.

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)