

COST-BENEFIT ANALYSIS

In performing a cost-benefit analysis (“CBA”), each rulemaking entity must provide the information requested for the cost-benefit analysis to be considered a good faith effort. The cost-benefit analysis must be submitted to the Office of Policy, Research and Regulatory Reform at least ten (10) days before the administrative hearing on the proposed rule and posted on your agency’s web site. For all questions, please attach all underlying data that supports the statements or figures stated in this cost-benefit analysis.

DEPARTMENT: Department of Regulatory
Agencies (DORA)

AGENCY: Colorado Medical Board

CCR: 3 CCR 713-30

DATE: February 6, 2017

RULE TITLE OR SUBJECT:

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

Per the provisions of section 24-1-103(2.5)(a), Colorado Revised Statutes, the cost-benefit analysis must include the following:

1. The reason for the rule or amendment:

The rule amendment is needed to further clarify requirements regarding the delegation of medical services to unlicensed persons pursuant to section 12-36-106(3)(l), C.R.S., in order to protect the consumers by ensuring the delegation is proper, supervised, and that the consumer is aware that the service is being performed by a person not licensed to perform medical services. The request for a CBA cites sections 1.B.1; 1.D.5; 2.A.2.d.1 & 2; 2.B.1; 2.B.4; and 6 of the amended rule. The current rule and proposed amended rule in redline are attached hereto.

As proposed, the amended rule continues to permit unlicensed persons to perform properly delegated and supervised medical services so long as the delegator, the delegatee, the delegated services, and supervision meet the criteria set forth in the amended rule AND the consumer/patient is advised that the person performing the service is not licensed to perform medical services. The amended rule also adds telehealth as an option for supervision of the delegated service.

2. The anticipated economic benefits of the rule or amendment, which shall include economic growth, the creation of new jobs, and increased economic competitiveness:

Section 1.B.1

Section 1.B.1 of the proposed amended rule relocates and amends the definition of medical aesthetic services as defined in section IV.B., of the current rule. The proposed amended rule removes the language “Botox, Collagen, Restylane or any other substance injected for a primarily cosmetic purpose” and now classifies the injection of any substance into the human body except as permitted in section D as a medical service. The definition is further amended by specifying which laser use constitutes a “medical service” based on Federal Drug Administration classification. Clarification of lasers in the amendment reduces the scope of lasers included in “medical services” which would be subject to delegation and supervision by a physician.

This section of the proposed amended rule may lead to economic growth in that it limits the types of lasers included in the definition of “medical service.” In addition, a one-time economic benefit to physicians may be anticipated in relation to the development of standing orders and protocols for the injections of any substances outside the definition of the current rule the business may be currently injecting without the delegation and supervision of a physician.

Section 1.D.5

Section 1.D.5 of the proposed amended rule clarifies that the monitoring of medication compliance is not a medical service. Many health care and mental health workers, both licensed and unlicensed, have long engaged in medication compliance monitoring without physician delegation or supervision through home care services, clinics, and provider offices. This proposed provision is added for clarity and does not alter the status quo.

There are minimal to no anticipated economic benefits associated with this clarification. In any instance in which an organization mistakenly believed the monitoring of medication compliance was a medical service requiring delegation and supervision under this rule, this proposed clarification could allow the organization to redirect physician resources to medical services, perhaps increasing the number of patients/consumers served per day resulting in an economic benefit to the organization.

Section 2.A.2.d.1 & 2

Section 2.A.2.d.1 of the proposed amended rule relocates and further defines the requirements of “available in the community” in the current rule at section II.C.4. The clarified definition requires the delegating physician to be personally present in the state and able to personally consult with or provide follow-up care to the patient. This clarification may contribute to the creation of new jobs and therefore economic growth in Colorado by requiring the supervision to take place in Colorado.

Section 2.A.2.d.2 of the proposed amendment adds telehealth as an occasional mode of supervision of the delegated services. This additional mode of supervision, even on an occasional basis, may contribute to the creation of new jobs, particularly in rural areas, which may also increase economic competitiveness. The addition of telehealth as an occasional mode of delivery may also stimulate economic growth by allowing physicians to simultaneously supervise unlicensed persons in more than one location thereby increasing the number of consumers/patients served and job creation for unlicensed persons.

Section 2.B.1

Section 2.B.1 of the proposed amendment clarifies section 1.E.1 of the current rule which clarifies section 12-36-106(3)(l), C.R.S., requiring the delegation of medical services under the PERSONAL direction of a physician. This proposed provision clarifies the language of section 1.E.1 of the current rule and does not alter the status quo.

There is no anticipated economic benefit associated with this proposed amendment.

Section 2.B.4

Section 2.B.4 of the proposed amendment is an added provision prohibiting licensees with a restricted license from delegating medical services pursuant to Rule 800. The provision also prohibits licensees with limited licenses from delegating any medical service the licensee is prohibited from performing.

There is no anticipated economic benefit associated with this proposed amendment.

Section 6

Section 6 of the proposed amended rule relocates and clarifies the documentation requirements of delegated medical services. This section of the proposed amended rule clarifies that written protocols must be developed by the delegating physician, requires the physician to review the medical records of patients/consumers receiving delegated services within 14 days, and adds a required disclosure to patients that the service to be performed is a medical service, the medical service has been delegated by the physician to a person not licensed to perform medical services, and the name and contact information for the delegating physician.

Economic benefits to licensees may be anticipated as a result of this section of the proposed amended rule. First, physicians could derive increased income for the development of written protocols and chart review. In addition, it is possible this section of the proposed amended rule causes an increase in income for licensees because a consumer/patient may elect to seek the services of a person licensed to perform medical services for the desired medical service upon being advised that the person performing the desired service is not licensed to perform medical services. Economic growth, the creation of jobs and economic competition may also be anticipated. This section of the proposed amended rule may demonstrate to patients/consumers that the delegation of medical services includes protocols developed by a physician and are closely supervised with direct access to the delegating physician, all of which may increase public confidence in receiving delegated medical services and lead to an increase in patient/consumer demand for such services.

- 3. The anticipated costs of the rule or amendment, which shall include the direct costs to the government to administer the rule or amendment and the direct and indirect costs to businesses and other entities required to comply with the rule or amendment:**

Section 1.B.1

Section 1.B.1 of the proposed amended rule relocates and amends the definition of medical aesthetic services as defined in section IV.B., of the current rule. The proposed amended rule removes the language “Botox, Collagen, Restylane or any other substance injected for a primarily cosmetic purpose” and now classifies the injection of any

substance into the human body, except as permitted in section D, as a medical service. The definition is further amended by specifying which laser use constitutes a “medical service” based on Federal Drug Administration classification. Clarification of lasers in the amendment reduces the scope of lasers included in “medical services” which would be subject to delegation and supervision by a physician.

It is anticipated there may be costs to medical aesthetic businesses as a result of this amendment. The one-time costs would be associated with the development of standing orders and protocols for the injections of any substances outside the definition of the current rule the business may have been injecting without the delegation and supervision of a physician. The Government agency (Division of Professions and Occupations, Colorado Medical Board) will not incur direct or indirect costs to administer the proposed amended rule. The costs associated with enforcing the proposed rule amendment would be absorbed in the current costs the agency spends for investigations and enforcement actions.

Section 1.D.5

Section 1.D.5 of the proposed amended rule clarifies that the monitoring of medication compliance is not a medical service. Many health care and mental health workers, both licensed and unlicensed, have long engaged in medication compliance monitoring without physician delegation or supervision through home care services, clinics, and provider offices. This proposed provision is added for clarity and does not alter the status quo.

There are no anticipated costs to businesses, other entities, or the government associated with this clarification.

Section 2.A.2.d.1 & 2

Section 2.A.2.d.1 of the proposed amended rule relocates and further defines the requirements of “available in the community” in the current rule at section II.C.4. The clarified definition requires the delegating physician to be personally present in the state and able to personally consult with or provide follow-up care to the patient. Section 2.A.2.d.2 of the proposed amendment adds telehealth as an occasional mode of supervision of the delegated services.

There may be anticipated direct or indirect costs to business or other entities as a result of the proposed amendment. There is no change in the amendment to the requirement that unlicensed persons must be supervised by a physician “available in the community.” Clarifying that the location of the physician must be within the state of Colorado should not affect the costs associated with physician supervision. While the amendment’s clarification that “available in the community” means the supervising physician must be able to personally consult with or provide follow-up care to the patient, could lead to costs for the supervising physician such as securing coverage when out of town, the amendment’s addition of the occasional use of telehealth as a permissible method of supervision may off-set this cost. Because the current rule does not authorize any supervision through telehealth technologies, the proposed addition of this method of supervision, even on only an occasional basis, increases rather than decreases the availability of supervision and therefore may not lead to increased costs. Further, the Government agency (Division of Professions and Occupations, Colorado Medical Board) will not incur direct or indirect costs to administer the proposed amended rule. The costs associated with enforcing the proposed rule amendment would be absorbed in the current costs the agency spends for investigations and enforcement actions.

Section 2.B.1

Section 2.B.1 of the proposed amendment clarifies section 1.E.1 of the current rule and section 12-36-106(3)(l), C.R.S., requiring the delegation of medical services under the PERSONAL direction of a physician. This proposed provision clarifies the language of section 1.E.1 of the current rule and does not alter the status quo.

There are no anticipated costs to businesses, other entities, or the government associated with this clarification of current rule.

Of note, Athletic Trainers are registered and regulated by the Division of Profession and Occupations through the Athletic Trainer Practice Act, sections 12-29.7-101, C.R.S., *et. seq.* Accordingly, Athletic Trainers’ independent practice within the statutorily mandated scope of practice is not limited by this proposed amendment.

Section 2.B.4

Section 2.B.4 of the proposed amendment is an added provision prohibiting licensees with a restricted license from delegating medical services pursuant to Rule 800. The provision also prohibits licensees with limited licenses from delegating any medical service the licensee is prohibited from performing.

Indirect and direct costs to businesses and licensees may be anticipated as a result of this section of the proposed amendment. To the extent that licensees with restricted licenses are delegating medical services or licensees are delegating medical services they are prohibited from performing under a limited license, business may incur the direct cost of securing a new delegating licensee and indirect costs related to business loss during the time required to secure

the new delegating licensee. Further, those licensees delegating services under the current rule who would be prohibited under the proposed amendment may see a loss of income.

Section 6

Section 6 of the proposed amended rule relocates and clarifies the documentation requirements of delegated medical services. This section of the proposed amended rule clarifies that written protocols must be developed by the delegating physician, requires the physician to review the medical records of patients/consumers receiving delegated services within 14 days, requires the posting of a notice with the delegating physician's name and contact information for medical aesthetic services, and adds a required disclosure to patients that the service to be performed is a medical service, the medical service has been delegated by the physician to a person not licensed to perform medical services, and the name and contact information for the delegating physician.

Costs to businesses and other entities may be anticipated as a result of this section of the proposed amended rule. To the extent a business is using protocols that have not been developed by the delegating physician, there would be a one-time direct cost for physician developed protocols. The proposed rule amendment may also create a direct one-time cost to businesses for the notice providing the name and contact information of the delegating physician and for revising consent or agreement for treatment forms to include the advisement that the service being performed is a medical service, that the person performing the service is not licensed to perform medical services, and the name and contact information of the delegating physician. In addition, direct costs may be anticipated as it relates to payment for chart review every 14 days.

This section of the proposed amended rule may also create an indirect cost to the business offering medical services delegated to an unlicensed person once the consumer/patient is advised that the service is a medical service and the person performing the service is unlicensed, the consumer/patient may elect to seek services from a licensee.

4 Any adverse effects on the economy, consumers, private markets, small businesses, job creation, and economic competitiveness:

Section 1.B.1

Section 1.B.1 of the proposed amended rule relocates and amends the definition of medical aesthetic services as defined in section IV.B., of the current rule. The proposed amended rule removes the language "Botox, Collagen, Restylane or any other substance injected for a primarily cosmetic purpose" and now classifies the injection of any substance into the human body, except as permitted in section D, as a medical service. The definition is further amended by specifying which laser use constitutes a "medical service" based on Federal Drug Administration classification. Clarification of lasers in the amendment reduces the scope of lasers included in "medical services" which would be subject to delegation and supervision by a physician.

Adverse effects on the economy, consumers, private markets, small businesses, job creation, and economic competitiveness are not anticipated as a result of this section of the proposed amended rule.

Not adopting this section of the proposed amended rule has the potential to cause unnecessary physical and irreversible harm to consumer/patient clients who utilize unlicensed persons for the delivery of medical services.

Section 1.D.5

Section 1.D.5 of the proposed amended rule clarifies that the monitoring of medication compliance is not a medical service. Many health care and mental health workers, both licensed and unlicensed, have long engaged in medication compliance monitoring without physician delegation or supervision through home care services, clinics, and provider offices. This proposed provision is added for clarity and does not alter the status quo.

It is not anticipated that this section of the proposed amended rule would result in any adverse effects on the economy, consumers, private markets, small businesses, job creation, and economic competitiveness.

Not adopting this section of the proposed amended rule has the potential to cause unnecessary physical and irreversible harm to consumers/patients who utilize unlicensed persons for the delivery of medical services.

Section 2.A.2.d.1 & 2

Section 2.A.2.d.1 of the proposed amended rule relocates and further defines the requirements of "available in the community" in the current rule at section II.C.4. The clarified definition requires the delegating physician to be personally present in the state and able to personally consult with or provide follow-up care to the patient. Section 2.A.2.d.2 of the proposed amendment adds telehealth as an occasional mode of supervision of the delegated services.

Adverse events to small businesses and consumers, particularly in rural communities may be anticipated as a result of this section of the proposed amendment. To the extent small businesses did not consider “available in the community” in the current rule to mean that the physician must be located in the state of Colorado and available to personally consult with or provide follow-up care to patients, this section may adversely affect a rural small business’ ability to now secure a physician to delegate and supervise the medical services provided by the business. If the business were unable to find a local physician, the business may close, affecting consumers, the economy and economic competitiveness. The newly added provision permitting supervision by telehealth on an occasional basis may mitigate any adverse effect.

Not adopting this section of the proposed amended rule has the potential to cause unnecessary physical and irreversible harm to consumers/patients who utilize unlicensed persons for the delivery of medical services.

Section 2.B.1

Section 2.B.1 of the proposed amendment clarifies section 1.E.1 of the current rule and section 12-36-106(3)(l), C.R.S., requiring the delegation of medical services under the PERSONAL direction of a physician. This proposed provision clarifies the language of section 1.E.1 of the current rule and does not alter the status quo.

It is not anticipated that this section of the proposed amended rule would result in any adverse effects on the economy, consumers, private markets, small businesses, job creation, and economic competitiveness.

Section 2.B.4

Section 2.B.4 of the proposed amended rule is an added provision prohibiting licensees with a restricted license from delegating medical services pursuant to Rule 800. The provision also prohibits licensees with limited licenses from delegating any medical service the licensee is prohibited from performing.

It is not anticipated that this section of the proposed amended rule would result in any adverse effects on the economy, consumers, private markets, small businesses, job creation, and economic competitiveness.

Not adopting this section of the proposed amended rule has the potential to cause unnecessary physical and irreversible harm to consumers/patients who utilize unlicensed persons for the delivery of medical services.

Section 6

Section 6 of the proposed amended rule relocates and clarifies the documentation requirements of delegated medical services. This section of the proposed amended rule clarifies that written protocols must be developed by the delegating physician, requires the physician to review the medical records of patients/consumers receiving delegated services within 14 days, and adds a required disclosure to patients that the service to be performed is a medical service, the medical service has been delegated by the physician to a person not licensed to perform medical services, and the name and contact information for the delegating physician.

Adverse effects on small businesses may be anticipated as a result of this section of the proposed amended rule. Specifically, small businesses may not have the ability to withstand the aforementioned direct and indirect costs. This could lead to business closure and subsequent effects on the economy and availability of services to consumers, particularly in rural communities. The addition of the use of telehealth technologies in section 2.A.2.d.2 may mitigate some of the direct and indirect costs and therefore these adverse effects.

Not adopting the amended rule as proposed has the potential to cause unnecessary physical and irreversible harm to consumer/patient clients who utilize unlicensed persons for the delivery of medical services. As the rule currently stands, consumers/patients are unable to locate or access the delegating physician for emergency follow-up. In many cases, the consumer/patient is not aware the service being provided is a medical service or that a physician has delegated the medical service to a person not licensed to perform medical services.

5. At least two alternatives to the proposed rule or amendment that can be identified by the submitting agency or a member of the public, including the costs and benefits of pursuing each of the alternatives identified:

Alternative One: Eliminate the new requirements of section 6 of the proposed amended rules.

This alternative may eliminate the one-time direct costs of developing protocols, developing a notice that includes the physician’s name and contact information and revising consent forms to include disclosure to patients. The alternative may also eliminate the direct cost associated with chart review every 14 days and any indirect costs resulting in loss of business once consumers/patients are advised that the medical service is being provided by an unlicensed person. This alternative may also eliminate any benefit those licensees may see from consumers/patients electing to seek treatment from them rather than unlicensed persons upon advisement that a medical service is being performed by an

unlicensed person, and any benefit derived from developing the protocols and chart review. Potential adverse effects on the business may be diminished; however, it increases the potential to cause unnecessary physical and irreversible harm to consumer/patient clients who utilize unlicensed persons for the delivery of medical services because as the rule currently stands, consumers/patients are unable to locate or access the delegating physician for emergency follow-up. In many cases, the consumer/patient is not aware the service being provided is a medical service or that a physician has delegated the medical service to a person not licensed to perform medical services.

Alternative Two: Amend section 2.A.2.d.2 of the proposed amended rule to remove the word “occasionally” from the use of telehealth technologies in the supervision of delegated medical services.

The removal of the term “occasionally” may diminish any potential direct or indirect costs associated with rural businesses securing a local licensee able to personally consult with and provide follow-up to consumers/patients. The removal of the term “occasionally” may increase the economic benefits derived by the business and the rural community. The removal of this modifier may also improve access to services in rural communities. Potential adverse effects on the business, economy, and consumer may be diminished with the alternative. The increased use of telehealth technologies may mitigate any potential to cause unnecessary physical and irreversible harm to consumer/patient clients who utilize unlicensed persons for the delivery of medical services.

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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COLORADO MEDICAL BOARD RULES

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~~ physician assistant or anesthesiologist assistant, and is not otherwise exempt

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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, performed by by unlicensed person or licensed healthcare professionals. unlicensed medical assistants, other than those acts excluded by subsection (E) 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 II or higher or III laser as defined by the Food and Drug Administration, 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 Botox, Collagen, Restylane, or any other substance injected for a primarily cosmetic purpose any substance into the human body except as may be permitted pursuant to section D.-

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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 lasers or pulse light devices identified by the FDA as Class II or higher ~~laser devices~~ constitutes the practice of medicine.

~~3. Laser surgery may only be performed by a physician, another licensed healthcare provider working within his or her scope of practice as defined by Colorado law, or by a person functioning as a delegatee of a licensed physician.~~

~~4. The use of devices commonly known as electrolysis devices and identified as Class I devices, does not constitute the practice of medicine and, therefore, does not require physician delegation or supervision.~~

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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, 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.

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, and other superficial skin treatments, and those services regulated by the Barber and Cosmetology Practice Act, section 12-8-101, et. seq., C.R.S., are not medical services.

4. The use of Class I medical devices, including Class I 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. ~~delegated medical service may not require the exercise of medical judgment.~~

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2. Delegated medical services should be limited to include 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:

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 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.,~~

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~~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.~~

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- ~~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.~~

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. ~~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.

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2. A delegating physician may occasionally 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 ~~subsequently 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. Physician assistants or anesthesiologist assistants may not delegate medical services to another person pursuant to these Rules. Notwithstanding this prohibition, physician assistants and anesthesiologist assistants may delegate medical services to nursing staff or medical assistants who are acting under the direct supervision of the licensed physician assistant or anesthesiologist assistant so long as the medical services was not originally delegated to the physician assistant or anesthesiologist assistant pursuant to Rule 400 or Rule 510.
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4. When a licensee's license has been restricted or is otherwise limited, that licensee may not delegate pursuant to these rules. 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~~

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~~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-~~

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~~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.~~

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

A. Persons Who May Serve as Delegates

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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

~~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. As part of his or her evaluation, the delegating physician shall personally assess and review:

~~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; and~~

~~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, Board or institution, if applicable.~~

~~4. 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 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.

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

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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.

~~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.~~

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

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delegated medical services pursuant to section 12-36-106(3)(l), 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 anesthesiologist assistant 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.

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.

~~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;~~

~~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;~~

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 does not possess a Colorado license to perform the medical services at issue; or

3. A delegatee uses the word "doctor" or the abbreviation "Dr." when acting as a ~~delegated~~ delegatee; or

4. A delegate who is an "aesthetician" uses the word "medical" as

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part of a title, such as “medical aesthetician”, when the delegate 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, ~~or physician assistant or anesthesiologist assistant~~ but who is not so licensed, including, but not limited to:

a. Any physician, ~~or 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 assistant ~~—~~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, ~~or 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.

3. ~~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.

~~3. —esilicense~~

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

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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. The delegating physician is responsible for assuring the qualifications and competence of the delegatee to perform the delegated medical services as follows:~~

~~1. Prior to authorizing a delegatee to perform any medical services, the delegating physician must personally assess the qualifications and competence of the delegatee to perform the medical 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 service.~~

~~B. All patients receiving a delegated medical 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 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.~~

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CA. 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 the exercise of the judgment required of a physician.

C. Delegated services must be provided in the context of an appropriate physician/patient relationship.

~~D.~~ 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

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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.

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 ~~weekly~~ 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 ~~weekly~~ 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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SECTION 6. DOCUMENTATION REQUIREMENTS

A. Written Procedure Protocols

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.

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

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.

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.

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

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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~~ **seven** 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 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.

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.

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2. The delegating physician or healthcare facility is required to maintain all documentation required by these Rules. ~~and may not rely solely on a medical office or other entity to provide the documents to the Board.~~

3. Upon request, the delegating physician is responsible to provide all documentation maintained by the physician or healthcare facility in accordance with these Rules ~~shall be provided to the Board.~~ The delegating physician may not rely solely on the medical office or other entity to provide the requested documents.

F. Disclosure Requirements to Patients

1. ~~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 person 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 ~~provider is~~ 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.

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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, the fact that the medical service was delegated to ~~an unlicensed a~~ delegatee, the name of the delegatee, and the name and contact information for the delegating physician. The written disclosure shall be signed by the patient ~~as part of the informed consent~~ prior to ~~receiving the medical service for each procedure.~~ 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 to 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.~~

- ~~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;~~~~

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- ~~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~~

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~~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.~~

~~1.5. _____ 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;~~

~~2.6. _____ 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;~~

~~3.7. _____ 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;~~

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~~4.8. 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~~

~~5.9. 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 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 too many delegatees 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~~

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

~~b.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 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:~~

~~1.2. 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.~~

~~2.3. 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~~

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~~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.~~

~~3.4. 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 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.~~

~~4.5. 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~~

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~~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.~~

SECTION 7. UNPROFESSIONAL CONDUCT

A. It is a violation of these Rules for any licensee 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.

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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 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

~~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.~~

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~~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; Revised 2/16/17, Effective 4/14/17

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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 Pphysician)

_____,
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

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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 Pphysician)

(Signature of Delegatee)

(Date)

(Date)