DEPARTMENT OF REGULATORY AGENCIES

State Board of Pharmacy

STATE BOARD OF PHARMACY RULES AND REGULATIONS

3 CCR 719-1

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

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3.00.00 DISPENSING.

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3.00.80 Return or Exchange of Drugs, Prescriptions, Medical Devices, and Medical Supplies for Dispensing or Donation.

3.00.81 Definitions.

For the purposes of this Rule 3.00.00, the following definitions apply:

a. "Automated cassette" is a container that is filled with a drug. This container may count the drug and may package the drug into a container suitable for dispensing, and may affix a label to the container. These cassettes may be used to dispense drugs in a traditional dispensing system or may be used to package unit-dose medication, or drugs in a unit of issue packaging system.

b. "Correctional facility" means a facility under the supervision of the United States, the Department of Corrections, or a similar state agency or department in a state other than Colorado in which persons are or may be lawfully held in custody as a result of conviction of a crime; a jail or an adult detention center of a county, city, or city and county; and a private contract prison operated by a state, county, city or city and county.

c. "Customized patient medication package" means a package which contains two or more drugs.

d. "Licensed Facility" means any of the following facilities licensed by the Colorado Department of Public Health and Environment: community mental health center, acute treatment unit, hospital unit, inpatient hospice, nursing care facility, assisted living residence, or long-term care facility.

e. "Medical Device" means an instrument, apparatus, implement, machine, contrivance, implant, or similar or related article that is required to be labeled pursuant to 21 CFR Part 801.

f. "Medical Supply" means a consumable supply item that is disposable and not intended for reuse.

g. "Nonprofit Entity" means a Board registered prescription drug outlet or other outlet which has nonprofit status, or an out-of-state entity with legal authority to both possess a prescription drug and receive a donated prescription drug distributed from a Boardregistered outlet in the state of Colorado.

h. "Originating Prescription Drug Outlet" means the prescription drug outlet which initially dispensed the prescription for a resident of a facility.

i. "Package" means to prepare a drug in a container other than the original container. The packaging might include a unit dose dispensing system, single dose, automated cassette, or a container suitable for a traditional system. Unless otherwise specified, this includes preparing a drug in advance of the immediate need for dispensing (prior to the receipt of an order), or pursuant to an existing order.

j. "Single dose package" means a package which contains a quantity of a drug intended for administration as a single dose.

k. "Traditional dispensing system" means a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages.

l. "Unique identifier" means an implicit or explicit unique identifier from which the originating prescription number can be determined.

m. "Unit dose dispensing system" means a drug distribution system which is in a prescription drug outlet or hospital other outlet and uses unit dose packages or unit of issue packages that enable distribution of packaged doses in a manner that preserves the identity of the drug until the time of administration.

n. "Unit dose package" means a package which contains one pharmaceutical unit.

o. "Unit of issue package" means a package which provides multiple units of doses but separated in a medication card or other specifically designed container.

3.00.82 General Provisions

a. No prescription drug outlet shall accept returned or donated prescriptions, medical devices, or medical supplies for dispensing, or donation except in the following situations:

1) A prescription drug outlet that complies with Rules 3.00.82 through 3.00.89 may accept prescriptions, medical devices, and medical supplies for return, dispensing, and donation.

2) A hospital prescription drug outlet may accept prescriptions and drugs for dispensing or reissue from all areas of the hospital, provided that the integrity of the product and package are maintained and the following requirements are met:

(a) An appropriate, uniformly maintained and readily retrievable record shall be maintained which indicates at least the total number of doses of the drug which were actually administered. This record may be combined with the record permitted by Rule 2.01.20(c); or

(b) If the drug was distributed as floor stock in the facility, an appropriate, uniformly maintained and readily retrievable record of such return shall be made. This record shall state the following:

(I) The name of the drug;

(II) The strength of the drug;

(III) The dosage form of the drug if appropriate;

(IV) The quantity of the drug;

(V) The location within the facility to which the drug was originally distributed; and

(VI) The date of the return.

b. No prescription drug returned for redispensing or donation from a facility or donated by a prescription drug outlet shall be redispensed if it expires prior to utilization by the consumer based on the prescribing practitioner's directions for use.

c. Rules 3.00.80 through 3.00.89 do not apply to the Colorado Cancer Drug Repository.

3.00.83 Entities Eligible to Donate or Return Prescriptions.

The following may donate or return drugs:

a. A correctional facility as defined in Rule 3.00.81(b), a licensed facility as defined in Rule 3.00.81(d), or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., may return prescriptions to a prescription drug outlet.

b. A correctional facility, a licensed facility, or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., may donate prescriptions to a nonprofit entity as defined in Rule 3.00.81(g) or to a practitioner authorized by law to dispense the prescription.

c. A prescription drug outlet may donate a returned or donated prescription to a nonprofit entity as defined in Rule 3.00.81(g) or to a practitioner authorized by law to dispense the prescription.

3.00.84 Eligibility for Return or Donation.

a. For all prescriptions, medical devices, or medical supplies accepted for return or donation, the prescription drug outlet must ensure that the prescription, medical device, or medical supply was properly stored prior to return or donation. This includes storage at the facility, and shipment to and from the facility.

b. Drugs which have been dispensed to a resident of a correctional facility, licensed facility, or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., that are eligible for return or donation are as follows:

1) Drugs which are liquid and the vial is still sealed and properly stored;

2) Drugs that have been individually packaged and the packaging has not been damaged; and

3) Drugs that are in the original, unopened, sealed, and tamper-evident unit dose package, unit of issue package, or unit dose dispensing system.

c. Drugs which have been dispensed to a resident of a correctional facility, licensed facility, or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., that are not eligible for Return or Donation are as follows:

1) Any drug declared to be a controlled substance under any state or federal law or rule except as provided in Rule 3.00.82(a)(2);

2) Any drug dispensed in a traditional dispensing system;

3) Any drugs dispensed in a customized patient medication package;

4) Any drug packaged in a single dose package, a unit dose dispensing system, a unit dose package, or a unit of issue package that is not labeled in accordance with Rules 3.01.20 and 3.01.21;

5) A compounded drug;

6) Drugs that are adulterated or misbranded as determined by the pharmacist;

7) Drugs that require refrigeration, freezing, or special storage;

8) Drugs that require special registration with the manufacturer;

9) Drugs that will expire prior to utilization by the consumer, based on the prescribing practitioner's directions for use;

10) Dispensed drugs that are received from facilities or pharmacies located outside of Colorado; and

11) Any drug that was not dispensed pursuant to an order.

3.00.85 Records of Receipt of Returned or Donated Prescriptions, Medical Devices, and Medical Supplies.

a. The prescription drug outlet shall retain records for at least two years detailing receipt of donated or returned prescriptions that contain at least the following information:

1) Name and address of facility or donating prescription drug outlet;

2) Name and address of originating prescription drug outlet;

3) Prescription number or unique identifier assigned at originating prescription drug outlet;

4) Name and address of each prescription drug outlet having possession of the drug, device, or supply after the originating prescription drug outlet and the dates the product was in each prescription drug outlet's possession.

5) Date of return or donation;

6) Name, strength, and NDC number of drug received;

7) Name of medical device or medical supply received; if applicable;

8) Quantity received;

9) Date received;

10) Drug, medical device, or medical supply expiration date;

11) Receipt record must state, “Returned or Donated Prescription, Device, or “Supply”

b. Records detailing the receipt of returned or donated prescriptions, devices, and supplies, as required by Rule 3.00.84(a)(1) through (11) may be maintained electronically if the following requirements are met:

1) The prescription drug outlet must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure;

2) Have and maintain a complete on-line receipt file that is printable on the inspector’s request;

3) Have a “lock-out” feature that prevents editing of receipt information;

4) The Board or its inspectors must be able to inspect and review all of the prescription drug receipt transactions of the outlet for the preceding two years. Therefore, immediately upon the oral or written request of the Board or its inspectors, the outlet shall either:

(a) Print a report of all prescription drug receipt transactions for a period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours; or

(b) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review prescription drug receipt transactions, and if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1); or

5) It is the responsibility of the pharmacist manager of the outlet to ensure that all outlet staff is aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the pharmacist manager and/or staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these Rules.

3.00.86 Storage of Returned or Donated Prescription, Medical Devices/Supplies, and Establishment of Handling Fee.

a. Returned or donated prescriptions, medical devices, and medical supplies shall be stored in a separate area from other drug stocks belonging to the pharmacy. This area shall be conspicuously labeled with a sign indicating that such area contains only returned or donated prescriptions, medical devices, or medical supplies.

b. An entity that receives a donated medication, medical device or medical supply may charge the end user a handling fee, which shall not exceed three dollars for each complete prescription, medical device or medical supply dispensed to the end user and shall not resell the donated medication, medical device or medical supply for profit.

3.00.87 Dispensing of Returned or Donated Prescriptions, Medical Devices, or Medical Supplies.

a. Special Conditions for Dispensing Returned or Donated Drugs:

1) Drug products in manufacturer's unit dose or unit of issue packages may be redispensed as often as necessary, provided that the integrity of the product and package are maintained.

2) Drug products which have been packaged into unit dose or unit of issue packages in the prescription drug outlet may be redispensed one time only, except as provided for in Rule 3.00.82((a)(2), provided that the integrity of the product and the package are maintained.

3) Drug products which have been packaged into unit of issue packages in the prescription drug outlet may be redispensed one time only and then only in the package in which originally dispensed, except as provided in (5) below. Partiallyused unit of issue packages may not be emptied and the drugs removed and packaged, nor may additional units of medication be added to partially-used unit of issue packages.

4) Drug products which have been packaged into single dose packages in the prescription drug outlet may be redispensed one time only and then only in the package in which originally dispensed, except as provided in (5) below. Single dose packages may not be emptied and the drugs removed and packaged.

5) Drug products which have been packaged into unit of issue packages or single dose packages may be removed from such packages and packaged for dispensing in a traditional dispensing system.

6) Prescriptions dispensed using returned or donated prescriptions shall be labeled according to section 12-280-124, C.R.S. Additionally, the label shall state, “Donated or Returned Drug.”

b. Records of Dispensing

All records of dispensing shall be compliant with Rules 2.00.00, 3.00.00, and 11.00.00. These records of dispensing, including prescription orders, shall be maintained separately from dispensing records of drugs that were not donated or returned.

3.00.88 Donating Returned or Donated Prescriptions, Medical Devices, or Medical Supplies.

a. Prescription drug outlets may donate the returned or donated prescriptions, medical devices, or medical supplies to any of the following:

1) Nonprofit entity as defined in Rule 3.00.81(g); or

2) A practitioner authorized by law to dispense the drug.

b. Records of donation shall include the following:

1) The name of the drug, medical device, or medical supply;

2) The strength of the drug;

3) The dosage form if appropriate;

4) The quantity of the drug, medical device, or medical supply;

5) The manufacturer name and/or NDC number of the drug if labeled only with its generic name;

6) The date of donation;

7) The name and address of the donating prescription drug outlet;

8) The name and address and registration number of the nonprofit entity receiving the drug, medical device, or medical supply, or the name, address, and license number of the practitioner receiving the drug, medical device, or medical supply.

9) The name and address of the originating prescription drug outlet;

10) The prescription number or unique identifier assigned to the prescription at the originating prescription drug outlet.

11) The date the medication expires; and

12) The name and address of each prescription drug outlet, other than the originating prescription drug outlet, having possession of the prescription and the dates the prescription was in that prescription drug outlet's possession.

c. A copy of the donation record shall be maintained at the prescription drug outlet and a copy of the same record shall be furnished to the receiving individual or entity.

d. Records detailing the donation of prescriptions, medical devices, and medical supplies, as required by Rules 3.00.88(b)(1) through (12) may be maintained electronically if the following requirements are met:

1) The prescription drug outlet must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure;

2) Have and maintain a complete on-line donation file that is printable on the inspector's request;

3) Have a "lock-out" feature that prevents editing of donation information;

4) The Board or its inspectors must be able to inspect and review all of the donation transactions of the outlet for the preceding two years. Therefore, immediately upon the oral or written request of the Board or its inspectors, the outlet shall either:

(a) Print a report of all donation transactions for a period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours; or

(b) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review donation transactions, and if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the

outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1).

5) It is the responsibility of the pharmacist manager of the outlet to ensure that all outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the pharmacist manager and/or staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these Rules.

3.00.89 Record Retention

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3.00.90 Prescriptions Dispensed but Not Delivered. When a drug has been dispensed pursuant to a prescription or LTCF chart order but has not been delivered to the ultimate consumer, the drug may be returned to stock for subsequent redispensing provided that:

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3.00.91 Prescriptions dispensed by prescription drug outlets for delivery to consumers in other other outlet settings. When a drug has been dispensed pursuant to prescription order at a prescription drug outlet but has not been delivered to the ultimate consumer at an other outlet, the drug may be returned to stock only at the originating Prescription Drug Outlet, for subsequent redispensing provided that:

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3.00.92 A prescription drug that has been dispensed by an automated cassette device may be returned to a pharmacy cassette or any automated dispensing device receptacle for redispensing as long as the integrity of the medication has not been altered, bar code scanning technology is used for returning the drug, qualifications for returning the drug are maintained, and the expiration date of the drug has not passed. A pharmacy technician may carry out the process of prepackaging the drug into an automated cassette.

3.01.00 Packaging.

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5.00.00 OUTLETS.

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5.01.50 Security. In every prescription drug outlet, all compounding/dispensing areas shall comply with this regulation.

a. When any compounding/dispensing area of a prescription drug outlet is occupied by any employee, a pharmacist must be physically present within the same building of the prescription drug outlet. This Rule shall not apply if the prescription drug outlet does not possess prescription drug or controlled substance stocks or patient information within the first 120 calendar days after the prescription drug outlet has been registered by the Board.

b. In the event a pharmacist is within the building but absent from a compounding/dispensing area, it is the responsibility of the pharmacist to ensure the proper safeguard of all drugs.

c. If a compounding/dispensing area is continually attended by a pharmacist when other people are in the building, the compounding/dispensing area need not be enclosed. However, if other people are in the building when there is not a pharmacist present, every compounding/dispensing area must be enclosed by a barrier as specified in paragraph e below unless the prescription drug outlet qualifies for the exemption provided under Rule 5.01.50(a).

d. If more than one prescription drug outlet is located within the same building, a pharmacist shall not operate more than one outlet at the same time. If a pharmacist physically leaves one outlet for the purpose of entering into another outlet within the same building, any outlet not being physically attended to by a pharmacist shall be enclosed by a barrier as specified in paragraph e below and a non-pharmacist shall not remain inside the enclosed outlet during that time unless the prescription drug outlet qualifies for the exemption provided under Rule 5.01.50(a).

e. A prescription drug outlet constituting part of a large establishment may be closed while the balance of the establishment is open for business, provided every compounding/dispensing area is enclosed with a secure floor-to-ceiling physical barrier, which shall be a divider or secure total enclosure, in which any openings shall not be large enough to permit removal of items from the compounding/dispensing area. The barrier must be of weight and strength sufficient to prevent it from being readily lifted, removed, penetrated or bent.

f. All entrances to every compounding/dispensing area shall be secured from unauthorized entry when the pharmacist leaves the building except as provided in Rule 5,01.50(a). No one other than a pharmacist shall be permitted to enter any compounding/dispensing area containing drugs, devices or patient information except in extreme emergencies, which shall be defined as a threat to property, public disaster or other catastrophe whereby the public is better served by overlooking the security restrictions of drugs and devices. If any compounding/dispensing area containing drugs, devices or patient information is opened in the absence of a pharmacist or left unsecured from unauthorized entry when the pharmacist leaves the building, the pharmacist manager shall notify the Board in writing within ten days of the discovery of the occurrence. This written notice shall state:

(1) The name of the person authorizing the opening of the compounding/dispensing area if known, or the name of the pharmacist responsible for securing the compounding/dispensing area from unauthorized entry;

(2) The name of the person opening the compounding/dispensing area if known; and

(3) A description of the situation requiring opening of the compounding/dispensing area including the date and time of the opening.

g. While the compounding/dispensing area is closed and the rest of the establishment is open, a person on duty in the establishment shall be able to contact a pharmacist in case of emergency.

h. The hours of business of the compounding/dispensing area shall be submitted to the Board in writing.

i. No prescription drug outlet shall avail itself of the privileges of this Rule until the barrier system and other requirements have been acknowledged, subject to final approval by the Board.

j. This paragraph applies only to the compounding/dispensing areas of a hospital which operates a prescription drug outlet pursuant to a certificate of compliance; or which operates a registered prescription drug outlet on the premises of the hospital for the primary purpose of providing pharmaceutical services to the hospital's in-patients; or permits a registered prescription drug outlet to be operated on the premises of the hospital by another business entity for the primary purpose of providing pharmaceutical service to the hospital's in-patients.

(1) In an emergency situation and when a pharmacist is not on the premises of the hospital and administration of a drug to, or use of a device by or on, an in-patient is necessary pursuant to a chart order, and such drug or device is only available from a locked compounding/dispensing area, an authorized registered nurse may enter a locked compounding/dispensing area to obtain the drug or device. In the case of a drug, only pre-labeled packages, such as unit dose or unit-of-use packages, or a pre-labeled container, may be removed from the compounding/dispensing area.

(2) The following information regarding the removal of such drug or device shall be consistently recorded and maintained in a retrievable document: date; time; name, strength and dosage form of drug, and/or name, and size, if applicable, of device; total quantity of drug or device removed; name and location of patient for whose use the drug or device is necessary; name of the practitioner ordering the drug or device; and the initials or signature of the nursing obtaining the drug or device. This document shall be available for inspection by the Board for a period of two years. Additionally, the original, duplicate or electronic or mechanical facsimile of the chart order shall be left with the above document by the nurse at the time of obtaining the drug or device.

(3) Any unused portion of a drug or device so removed shall be returned to the compounding/dispensing area when a pharmacist is again on the premises. Additional quantities of the drug or device shall be supplied by a pharmacist and properly recorded as required by sections 12-280-120(4) and 12-280-123(1), C.R.S., and Rule 11.05.20.

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8.00.00 ADVERTISING.

8.00.10 Labels. At least one address shall appear on a prescription label and that shall include the address of the prescription drug outlet from which the prescription was dispensed. In the case of a central fill prescription processing contract, the label shall contain at least the name and address of the originating and/or fulfillment pharmacy.

8.00.20 Prescription Order Forms. No prescription drug outlet shall provide any practitioner with prescription order forms that refer to a pharmacist or prescription drug outlet.

8.00.20 No prescription drug outlet shall provide generic, non-patient specific, prescription recommendation sheets or order forms that refer to a specific prescription drug outlet or chain. This does not include patient specific prescription change requests or recommendations for alternative therapy

8.00.30 Multiple Names. A prescription drug outlet shall only use, operate or advertise under the name that appears on the current registration issued by the Board.

8.00.40 Truth in Advertising. No pharmacist or prescription drug outlet shall advertise or allow advertisement that is untrue or misleading in any manner regarding prescription drugs.

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11.00.00 RECORDS AND RECORDKEEPING.

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11.04.10

A hard copy of every prescription order shall be readily retrievable, legible, and available for inspection for a period of two years from the date of any transaction relating to such prescription order unless the prescription drug outlet can comply with all conditions as outlined in Board Rule 11.11.00 in order to not retain the original prescription order for non-controlled substance prescription drugs and Schedule II, III, IV, and V controlled substances. Prescription orders will be deemed to be readily retrievable, legible, and available if they are filed according to the numerical sequence of the serial numbers assigned pursuant to Rule 2.01.10, and are easily readable without the aid of any special device. Prescription drug outlets electronically maintaining prescription orders shall maintain all hard copy controlled substance prescription orders that are not e-prescribed in accordance with section 12-280-134(1)(a), C.R.S., Rules 11.01.00 and 11.02.00(a)(3) and (4), and Title 21 CFR 1304.04 and file the affected hard copy orders by the date of dispensing. In addition to being filed in numerical sequence, three different prescription files shall be maintained: one file shall consist only of Schedule II controlled substance prescription orders; the second file shall consist only of Schedule III, IV and V controlled substance prescription orders; and the third file shall consist of all non-controlled substance prescription drug prescription orders. Filing of prescription orders in any manner other than by numerical sequence will result in such prescription orders being deemed not readily retrievable and available.

A hard copy of every LTCF chart order shall be readily retrievable and available for inspection for a period of two years from the date of any transaction relating to such order. The LTCF chart orders will be deemed to be readily retrievable and available if they are filed according to the date of dispensing. LTCF chart orders for Schedule III, IV, and V controlled substances shall be readily identifiable from non-controlled substance prescription drug LTCF chart orders. Schedule II controlled substance LTCF chart orders shall be retained separately from all other LTCF chart orders.

If a prescription drug outlet utilizes both prescription orders and chart orders, assigning serial numbers to both with the same computer system, the orders must be filed sequentially by serial number.

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15.01.14 Change of name, location, or ownership, or designated representative.

a. Any change in the name or location of the wholesaler shall be reported to the Board on an application provided by the Board within thirty (30) days of such change.

b. Any change in ownership shall be reported on an application provided by the Board within thirty (30) days prior tothe change, with a final notice of the ownership change reported to the Board the dayof such change. The new owner(s) shall pay the appropriate fee. A change of ownership shall be deemed to have occurred:

(1) In the event the owner is a corporation, upon sale or transfer of twenty percent or more of the shares of the corporation to a single individual or entity;

(2) In the event the outlet is owned by a partnership, upon sale or transfer of twenty percent or more of any ownership interest.

(3) In the event the outlet is owned by a limited liability company (LLC), upon sale or transfer of twenty percent or more of the membership interests.

(4) Upon incorporation of an existing wholesaler.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

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32.00.00 CONCERNING HEALTH CARE PROVIDER DISCLOSURES TO CONSUMERS ABOUT THE POTENTIAL EFFECTS OF RECEIVING EMERGENCY OR NONEMERGENCY SERVICES FROM AN OUT-OF-NETWORK PROVIDER

A. Basis: The basis for this rule is to implement the requirements of section 12-30-112, C.R.S., in consultation with the Commissioner of Insurance and the State Board of Health.

B. Purpose: The purpose of these rules and regulations is to establish the requirements for healthcare providers to provide disclosures to consumers about the potential effects of receiving emergency or non-emergency services from an out-of-network provider as required by section 12-30-112, C.R.S.

C. Definitions, for purposes of this Rule, are as follows:

1. “Publicly available” means, for the purposes of this regulation, searchable on the healthcare provider’s public website, displayed in a manner that is easily accessible, without barriers, and that ensures that the information is accessible to the general public, including that it is findable through public search engines. The health care provider’s public website must be accessible free of charge, without having to establish a user account, password, or other credentials, accept any terms or conditions, and without having to submit any personal identifying information.

D. Disclosure requirements.

1. An out of network provider may balance bill a covered person for post-stabilization services in accordance with section 10-16-704, C.R.S., and covered nonemergency services in an in-network facility that are not ancillary services if the provider meets the requirements set forth in section 12-30-112(3.5), C.R.S. If a consumer has incurred a claim for emergency or nonemergency health care services from an out-of-network

provider, the health care provider shall provide the disclosures contained in Appendix F in compliance with section 12-30-112(3.5), C.R.S.

2. The health care provider shall provide the disclosure contained in Appendix F as set forth in section 12-30-112(3.5), C.R.S.:

E. Noncompliance with this Rule may result in the imposition of any of discipline made available by section 12-280-126(1)(c), C.R.S. Appendix A

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APPENDIX F

Your Rights and Protections Against Surprise Medical Bills

When you get emergency care or get treated by an out-of-network provider at an in-network hospital or ambulatory surgical center, you are protected from surprise billing or balance billing.

What is "balance billing" (sometimes called "surprise billing")?

When you see a doctor or other health care provider, you may owe certain out-of-pocket costs, like a copayment, coinsurance, or deductible. You may have additional costs or have to pay the entire bill if you see a provider or visit a health care facility that isn't in your health plan's network.

"Out-of-network" means providers and facilities that haven't signed a contract with your health plan to provide services. Out-of-network providers may be allowed to bill you for the difference between what your plan pays and the full amount charged for a service. This is called "balance billing." This amount is likely more than in-network costs for the same service and might not count toward your plan's deductible or annual out-of-pocket limit.

"Surprise billing" is an unexpected balance bill. This can happen when you can't control who is involved in your care—like when you have an emergency or when you schedule a visit at an in-network facility but are unexpectedly treated by an out-of-network provider. Surprise medical bills could cost thousands of dollars depending on the procedure or service.

You're protected from balance billing for:

Emergency services

If you have an emergency medical condition and get emergency services from an out-of-network provider or facility, the most they can bill you is your plan's in-network cost-sharing amount (such as copayments, coinsurance, and deductibles). You can't be balance billed for these emergency services. This includes services you may get after you're in stable condition, unless you give written consent and give up your protections not to be balanced billed for these post-stabilization services.

If you believe you've been wrongly billed by a healthcare provider, please contact the State Board of Pharmacy at 303-894-7800 or dora_pharmacyboard@state.co.us.

Visit the CMS No Surprises Act website (https://www.cms.gov/nosurprises/consumers) for more information about your rights under federal law.

Review section 12-30-112, C.R.S., for more information about your rights under Colorado state law.

Certain services at an in-network hospital or ambulatory surgical center

When you get services from an in-network hospital or ambulatory surgical center, certain providers there may be out-of-network. In these cases, the most those providers can bill you is your plan's in-network cost-sharing amount. This applies to emergency medicine, anesthesia, pathology, radiology, laboratory, neonatology, assistant surgeon, hospitalist, or intensivist services. These providers can't balance bill you and may not ask you to give up your protections not to be balance billed.

If you get other types of services at these in-network facilities, out-of-network providers can't balance bill you, unless you give written consent and give up your protections. You're never required to give up your protections from balance billing.

You also aren't required to get out-of-network care. You can choose a provider or facility in your plan's network.

When balance billing isn't allowed, you also have these protections:

- You're only responsible for paying your share of the cost (like the copayments, coinsurance, and deductible that you would pay if the provider or facility was in-network). Your health plan will pay any additional costs to out-of-network providers and facilities directly.
- Generally, your health plan must:
  - Cover emergency services without requiring you to get approval for services in advance (also known as "prior authorization").
  - Cover emergency services by out-of-network providers.
  - Base what you owe the provider or facility (cost-sharing) on what it would pay an in network provider or facility and show that amount in your explanation of benefits.
  - Count any amount you pay for emergency services or out-of-network services toward your in-network deductible and out-of-pocket limit.

If you believe you've been wrongly billed by a healthcare provider, please contact the State Board of Pharmacy at 303-894-7800 or dora_pharmacyboard@state.co.us. The federal phone number for information and complaints is: 1-800-985-3059.

Visit www.cms.gov/nosurprises/consumers for more information about your rights under federal law.

Visit https://dpo.colorado.gov/Pharmacy for more information about your rights under Colorado state law, pursuant to section 12-30-112, C.R.S.

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Editor's Notes

History

Rules 2.01.10; 2.01.30; 3.00.50; 3.00.70, 6.00.20; 6.00.30; 6.00.40; 8.00.10; 11.04.20; 14.03.10 eff. 07/30/2007.

Rules 8.00.10; 11.04.10; 20.00.00 eff. 09/30/2007.

Rule 4.00.00 eff. 11/30/2007.

Rules 3.01.20, 10.00.00 eff. 03/01/2008.

Rules 5.01.31; 15.01.11; 15.01.12; 15.09.11; 15.09.14; 22.00.00 eff. 05/30/2008.

Rules 4.02.00 (c), 21.00.00, 23.00.00 eff. 06/30/2008.

Rules 1.00.00, 2.00.00, 3.00.00, 5.00.00, 7.00.00, 11.00.00, 12.00.00, 14.00.00 eff. 11/30/2008.

Rule 15.09.11 eff. 01/31/2009.

Rules 6.00.30, 11.06.00, 22.00.00 eff. 03/02/2009.

Rule 9.00.00 eff. 04/30/2009.

Rules 5.00.55, 5.01.31(a), 6.00.20(f), 14.00.40, 15.01.17, 15.01.18, 15.08.19(f), 15.09.11(d), 15. 09.15, 15.09.19, 15.09.20(g-h), 15.09.23, 15.09.24, 15.10.10, 16.00.20(d), 19.01.10(b), 19.01.30(a) eff. 12/30/2009.

Rules 4.00, 18.00 eff. 03/17/2010.

Rules 3.00.80 – 3.00.90; 5.00.55; 15.01.12; 19.00.00 – 19.01.50. Rule 22.00.00 repealed eff. 07/15/2010.

Rules 1.00.21, 5.01.31(e), 5.01.50 eff. 08/30/2010.

Rules 5.00.55, 21.11.10 (a), 21.21.70 (a) eff. 11/14/2010.

Rules 1.00.18, 2.01.50 – 2.01.53, 3.00.50 – 3.00.51, 5.00.50, 5.00.60, 5.01.31.a, 11.04.10, 15.01.11, 15.09.11.e eff. 06/14/2011.

Rules 3.01.24, 4.00.00, 11.04.20, 11.04.30, 21.00.00 - 21.11.20, 23.00.00 eff. 04/14/2012.

Rule 14.00.10 eff. 05/15/2012.

Entire rule eff. 01/01/2013. Rule 17.00.00 repealed eff. 01/01/2013.

Rules 3.00.21 – 3.00.22, 3.00.55, 3.00.90.e.(4), 3.01.20.c, 3.01.30, 3.01.32, 3.01.34, 4.00.10.f, 4.00.20, 5.01.31.a.(1)(C), 15.10.14.a, 23.00.90 eff. 09/14/2013.

Rules 2.01.10, 3.00.25, 3.00.91, 5.00.15, 6.00.30, 10.00.00, 11.03.00, 11.07.10, 14.00.05.k-l, 14.00.80.e.(2), 14.00.80.j, 16.00.00, 18.00.00, 20.00.00, 21.00.20, 21.10.80, 21.11.00.a.(12), 21.11.10.c, 21.20.20, 21.20.30.b(14), 21.21.40.c, 21.21.70.c, 21.22.00.b(1), 23.00.30, 23.00.50, 23.00.65, 23.00.70, eff. 10/15/2014.

Rules 3.00.22, 3.00.81.l-o, 3.00.82-3.00.84, 3.00.85.a(3), 3.00.86, 3.00.88.a(2), 3.00.88.b(10), 4.06.00, 6.00.10-6.00.20, 6.00.40.a, 6.00.50, 6.00.60.a, 6.00.60.b.10, 6.00.70.a, 6.00.90.b, 6.01.10.a, 19.01.40.c, 21.00.10, 21.00.20.b, 21.10.60.b, 21.10.80.b(4), 21.11.10.a(5), 21.11.10.c(9), 21.20.10.d, 21.20.20.b(2)(a), 21.20.25.b, 21.20.70.f, 21.20.90.b-c, 21.21.10.b, 21.21.70.a(6), 21.21.70.c(10), 23.00.40.y-z, 23.00.70.h-j eff. 09/14/2015.

Rules 3.00.21, 3.00.27, 19.01.10(1), 21.00.20, 21.11.20.d, 21.20.16, 21.20.20.b.(2), 21.20.60.b, 21.20.60.e, 21.21.90.d eff. 03/16/2016.

Rules 3.00.20, 3.00.22 e, 3.00.81 g, 3.00.84, 3.01.10 d, 4.00.10, 4.00.25, 4.05.00, 5.00.15 d, 5.01.31, 6.00.20 e, 7.00.10, 8.00.10, 14.00.80 i-k, 19.01.10 b.(2), 20.00.80 a.1, 21.00.20, 21.00.30, 21.20.20 b, 27.00.00, 28.00.00 eff. 11/14/2016. Rule 10.00.51 repealed eff. 11/14/2016.

Rule 17 eff. 03/17/2017. Rule 18 repealed eff. 03/17/2017.

Rules 3.01.10 d, 7.00.30 b.4, 21.00.20, 21.00.30, 23.00.10, 23.00.70 eff. 11/14/2017. Rules 1.00.15, 5.00.55 a.(6) repealed eff. 11/14/2017.

Rules 3.05.00, 5.01.31 m, 5.01.31 r, 5.01.40 a, 5.01.50 a-f, 11.03.05, 11.04.10, 11.06.10 j, 14.02.30 d, 20.00.90 c, 20.01.00 a.2.iv, 21.00.20 d.ii, 21.20.70 g, 25.00.12 d-e, 25.00.14 c-d, 25.00.16 e eff. 09/17/2018.

Rules 1.00.24, 2.01.50, 2.01.52, 2.01.53, 2.01.56, 2.01.80, 3.00.23, 3.00.30, 3.05.10-3.05.30, 3.05.80, 7.00.30 c, 11.03.00 a, 11.07.10 a, 14.00.05 m, 14.00.40 f.1, 14.00.80 e, 15.01.11 a.(8)(i), 15.01.11 a.(9), 15.09.14 a, 19.01.10 b.-c, 23.00.10, 23.00.70, 29.00.00 eff. 11/30/2019.

Rule 30.00.00 emer. rule eff. 05/01/2020; expired 08/28/2020.

Rules 17.00.10, 17.00.30 a.7, 17.00.50 b.2, 17.00.70, 17.00.80, 17.01.00, 17.02.00 a, 17.03.00 b, 17.04.00 eff. 05/15/2020. Rule 6.00.00 repealed eff. 05/15/2020.

Rule 30.00.00 eff. 08/30/2020. Rule 3.04.00 repealed eff. 08/30/2020.

Rules 2.01.20, 3.00.81 a, 3.01.22 b, 5.00.40, 5.00.50 a, 7.00.30 b, 10.00.60, 11.08.00, 11.08.50, 14.00.05 b, 14.00.40 b-c, 14.05.11, 15.05.20, 15.01.11 b-d, 15.01.14 a-b, 15.01.17, 17.00.50 c, 24.00.50, Appendix C eff. 11/14/2020.

Rule 19.00.00 emer rule eff. 11/19/2020.

Rule 1.00.25, Appendix D eff. 12/30/2020.

Rules 5.01.31 j-k, 17.00.10 d, 19.01.10, 19.01.20, 19.01.30 a, 19.01.40 a.(5)-(9), 19.01.50 a.(3) eff. 03/17/2021.

Rule 1.00.25 E-F eff. 05/15/2021.

Rules 1.00.18, 1.00.24, 2.01.10 d-f, 2.01.20, 3.00.21, 3.00.22, 3.03.10 a(2), 3.03.10 a(7), 3.03.10 b(2), 5.00.01, 5.00.10, 5.00.17, 5.00.19, 5.00.40, 5.00.50, 5.00.55 b, 5.00.60, 7.00.30, 9.00.10 e, 14.00.05, 14.00.80 e(1), 15.01.00 a, 15.02.10, 15.09.11, 15.09.12 c, 15.09.14 a, 15.10.10 l, 17.00.10, 21.00.10, 21.00.20, 21.11.10 c, 21.21.70 a, 23.00.10 n, 23.00.30, 23.00.40, 23.00.50, 23.00.90 a.2, 23.00.90 c, 29.00.50, Appendix C eff. 11/30/2021.

Rules 32.00.00, 33.00.00 emer. rules eff. 09/29/2022.

Rules 3.00.22, 4.00.30 e, 4.00.40 e.-f, 5.00.19 a, 7.00.10 a, 14.00.05 l.-o, 14.00.40 f.(1), 14.00.80 e, 16.00.10, 16.00.20 d.(2), 16.00.80, 16.02.00, 16.02.01, 16.02.03, 17.00.70, 17.00.80, 17.01.00 a, 25.00.10, 25.00.12 a, 25.00.18, 25.00.24 a, 31.00.00, 33.00.00, 34.00.00, Appendices A, C, E, F eff. 11/30/2022.

Rules 5.00.01 g, 5.00.21 emer. rules eff. 07/20/2023.

Rules 5.00.01 g, 5.00.21 eff. 09/14/2023.

Rule 33.00.00 emer. rule eff. 10/01/2023.

Rule 33.00.00 eff. 11/14/2023.

Rules 1.00.25, 2.01.20, 2.01.50, 3.00.51, 5.00.01, 5.00.21, 5.00.60, 5.01.31, 5.01.40, 7.00.10, 11.03.00, 11.06.10, 11.06.30-11.06.50, 11.10.00, 11.11.00, 12.00.32, 14.00.20, 14.00.40, 14.00.60, 14.00.80, 14.02.30, 17.00.10, 17.00.70, 17.00.80, 19.01.10, 20.01.20, 21.00.30, 21.10.00-21.10.40, 21.10.60-21.10.90, 21.11.00, 21.11.10, 21.11.20, 21.11.25, 21.20.10-21.20.23, 21.20.30, 21.20.50-21.20.90, 21.21.10, 21.21.20-21.21.80, 21.22.00, 21.22.10, 23.00.70, 26.00.10, 26.00.20, 27.00.10, 27.00.20, 27.00.40, 31.06.00, Appendix A eff. 11/30/2023.

Rules 2.01.58, 3.01.30-3.01.34, 14.00.30, 14.00.50, 21.10.70, 21.10.90, 21.11.00, 21.11.10, 21.20.40, 30.00.00, 32.00.00, 33.00.00 repealed eff. 11/30/2023.

Rules 14.03.00 a.(13), 14.03.10 c.(12), 14.03.10 e, 14.03.30 eff. 03/16/2024.

Rules 2.01.20 a, 3.00.30 c, 3.00.90 a, 3.00.92, 3.01.22 f, 11.04.10, 15.01.11 (9), 15.10.14 h-i, 17.00.10 a, 17.00.10 a.1, 17.00.10 d, 17.00.30 a.5, 17.00.30 a.7.b, 17.00.30 b, 21.00.20 iii, 23.00.30 e, 31.00.05, Appendix A, Appendix E eff. 11/30/2024.

Rule Appendix G eff. 03/17/2025.

Annotations Rules 33.00.00 D. and 33.00.00 E. (adopted 09/29/2022) were not extended by Senate Bill 23-102 and therefore expired 05/15/2023.