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SALUS POPULI SUPREMA LEX ESTO

"The welfare of the people shall be the supreme law."



JASON KANDER SECRETARY OF STATE

MISSOURI REGISTER

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Missouri



REGISTER

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Documents will be accepted for filing on all regular workdays from 8:00 a.m. until 5:00 p.m. We encourage early filings to facilitate the timely publication of the *Missouri Register*. Orders of Rulemaking appearing in the *Missouri Register* will be published in the *Code of State Regulations* and become effective as listed in the chart above. Advance notice of large volume filings will facilitate their timely publication. We reserve the right to change the schedule due to special circumstances. Please check the latest publication to verify that no changes have been made in this schedule. To review the entire year's schedule, please check out the website at http://www.sos.mo.gov/adrules/pubsched.asp

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HOW TO CITE RULES AND RSMo

RULES—Cite material in the *Missouri Register* by volume and page number, for example, Vol. 28, *Missouri Register*, page 27. The approved short form of citation is 28 MoReg 27.

The rules are codified in the Code of State Regulations in this system—

 Title
 Code of State Regulations
 Division
 Chapter
 Rule

 1
 CSR
 10 1.
 010

 Department
 Agency, Division
 General area regulated
 Specific area regulated

They are properly cited by using the full citation, i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division within the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

ules appearing under this heading are filed under the authority granted by section 536.025, RSMo 2000. An emergency rule may be adopted by an agency if the agency finds that an immediate danger to the public health, safety, or welfare, or a compelling governmental interest requires emergency action; follows procedures best calculated to assure fairness to all interested persons and parties under the circumstances; follows procedures which comply with the protections extended by the Missouri and the United States Constitutions; limits the scope of such rule to the circumstances creating an emergency and requiring emergency procedure, and at the time of or prior to the adoption of such rule files with the secretary of state the text of the rule together with the specific facts, reasons, and findings which support its conclusion that there is an immediate danger to the public health, safety, or welfare which can be met only through the adoption of such rule and its reasons for concluding that the procedure employed is fair to all interested persons and parties under the circumstances.

ules filed as emergency rules may be effective not less than ten (10) days after filing or at such later date as may be specified in the rule and may be terminated at any time by the state agency by filing an order with the secretary of state fixing the date of such termination, which order shall be published by the secretary of state in the *Missouri Register* as soon as practicable.

Il emergency rules must state the period during which they are in effect, and in no case can they be in effect more than one hundred eighty (180) calendar days or thirty (30) legislative days, whichever period is longer. Emergency rules are not renewable, although an agency may at any time adopt an identical rule under the normal rulemaking procedures.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION

Division 2095—Committee for Professional Counselors Chapter 1—General Rules

EMERGENCY AMENDMENT

20 CSR 2095-1.020 Fees. The committee is proposing to amend subsection (1)(D).

PURPOSE: The Division of Professional Registration and the Committee for Professional Counselors are statutorily obligated to enforce and administer the provisions of Chapter 337, RSMo. Pursuant to section 337.507, RSMo, the committee shall by rule and regulation set the amount of fees authorized by Chapter 337 so that the revenue produced is sufficient, but not excessive, to cover the cost and expense to the committee for administering the provisions of Chapter 337, RSMo.

EMERGENCY STATEMENT: The Committee for Professional Counselors is statutorily obligated to set all fees, by regulation, necessary to administer the provisions of sections 337.500–337.540, RSMo. Pursuant to section 337.507, RSMo, the committee shall by regulation set the amount of fees authorized by sections 337.500–337.540, RSMo, to produce revenue which shall not substantially exceed the cost and expense of administering the provisions of sec-

tions 337.500-337.540. Therefore, the committee is proposing to decrease the biennial renewal fee from one hundred twenty-five dollars (\$125) to seventy-five dollars (\$75) for the 2015 renewal period.

The professional counselor license expires on June 30, 2015. The renewal notices for professional counselors will be mailed April 1, 2015 and any professional counselor wishing to reinstate or renew their license beginning April 1, 2015 will be assessed the decreased renewal fee. Without this emergency amendment the decreased fee requirement will not be effective in time for the renewal notice and the advisory committee will collect more revenue than it is statutorily authorized to collect.

The scope of the emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. In developing this emergency amendment, the committee has determined that the fee decrease is necessary for the 2015 renewal period to prevent funds from exceeding the maximum fund balance thereby resulting in a transfer from the fund to general revenue as set forth in section 337.507.4, RSMo. Pursuant to section 324.001.10, RSMo, a compelling governmental interest is deemed to exist for the purposes of section 536.025, RSMo, for licensure fees to be reduced by emergency rule, if the projected fund balance of any agency assigned to the Division of Professional Registration is reasonably expected to exceed an amount that would require transfer from that fund to general revenue. The committee believes this emergency amendment to be fair to all interested parties under the circumstances. This emergency amendment was filed February 24, 2015, becomes effective March 16, 2015, and expires September 11, 2015.

(1) The following fees are established by the Committee for Professional Counselors and are payable in the form of a cashier's check, personal check, or money order:

(D) Biennial Renewal [\$125.00] \$75.00

1. Renewal received 1–60 days late \$50.00 2. Renewal received 61 days–2 years late \$100.00

AUTHORITY: section 337.507, RSMo Supp. [2012] 2014, and section 337.520.1(2), RSMo 2000. This rule originally filed as 4 CSR 95-1.020. Original rule filed Oct. 16, 1986, effective Jan. 30, 1987. For intervening history, please consult the Code of State Regulations. Emergency amendment filed Feb. 24, 2015, effective March 16, 2015, expires Sept. 11, 2015. A proposed amendment covering this same material is published in this issue of the Missouri Register.

nder this heading will appear the text of proposed rules and changes. The notice of proposed rulemaking is required to contain an explanation of any new rule or any change in an existing rule and the reasons therefor. This is set out in the Purpose section with each rule. Also required is a citation to the legal authority to make rules. This appears following the text of the rule, after the word "Authority."

ntirely new rules are printed without any special symbology under the heading of proposed rule. If an existing rule is to be amended or rescinded, it will have a heading of proposed amendment or proposed rescission. Rules which are proposed to be amended will have new matter printed in boldface type and matter to be deleted placed in brackets.

n important function of the *Missouri Register* is to solicit and encourage public participation in the rulemaking process. The law provides that for every proposed rule, amendment, or rescission there must be a notice that anyone may comment on the proposed action. This comment may take different forms.

If an agency is required by statute to hold a public hearing before making any new rules, then a Notice of Public Hearing will appear following the text of the rule. Hearing dates must be at least thirty (30) days after publication of the notice in the *Missouri Register*. If no hearing is planned or required, the agency must give a Notice to Submit Comments. This allows anyone to file statements in support of or in opposition to the proposed action with the agency within a specified time, no less than thirty (30) days after publication of the notice in the *Missouri Register*.

n agency may hold a public hearing on a rule even though not required by law to hold one. If an agency allows comments to be received following the hearing date, the close of comments date will be used as the beginning day in the ninety- (90-) day-count necessary for the filing of the order of rulemaking.

If an agency decides to hold a public hearing after planning not to, it must withdraw the earlier notice and file a new notice of proposed rulemaking and schedule a hearing for a date not less than thirty (30) days from the date of publication of the new notice.

Proposed Amendment Text Reminder: **Boldface text indicates new matter**.

[Bracketed text indicates matter being deleted.]

Title 1—OFFICE OF ADMINISTRATION Division 50—Missouri Ethics Commission Chapter 3—Late Fee

PROPOSED AMENDMENT

1 CSR 50-3.010 Late Fee. The commission is amending sections (1)–(2) and (4)–(9), adding a new section (6), and renumbering as needed.

PURPOSE: This amendment conforms to section 105.963.7. SB844 passed by the 95th General Assembly amended the procedure by which late fee appeals may be appealed per section 105.963.7. Because Senate Bill 844 was declared unconstitutional as a violation of the original purpose requirement of Art. III, Sec. 21, of the Missouri Constitution, this amendment makes the rule consistent with the statute as it existed prior to the passage of SB 844. Legends Bank v. State, 361 S.W.3d 383 (Mo. Banc 2012). The amendment further clarifies the process for late fee appeals and the consideration

of these appeals by the commission.

- (1) When the executive director assesses a late filing fee against a candidate committee for failure to timely file a campaign finance disclosure report, the candidate, candidate committee treasurer, or candidate committee deputy treasurer, [A]as provided by section 105.963.7, RSMo, [candidates, committee treasurers, lobbyists, or individuals required to file a personal financial disclosure statement with the commission] may make a written appeal of late filing fees assessed by the executive director of the Missouri Ethics Commission [(commission) for failure to file a report or statement in a timely manner].
- (2) Any candidate, candidate committee treasurer, or deputy treasurer shall file [T]/the written appeal [must be filed] with the commission within ten (10) days of the receipt of notice of the assessment of the late filing fee [from the executive director] and shall set forth in writing the reasons for the appeal, including the facts which are alleged to constitute good cause for the failure to timely file the report [or statement in a timely manner].
- (4) The sole issue of the appeal shall be whether the [individual's] failure to timely file a campaign finance disclosure report [or statement in a timely manner] was due to good cause as determined by the commission.
- (5) [Appeals may be scheduled and conducted as a written appeal, by telephone, or in person before the executive director. The executive director shall review the appeal no later than twenty-five (25) days after receipt of the notice of appeal or as soon as agreed to by both parties.] When the executive director receives an appeal, the director shall include such appeal on the agenda of a future commission meeting and shall provide written notice to the party bringing the appeal of the date and time of such meeting. The executive director shall have discretion in scheduling the commission's consideration of the appeal.
- (6) The director may contact the party filing the appeal to obtain additional background on the appeal. When the director places the appeal on the commission agenda, the director shall also make a recommendation to the commission regarding the appeal.
- (7) The commission shall consider the written appeal [unless a request for an in-person or telephonic appeal is included in the written appeal filed under section (2). Appeals conducted in person shall be held at the offices of the Missouri Ethics Commission or at a location determined by the executive director.] at a meeting of the commission. The party bringing the appeal shall have the opportunity to appear before the commission upon filing a written request with the commission no less than two (2) business days before the scheduled meeting. At the commission's discretion, the party timely filing the written request to appear may appear by telephone or, if the commission is conducting an in-person meeting, the commission may allow the party to appear in person.
- [(6)](8) The party requesting an appeal of a late fee assessment may be represented by an attorney [during any appeal].
- [(7)](9) Notice of the **commission's consideration of the** appeal, including place, date, and time, shall be sent concurrently to the person requesting an appeal of a late fee assessment and to [the] any attorney of record[, if applicable].

[(8)](10) [A] If the party filing an appeal has previously and timely filed a written request to appear at a meeting of the commission under section (7) of this rule, the commission may grant a continuance [may be granted at the discretion of the executive director] upon receiving a written request by the party filing the appeal.

[(9)](11) [After the appeal, the executive director shall forward to the commission a recommendation on the appeal and place the appeal on the agenda for the next regularly scheduled commission meeting.] After considering the appeal, [T]the commission shall render a final decision[, separately stating their findings]. The executive director shall send a copy of the commission's decision to the [individual requesting] party who requested the appeal [and] or, if an attorney is on record as representing the appealing party, the executive director shall send a copy of the commission's decision to the attorney of record.

AUTHORITY: section 105.955.14(8), RSMo Supp. [2010] 2014. Original rule filed Oct. 4, 2001, effective April 30, 2002. Emergency amendment filed Aug. 30, 2010, effective Sept. 9, 2010, expired March 7, 2011. Amended: Filed Aug. 30, 2010, effective March 30, 2011. Amended: Filed Feb. 27, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Ethics Commission, PO Box 1370, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 4—Wildlife Code: General Provisions

PROPOSED AMENDMENT

3 CSR 10-4.110 General Prohibition; Applications. The commission is amending the authority section of this rule.

PURPOSE: This amendment corrects an inaccurate reference in the authority section.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. Original rule filed June 26, 1975, effective July 7, 1975. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 5—Wildlife Code: Permits

PROPOSED AMENDMENT

3 CSR 10-5.205 Permits Required: Exceptions. The commission proposes to amend subsection (1)(I) and the authority section of this rule.

PURPOSE: This amendment allows for any resident of Missouri with a developmental disability and at least sixteen (16) years of age to purchase any firearms hunting permit without having to take and fail the Hunter Education certification tests and corrects an inaccurate reference in the authority section.

- (1) Any person who chases, pursues, takes, transports, ships, buys, sells, possesses, or uses wildlife in any manner must first obtain the prescribed hunting, fishing, trapping, or other permit, or be exempted under 3 CSR 10-9.110, with the following exceptions:
- (I) Any resident of Missouri with a developmental disability as defined in section 630.005, RSMo, born on or after January 1, 1967, and at least sixteen (16) years of age who has taken the Hunter Education Certification Course, but fails to successfully pass the certification tests,] may purchase any firearms hunting permit as provided in this chapter without display of a valid hunter education certificate card[;], provided s/he carries a physician's statement provided by the department and signed by a licensed physician qualified to evaluate and treat the condition described and certifies the person has this disability. Such person must hunt in the immediate presence of a properly licensed adult hunter who is eighteen (18) years of age or older and who has in his/her possession a valid hunter education certificate card or was born before January 1, 1967. Printed copies of the physician's statement form can be obtained from the Missouri Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180 and online at www.missouriconservation.org;

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. Original rule filed July 22, 1974, effective Dec. 31, 1974. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 5—Wildlife Code: Permits

PROPOSED AMENDMENT

3 CSR 10-5,210 Permits to be Signed and Carried. The commission proposes to amend this rule.

PURPOSE: This amendment allows all permits to be carried in electronic format and exempts permits carried in an electronic format from the permittee signature requirement.

All permits and method exemptions shall be signed and carried by the permittee[.] in either paper or electronic format. Acceptable electronic forms of permits include display of electronic images on a cellular phone or any other type of portable electronic device. Permits carried in an electronic format shall display either a digitized image of a handwritten signature or some other form of an electronic signature. All [P]permits, or temporary permit authorization number(s), and method exemptions shall be exhibited to any officer charged with the enforcement of this Code, or to any transportation company or postal employee when presenting wildlife for shipment.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. This version of rule filed Sept. 19, 1957, effective Dec. 31, 1957. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 7—Wildlife Code: Hunting: Seasons, Methods, Limits

PROPOSED AMENDMENT

3 CSR 10-7.405 General Provisions. The commission proposes to amend section (5) of this rule.

PURPOSE: This amendment allows incidental viewing of wildlife when unintentionally exposed to artificial light.

(5) Wildlife, except raccoons or other furbearing animals when treed with the aid of dogs, may not be searched for, *[spotlighted, located,]* harassed, or disturbed in any manner with the aid of an artificial light, headlight, or spotlight from any roadway, whether public or private, or in any field, woodland, or forest, by any person acting either singly or as one (1) of a group of persons. This section shall not apply to the use of a light by a landowner or lessee as defined by this Code on property under his/her control.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. Original rule filed Aug. 26, 1964, effective Dec. 31, 1964. For intervening history, please consult the **Code of State Regulations**. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 7—Wildlife Code: Hunting: Seasons, Methods, Limits

PROPOSED AMENDMENT

3 CSR 10-7.431 Deer Hunting Seasons: General Provisions. The commission proposes to amend paragraph (5)(D)2. and the authority section of this rule.

PURPOSE: This amendment removes reference to a concealed carry endorsement on a driver license or non-driver license in order to be consistent with the recent change in the law and corrects an inaccurate reference in the authority section.

- (5) Deer Hunting Methods.
 - (D) Prohibited, in use or possession:
 - 1. Methods restricted by local ordinance;
- 2. Self-loading firearms with capacity of more than eleven (11) cartridges in magazine and chamber combined with the exception of concealed firearms carried by persons issued a **valid** concealed carry *[endorsement on a driver license or non-driver license]* **permit** and any qualified law enforcement officer or qualified retired law enforcement officer as defined in the Federal Law Enforcement Officers Safety Act (18 USC 926B or 18 USC 926C). (Firearms possessed under this exception may not be used to take wildlife while deer hunting.);
- 3. Ammunition propelling more than one (1) projectile at a single discharge, such as buckshot;
 - 4. Full hard metal case projectiles;
 - 5. Fully automatic firearms; and
 - 6. Electronic calls or electronically activated calls.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. Original rule filed April 29, 2004, effective May 15, 2004. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 7—Wildlife Code: Hunting: Seasons, Methods, Limits

PROPOSED AMENDMENT

3 CSR 10-7.432 Deer: Archery Hunting Season. The commission proposes to amend subsection (1)(A) and the authority section of this rule.

PURPOSE: This amendment removes reference to a concealed carry endorsement on a driver license or non-driver license in order to be consistent with the recent change in the law and corrects an inaccurate reference in the authority section.

- (1) The archery deer hunting season is September 15 through January 15, excluding the November portion of the firearms deer hunting season. Use archery methods only; firearms may not be possessed with the following exceptions (Firearms possessed under these exceptions may not be used to take wildlife while archery hunting. Proof of this exception must be carried while hunting.):
- (A) Any person who has been issued a **valid** concealed carry *[endorsement on a driver license or non-driver license]* **permit** and such *[endorsement or license]* **permit** has not been suspended, revoked, canceled, or denied may carry concealed firearms on or about his/her person while hunting; and

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. Original rule filed April 29, 2004, effective May 15, 2004. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 7—Wildlife Code: Hunting: Seasons, Methods, Limits

PROPOSED AMENDMENT

3 CSR 10-7.455 Turkeys: Seasons, Methods, Limits. The commission proposes to amend subsection (1)(B), paragraphs (1)(B)1. and (1)(C)1., and the authority section of this rule.

PURPOSE: This amendment removes reference to a concealed carry endorsement on a driver license or non-driver license in order to be consistent with the recent change in the law and corrects an inaccurate reference in the authority section.

- (1) Turkeys may be pursued, taken, killed, possessed, or transported only as permitted in this rule.
- (B) Fall Firearms Season. Fall season annually will be October 1 through October 31. A person possessing the prescribed turkey hunting permit may take two (2) turkeys of either sex during the season. Turkeys may be taken only by shotgun, with shot no larger than No. 4, atlatl, or bow; without the use of dogs, bait, electronic calls, or live decoys; from one-half (1/2) hour before sunrise to sunset in all counties except: Dunklin, McDonald, Mississippi, New Madrid, Newton, Pemiscot, and Scott. Possession of electronic calls or shotshells loaded with shot larger than No. 4 is prohibited while hunting turkeys. A person, while in the act of pursuing or hunting turkey on a fall firearms permit, shall not have both a firearm and bow on his/her person with the following exceptions (Firearms possessed under these exceptions may not be used to take wildlife while hunting with a bow. Proof of this exception must be carried while hunting.):
- 1. Any person who has been issued a **valid** concealed carry *[endorsement on a driver license or non-driver license]* **permit** and such *[endorsement or license]* **permit** has not been suspended, revoked, canceled, or denied may carry concealed firearms on or about his/her person while hunting; and
- 2. Any qualified law enforcement officer or qualified retired law enforcement officer as defined in the Federal Law Enforcement Officers Safety Act (18 USC 926B or 18 USC 926C) may carry concealed firearms on or about his/her person while hunting.
- (C) Fall Archery Season. A person possessing the prescribed archer's hunting permit may take two (2) turkeys of either sex from September 15 through January 15, excluding the dates of the November portion of the firearms deer season. Turkeys may be taken only by bows and atlatl; without the use of dogs, bait, electronic calls, or live decoys; from one-half (1/2) hour before sunrise to one-half (1/2) hour after sunset. Possession of electronic calls is prohibited while hunting turkeys. An archer, while in the act of pursuing or hunting turkey on an archer's permit, shall not have a firearm on his/her person with the following exceptions (Firearms possessed under these exceptions may not be used to take wildlife while hunting with a bow. Proof of this exception must be carried while hunting.):
- 1. Any person who has been issued a **valid** concealed carry *[endorsement on a driver license or non-driver license]* **permit** and such *[endorsement or license]* **permit** has not been suspended, revoked, canceled, or denied may carry concealed firearms on or about his/her person while hunting; and
- 2. Any qualified law enforcement officer or qualified retired law enforcement officer as defined in the Federal Law Enforcement Officers Safety Act (18 USC 926B or 18 USC 926C) may carry concealed firearms on or about his/her person while hunting.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. Original rule filed Dec. 15, 1975, effective Dec. 31, 1975. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 8—Wildlife Code: Trapping: Seasons, Methods

PROPOSED AMENDMENT

3 CSR 10-8.510 Use of Traps. The commission proposes to amend subsection (3)(C) and the authority section of this rule.

PURPOSE: This amendment sets specific parameters for the use of Conibear® traps set in water and corrects an inaccurate reference in the authority section.

(3) Use of Conibear® or Other Killing-Type Traps:

(C) Conibear® or other killing-type traps of any size may be set under water. Conibear® or other killing-type traps having no food, scent, or visual lure placed within one foot (1') of the trap may be partially exposed above water provided the hinges are fully submerged.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. Original rule filed Sept. 20, 1957, effective Dec. 31, 1957. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 9—Wildlife Code: Confined Wildlife: Privileges,
Permits, Standards

PROPOSED AMENDMENT

3 CSR 10-9.220 Wildlife Confinement Standards. The commission is amending the authority section of this rule.

PURPOSE: This amendment corrects an inaccurate reference in the authority section.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. This rule was previously filed as 3 CSR 10-3.020. Original rule filed Nov. 2, 1984, effective Feb. II, 1985. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in

support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 9—Wildlife Code: Confined Wildlife: Privileges,
Permits, Standards

PROPOSED AMENDMENT

3 CSR 10-9.353 Privileges of Class I and Class II Wildlife Breeders. The commission is amending the authority section of this rule.

PURPOSE: This amendment corrects an inaccurate reference in the authority section.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. This rule was previously filed as 3 CSR 10-10.755. Original rule filed Aug. 18, 1970, effective Dec. 31, 1970. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 9—Wildlife Code: Confined Wildlife: Privileges,
Permits, Standards

PROPOSED AMENDMENT

3 CSR 10-9.359 Class I and Class II Wildlife Breeder: Records Required. The commission is amending the authority section of this rule.

PURPOSE: This amendment corrects an inaccurate reference in the authority section.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. This rule was previously filed as 3 CSR 10-10.753. This version of rule filed Aug. 16, 1973, effective Dec. 31, 1973. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 9—Wildlife Code: Confined Wildlife: Privileges, Permits, Standards

PROPOSED AMENDMENT

3 CSR 10-9.560 Licensed Hunting Preserve Permit. The commission is amending the authority section of this rule.

PURPOSE: This amendment corrects an inaccurate reference in the authority section and reorders verbiage for consistency.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. This rule previously filed as 3 CSR 10-10.760. This version of rule filed Jan. 19, 1972, effective Feb. 1, 1972. [This rule previously filed as 3 CSR 10-10.760.] For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 9—Wildlife Code: Confined Wildlife: Privileges, Permits, Standards

PROPOSED AMENDMENT

3 CSR 10-9.565 Licensed Hunting Preserve: Privileges. The commission is amending subparagraph (1)(B)4.A., part (1)(B)4.A.(II), and the authority section of this rule.

PURPOSE: This amendment corrects the name of a permit and an inaccurate reference in the authority section.

(1) Licensed hunting preserves are subject to inspection by an agent of the department at any reasonable time. Animal health standards and movement activities shall comply with all state and federal regulations. Any person holding a licensed hunting preserve permit may release on his/her licensed hunting preserve only legally obtained and captive-reared: pheasants, exotic partridges, quail, mallard

ducks, and ungulates (hoofed animals) for shooting throughout the year, under the following conditions:

- (B) Big Game Hunting Preserve.
- 1. A big game hunting preserve for ungulates shall be a fenced single body of land, not dissected by public roads, and not less than three hundred twenty (320) acres and no more than three thousand two hundred (3,200) acres in size. The hunting preserve shall not be cross-fenced into portions of less than three hundred twenty (320) acres. The hunting preserve shall be fenced so as to enclose and contain all released game and exclude all hoofed wildlife of the state from becoming a part of the enterprise and posted with signs specified by the department. Fence requirements shall meet standards specified in 3 CSR 10-9.220. Fencing for hogs shall be constructed of twelve (12) gauge woven wire, at least five feet (5') high, and topped with one (1) strand of electrified wire. An additional two feet (2') of such fencing shall be buried and angled underground toward the enclosure interior. A fence of equivalent or greater strength and design to prevent the escape of hogs may be substituted with written application and approval by an agent of the department.
- 2. The permittee may exercise privileges provided in 3 CSR 10-9.353 only for species held within breeding enclosure(s) contained within or directly adjacent to the big game hunting preserve. Any such breeding enclosure(s) shall meet standards specified in 3 CSR 10-9.220. Breeding enclosures may be separated from the hunting preserve by a public road, but must be directly adjacent. Other breeding enclosures not contained within or directly adjacent to the hunting preserve are not covered under the privileges of this rule.
- 3. Any person taking or hunting ungulates on a big game hunting preserve shall have in his/her possession a valid licensed hunting preserve hunting permit. The permittee shall attach to the leg of each ungulate taken on the hunting preserve a locking leg seal furnished by the department, for which the permittee shall pay ten dollars (\$10) per one hundred (100) seals. Any packaged or processed meat shall be labeled with the licensed hunting preserve permit number.
- 4. Except as provided in this section, the holder of a Big Game Hunting Preserve Permit shall have an accredited veterinarian collect and submit samples from all known cases of mortality for cervids over six (6) months of age to a United States Department of Agriculture approved laboratory for Chronic Wasting Disease testing. The department reserves the right to require additional sampling and testing during disease investigations or morbidity/mortality events. Animal health standards and movement activities shall comply with all state and federal regulations.
- A. In the event of a mass casualty/mortality event, the director of the department may exempt the holder of a *[big game hunting preserve permit]* Big Game Hunting Preserve Permit from the Chronic Wasting Disease testing requirements within this rule. The following conditions apply:
- (I) All mass casualty/mortality event exemption requests must originate from an accredited veterinarian and must be verbally reported to a conservation agent, regional protection supervisor, or the state wildlife veterinarian of the department.
- (II) The department will have access to collect and submit disease samples from all known cases of mortality for cervids, pertaining to, and in the event of, a mass casualty/mortality event.
- 5. Big game hunting preserve permittees shall report escaped animals immediately to an agent of the department.
- 6. Confirmed positive results from any disease test for a cervid must be verbally reported by the permit holder to a conservation agent or regional protection supervisor of the department within twenty-four (24) hours of receiving the report and provide a copy of the testing report to the state wildlife veterinarian of the department within seventy-two (72) hours. In the event of confirmed positive results from a Chronic Wasting Disease test, the permit holder shall comply with a herd disease response plan approved by the department. The plan may include, but not be limited to, quarantine requirements, testing and depopulation, premises cleaning and disinfection, additional fencing requirements, and restocking guidelines. Failure to comply with an approved herd disease response plan may

result in the suspension or revocation of permit privileges.

- 7. All ungulates acquired by a holder of a [b]Big [g]Game [h]Hunting [p]Preserve [p]Permit must be individually identified on a Breeder's Movement Certificate or a Certificate of Veterinary Inspection. A Breeder's Movement Certificate may be completed by the breeder. The form must list the official identification, age, gender, species, complete address of both the origin and destination, and complete address and name of buyer and seller. The original form must accompany the shipment and a copy shall be maintained by the herd of origin for at least five (5) years. Sources for cervids must be enrolled in a United States Department of Agriculture-approved Chronic Wasting Disease-herd certification program.
- 8. New permits for big game hunting preserves will not be issued for a period of five (5) years within twenty-five (25) miles of a location where Chronic Wasting Disease-positive animal(s) have been confirmed by the department.
- 9. Live cervids imported into the state shall not be held in a licensed big game hunting preserve. Only cervids born inside the state of Missouri may be propagated, held in captivity, and hunted on big game hunting preserves.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. This rule previously filed as 3 CSR 10-10.765. Original rule filed Jan. 19, 1972, effective Feb. 1, 1972. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 3—DEPARTMENT OF CONSERVATION Division 10—Conservation Commission Chapter 9—Wildlife Code: Confined Wildlife: Privileges, Permits, Standards

PROPOSED AMENDMENT

3 CSR 10-9.566 Licensed Hunting Preserve: Records Required. The commission is amending sections (1) and (4) and the authority section of this rule.

PURPOSE: This amendment corrects the name of a permit and an inaccurate reference in the authority section.

(1) Big game hunting preserve permittees shall keep a permanent record, by date, of the number of each species held, acquired, propagated, sold, released, the number of each species taken on the preserve, and the full name, address, and permit number (if applicable) of each buyer, seller, shooter, and/or taker, on forms provided by the department. Printed copies of these forms can be obtained from the Missouri Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180 and online at www.missouriconservation.org. The holder of a *[big game hunting preserve permit]* Big Game Hunting Preserve Permit must establish and maintain a system of inventory for all acquired ungulates that includes the following for each animal: permanent physical identification, species, date of

birth, gender, date of acquisition, complete address of source, complete address and name of both the current and previous owner, mortality date, cause of death (if known), official Chronic Wasting Disease test results as required in 3 CSR 10-9.565 (1)(B)4., method and location of carcass disposal, and the numbers from the Licensed Hunting Preserve Permit of the hunter and locking leg seal (if applicable). These records and applicable state and federal animal health and movement records and permits for each animal shall be maintained on the premises of the licensed big game hunting preserve for at least five (5) years and shall be subject to inspection by an authorized agent of the department at any reasonable time.

(4) Big *Igame hunting preserve permit*] **Game Hunting Preserve Permit** holders exercising the privileges provided in 3 CSR 10-9.353 shall also meet record keeping requirements specified in 3 CSR 10-9.359.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. and section [252.240] 252.040, RSMo 2000. Emergency rule filed March 11, 2002, effective March 21, 2002, expired Sept. 16, 2002. Original rule filed March 11, 2002, effective July 30, 2002. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Regulations Committee Chairman, Department of Conservation, PO Box 180, Jefferson City, MO 65102-0180, or via the department's website at http://mdc.mo.gov/node/24141. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 5—DEPARTMENT OF ELEMENTARY AND SECONDARY EDUCATION Division 20—Division of Learning Services Chapter 600—Office of Early and Extended Learning

PROPOSED RULE

5 CSR 20-600.140 Prekindergarten Program Standards

PURPOSE: This rule requires that any school district reporting children ages three (3) to five (5) for calculation in their average daily attendance must meet standards approved by the State Board of Education.

- (1) Any school district reporting children ages three (3) to five (5) for calculation in their average daily attendance must meet standards approved by the State Board of Education (board) including:
- (A) A lead teacher in each prekindergarten classroom who holds a bachelor's degree and teaching certificate in early childhood education or early childhood special education; and
- (B) A teacher assistant or paraprofessional who holds a child development associate's degree, associate's degree in early child-hood, or sixty (60) college hours with a minimum of three (3) college credit hours in early childhood, child development, or child/family related courses and experience working in a program with young children and their families for any classroom with more than ten (10) children.

AUTHORITY: sections 161.092, 163.011, and 163.018, RSMo Supp.

2014, and section 168.011, RSMo 2000. Original rule filed Feb. 20, 2015.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Department of Elementary and Secondary Education, Attention: Assistant Commissioner, Office of Quality Schools, PO Box 480, Jefferson City, MO 65102-0480 or by email at: eel@dese.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 5—DEPARTMENT OF ELEMENTARY AND SECONDARY EDUCATION

Division 100—Missouri Commission for the Deaf and Hard of Hearing Chapter 200—Board for Certification of Interpreters

PROPOSED AMENDMENT

5 CSR 100-200.130 Certification Maintenance. The Missouri Commission for the Deaf and Hard of Hearing is amending sections (2) and (3) and adding new section (9).

PURPOSE: These additions are to add an ethical requirement to earning annual CEUs and to define a mentorship relationship and how CEUs will be awarded for mentorships.

- (2) One (1) contact hour earns one-tenth (0.1) MICS CEU, except in the case of mentoring, whether as a mentor or a mentee, where one (1) contact hour earns five-hundredths (0.05) MICS CEU.
- (3) An interpreter shall be required to earn two (2.0) CEUs annually for certification maintenance in the MICS, with three-tenths (0.3) specifically focused on Ethics. An interpreter may earn up to one (1.0) MICS CEU per year through mentoring, whether as a mentor or as a mentee. Contact hours earned in another state will be accepted by the BCI provided that the hours acquired can be documented. The twelve- (12-) month period for annually earning CEUs will end ninety (90) days prior to the licensing deadline. This section will become effective for the CEU cycle beginning November 3, 2014 and ending November 2, 2015.
- (9) A "mentorship" is defined as a focused learning relationship between two (2) individuals with pre-approved goals and learning objectives for the enhancement of interpreting skills. The mentor shall be a licensed interpreter in the state of Missouri certified at an equal or higher level than the mentee.
- (A) All forms must be submitted per paragraph 5 CSR 100-200.130(1)(C)4.;
- (B) MICS will automatically accept mentoring hours from relationships that have already been approved by—
 - 1. RID; or
 - 2. Missouri State Committee of Interpreters.

AUTHORITY: section 209.292(10), RSMo Supp. [2013] 2014, and sections 209.295(1), (6), and (8), RSMo 2000. Original rule filed June 20, 1996, effective Jan. 30, 1997. For intervening history, please consult the Code of State Regulations. Amended: Filed Feb. 26, 2015.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Missouri Commission for the Deaf and Hard of Hearing, 1500 Southridge Drive, Suite 201, Jefferson City, MO 65109. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION

Division 2095—Committee for Professional Counselors Chapter 1—General Rules

PROPOSED AMENDMENT

20 CSR 2095-1.020 Fees. The committee is proposing to amend subsection (1)(D).

PURPOSE: The Division of Professional Registration and the Committee for Professional Counselors are statutorily obligated to enforce and administer the provisions of Chapter 337, RSMo. Pursuant to section 337.507, RSMo, the committee shall by rule and regulation set the amount of fees authorized by Chapter 337 so that the revenue produced is sufficient, but not excessive, to cover the cost and expense to the committee for administering the provisions of Chapter 337, RSMo.

(1) The following fees are established by the Committee for Professional Counselors and are payable in the form of a cashier's check, personal check, or money order:

(D) Biennial Renewal [\$125.00] \$75.00

1. Renewal received 1–60 days late \$50.00 2. Renewal received 61 days–2 years late \$100.00

AUTHORITY: section 337.507, RSMo Supp. [2012] 2014, and section 337.520.1(2), RSMo 2000. This rule originally filed as 4 CSR 95-1.020. Original rule filed Oct. 16, 1986, effective Jan. 30, 1987. For intervening history, please consult the Code of State Regulations. Emergency amendment filed Feb. 24, 2015, effective March 16, 2015, expires Sept. 11, 2015. Amended: Filed Feb. 24, 2015.

PUBLIC COST: This proposed amendment will cost state agencies approximately one hundred ninety thousand dollars (\$190,000) biennially for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation, and are expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE COST: This proposed amendment will save private entities approximately one hundred ninety thousand dollars (\$190,000) biennially for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation, and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Committee for Professional Counselors, PO Box 1335, 3605

Missouri Boulevard, Jefferson City, MO 65102-1335, by facsimile at (573) 751-0018, or via email at profcounselor@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the Missouri Register. No public hearing is scheduled.

PUBLIC FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration
Division 2095 - Committee for Professional Counselors
Chapter 1 - General Rules
Proposed Rule 20 CSR 2095-1.020 - Fees
Prepared February 17, 2015 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Loss of Revenue	
Committee for Professional Counselors		\$190,000
	Total Loss of Revenue Biennially for the Life of the Ruie	©100 000

III. WORKSHEET

See Private Entity Fiscal Note

IV. ASSUMPTION

- 1. The total loss of revenue is based on the cost savings to private entities reflected in the Private Fiscal Note filed with this rule.
- 2. The committee utilizes a rolling five-year financial analysis process to evaluate its fund balance, establish fee structure, and assess budgetary needs. The five-year analysis is based on the projected revenue, expenses, and number of licensees. Based on the board's recent five-year analysis, the committee voted on a reduction in individual biennial renewal fees for professional counselors.
- 3. The above figures are based on FY 2014 actuals.

PRIVATE FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration Division 2095 - Committee for Professional Counselors Chapter 1 - General Rules

Proposed Rule 20 CSR 2095-1.020 - Fees

Prepared February 17, 2015 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Estimate the number of entities by class which would likely be affected by the adoption of the proposed amendment:	Classification by type of the business entities which would likely be affected:	Estimated savings for compliance with the amendment by affected entities:
3,800	Biennial Renewal Fee (Renewal Fee - \$50 decrease)	(\$190,000)
	Estimated Biennial Cost Savings for the Life of the Rule	(8190.000)

III. WORKSHEET

See table above.

IV. ASSUMPTION

- 1. The figures reported above for renewals are based on FY14 actuals.
- 2. It is anticipated that the total cost savings will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

Note: The committee is statutorily obligated to enforce and administer the provisions of Chapter 337, RSMo. Pursuant to section 337.507, RSMo the committee shall by rule and regulation set the amount of fees authorized by sections 337.500 to 337.540, RSMo at a level to produce revenue which shall not substantially exceed the cost and expense of administering sections 337.500 to 337.540 RSMo.

by agencies. The order of rulemaking is required to contain a citation to the legal authority upon which the order of rulemaking is based; reference to the date and page or pages where the notice of proposed rulemaking was published in the *Missouri Register*, an explanation of any change between the text of the rule as contained in the notice of proposed rulemaking and the text of the rule as finally adopted, together with the reason for any such change; and the full text of any section or subsection of the rule as adopted which has been changed from that contained in the notice of proposed rulemaking. The effective date of the rule shall be not less than thirty (30) days after the date of publication of the revision to the *Code of State Regulations*.

he agency is also required to make a brief summary of the general nature and extent of comments submitted in support of or opposition to the proposed rule and a concise summary of the testimony presented at the hearing, if any, held in connection with the rulemaking, together with a concise summary of the agency's findings with respect to the merits of any such testimony or comments which are opposed in whole or in part to the proposed rule. The ninety-(90-) day period during which an agency shall file its Order of Rulemaking for publication in the Missouri Register begins either: 1) after the hearing on the Proposed Rulemaking is held; or 2) at the end of the time for submission of comments to the agency. During this period, the agency shall file with the secretary of state the order of rulemaking, either putting the proposed rule into effect, with or without further changes, or withdrawing the proposed rule.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.005 Preemption of All Ordinances and Rules of Political Subdivisions **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1735). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Agriculture (MDA) received one (1) comment on the proposed rule.

COMMENT: R. Smith, RPh, commented: I understand the Missouri Legislature can pass a law and enact a statute that may supersede local city and county ordinances. Does an executive department have the authority to promulgate a rule that supersedes any local ordinances that a city or county may want? I would think that cities and counties may want to address marijuana activities in their own jurisdictions, and I don't see how a state department can prohibit that with a regulation.

RESPONSE: The Missouri Legislature has the constitutional authority to enact laws that are enforceable statewide. The statewide enact-

ments have primacy over local standards unless the legislature provides otherwise. The Missouri Legislature statutorily delegated rule-making authority to the department regarding hemp oil. No change has been made to the rule as a result of this comment.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of

legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.010 Definitions is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1735–1736). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Agriculture (MDA) received two (2) comments on the proposed rule.

COMMENT #1: R. Smith, RPh, commented on section 2 CSR 70-14.010(8) Definition of Child Resistant Packaging. The bill that passed and signed into law requires all state departments to comply with existing federal laws. This definition does not comply with the Poison Prevention Packaging Act of 1970. Also, your rule should address exceptions for when this more secure packaging is not required.

RESPONSE: The Poison Prevention Packaging Act of 1970 requires the use of Child-resistant packaging for prescription drugs, over-the-counter (OTC) drugs, household chemicals, and other hazardous materials that could be considered dangerous for children. The proposed rule on its face complies with the act. No change has been made to the rule as a result of this comment.

COMMENT #2: Timothy Philipp of The Philipp Law Firm commented on section 2 CSR 70-14.010(16), Disqualifying Offense is an improper definition and is in conflict with other areas of the chapter. RESPONSE: MDA has reviewed the comment. The definition of disqualifying offense is appropriate. No change has been made to the rule as a result of this comment.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The

rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.020 Application for a Cultivation and Production Facility License **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39

MoReg 1736–1738). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the gov-

ernment's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.030 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1739–1741). The section with changes is reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Agriculture (MDA) received five (5) comments on the proposed rule from R. Smith, RPh.

COMMENT #1: 2 CSR 70-14.030(1)(A)6.-Practical System of Security. Can you please define and set a standard for what will be considered, "practical?" This is very subjective. Since the statute requires all departments to comply with existing federal laws, we assume that these manufacturers of controlled substance medications will have to meet the federal standards set forth by the United States Food & Drug Administration and the United States Drug Enforcement Administration. Not meeting their basic standards violates your own statute. An example would be how the DEA regulations describe the number of "man hours" it would take to break the integrity of a safe.

RESPONSE: A practical system will include, but not be limited to, lighting, physical barriers, video surveillance, and alarms. MDA will approve security measures during the application process. The rule meets the minimum standard of 261.265, RSMo. No change has been made to the rule as a result of this comment.

COMMENT #2: 2 CSR 70-14.030(1)(A)7.-Maintain a Waste Management System. The production of cannabidiol (CBD) oil from hemp plants requires the plants to be dipped and soaked in highly flammable solvents such as naphtha. This happens twice in the process and then the solvent is "cooked off," similar to making meth. Can you please provide more detail on how manufacturers may need to comply with EPA laws and Missouri DNR laws for boiling naphtha and releasing emissions from cooking flammable substances? Also, once the plant material has been soaked in flammable solvents, how is the facility to lawfully dispose of these plants? The Department of Agriculture needs to provide a standard of practice that will be enforced.

RESPONSE: In addition to meeting the requirements in 261.265, RSMo, manufactures will be responsible for compliance with all state and federal laws concerning emissions and disposal of wastes. These requirements do not fall under the authority of MDA. No change has been made to the rule as a result of this comment.

COMMENT #3: 2 CSR 70-14.030(1)(E)-Description of Licensed Property. Since the cooking and boiling down of highly concentrated solvents can create explosions similar to meth labs, are there additional restrictions being considered to move these facilities away from nursing homes, hospitals, and utility structures for electricity, water, and sewage?

RESPONSE AND EXPLANATION OF CHANGE: MDA concurs. Subsection (1)(E) will be changed.

COMMENT #4: 2 CSR 70-14.030(1)(A)6.-Description of Licensed Property. It is not clear if the marijuana plants have to be grown in a secure indoor facility or if the plants will be grown outside in a field like corn. Please specify if marijuana plants are to be grown strictly indoors or if the plants can be grown outside. If the plants can be grown outside, how do you expect growers to prevent theft? Any person could jump a fence and steal just like a corn field.

RESPONSE: The rule adequately addresses security and mirrors 261.265, RSMo. No change has been made to the rule as a result of this comment.

COMMENT #5: 2 CSR 70-14.030(1)(F)5.C.-Security Plans for Disposing of Adulterated Plants. This proposed language states that plants not fit for sale to the public shall be disposed of in coordination with the Department of Public Safety and local law enforcement. This does not meet the statutory requirements. The bill that was signed into law clearly states that all cannabis product not approved for sale shall be turned over to the Missouri Department of Agriculture. It will be the Department of Agriculture's duty to dispose of the material, and this is set in statute. The law passed also requires the department and agencies to comply with all state and federal existing laws so the EPA and the Missouri DNR will need to weigh in how the Department of Agriculture disposes of this hazardous material.

RESPONSE: The rule mirrors the statute. No change has been made to the rule as a result of this comment.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a

result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT # 5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has more than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances. RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

2 CSR 70-14.030 Supporting Forms, Documents, Plans, and Other Information to be Submitted with the Applicant's Application for a Cultivation and Production Facility License

(1) The applicant must submit to the director—

(E) A location map of the area surrounding the proposed cultivation and production facility. The map must clearly demonstrate that the proposed facility is not located within two thousand (2,000) feet of the property line of a pre-existing public or private preschool, elementary school, middle (junior high) school, high school, daycare facility, home day care, area zoned for residential use, or other locations deemed sensitive to public safety, health, and welfare.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.040 Application—Selection Criteria is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1742–1743). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers

are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director withdraws a proposed rule as

follows:

2 CSR 70-14.050 Retention of the Application and Supporting Forms, Documents, Plans and Other Information Submitted by the Applicant **is withdrawn**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1744). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: The Department of Agriculture (MDA) received one (1) comment on the proposed rule.

COMMENT: R. Smith, RPh, commented on 2 CSR 70-14.050 Retention of Application Records. The proposed language states that unsuccessful applications may be destroyed after one (1) year. Does this department have the authority to promulgate a rule that violates the record retention statutes of the Missouri Secretary of State? There is no provision that says the records shall be saved if there is litigation or a civil suit. The department could be in a lawsuit over the applications and then shred them after one (1) year.

RESPONSE: MDA concurs and will follow the record retention process of the Secretary of State. The rule is deleted.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled

substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.060 Rejection of Cultivation and Production Facility Application Request for Licensure and the Revocation or Suspension of a License is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1744). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insur-

ance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.070 Cultivation and Production Facility License Expiration is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1744). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of

Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT # 5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.080 License not Transferable and Request to Modify or Alter License is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1744–1745). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made

to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.090 Cultivation and Production Facility License Stipulations and Requirements **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1745–1747). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Agriculture (MDA) received one (1) comment on the proposed rule.

COMMENT: R. Smith, RPh, commented on 2 CSR 70-14.090(10) Requirements for Employees-Prohibited Acts. To comply with the federal guidelines from the U.S. Attorney General, are these dispensing care centers prohibited from selling to patients who do not live in Missouri? It seems to comply with all these laws, the department should go ahead and require that all the patients must show their Missouri cannabidiol (CBD) oil card and sales/dispensing may only be made to Missouri citizen/patients who live in Missouri.

RESPONSE: The rule mirrors the statue. The statute is silent on purchases by non- Missouri residents. No change has been made to the rule as a result of this comment.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal govern-

ment would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.100 is adopted.

A notice of proposed rulemaking containing the text of the proposed

rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1748–1750). The section with changes is reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Agriculture (MDA) received four (4) comments on the proposed rule. Three (3) comments were received from R. Smith, RPh, and an additional comment from Bradley L. Schlaggar, M.D., Ph.D., and K. Scott Gronowski, R.Ph., JD, representing Washington University School of Medicine and BJC HealthCare (hereinafter "BJC HealthCare").

COMMENT #1: R. Smith, RPh, commented on 2 CSR 70-14.100(2)(A)5. Storage in Approved Safe or Vault. What is an "approved safe" or "approved vault?"

RESPONSE: MDA will approve safes and/or vaults during the application process. No change has been made to the rule as a result of this comment.

COMMENT #2: R. Smith, RPh, commented on 2 CSR 70-14.100(2)(A)9. Storage Area Must Be Free of Vertebrates. This would mean that no animal with a vertebra could enter the storage area, such as humans. Did you actually mean to say "vermin" which is what the Board of Pharmacy requires for drug storage?

RESPONSE AND EXPLANATION OF CHANGE: MDA concurs that vermin would be more appropriate than vertebrates. Section will be amended to use the term vermin instead of vertebrate.

COMMENT #3: R. Smith, RPh, commented on 2 CSR 70-14.100(3) Inventory of plants/materials. I understand you need to keep an inventory in order to perform an audit to determine if any material is missing or stolen. However, there is no instruction on how to perform the inventory and document it. Do they count the plants, or are they documenting ounces or grams. They need an inventory for the plants, and then a post-production inventory for the bottles and liquids. Is that is ounces or milligrams?

RESPONSE: The rule adequately addresses the inventory process. No change has been made to the rule as a result of this comment.

COMMENT #4: BJC HealthCare commented on Manufacturing Process and Controls. The rule needs to specify standard safety and production protocols to ensure cannabidiol (CBD) oil products have a consistent concentration and are free of contamination. Moreover, there is some evidence that the concentration of different cannabidiods in cannabis products can vary depending on the growing season. To minimize such variation the rule should require the use of Current Good Manufacturing Processes (CGMP) in the production CBD oil, which is the industry standard used by pharmaceutical companies to ensure consistent quality, labeling, efficacy, and most important, safety. By requiring CGMP standards, manufacturers will be better able to demonstrate the consistency of their product, which is paramount to ensuring that an individual taking the product receives the appropriate dose.

RESPONSE: CGMP is governed by FDA and beyond the scope of MDA. As quoted by FDA www.fda.gov/newsevents/publichealthfocus/ucm421168.htm "The FDA understands the interest in making investigational products available to patients while they are being studied for approval, and there are expanded access provisions in both the FDA's statute and its regulations to make this possible." No change has been made to the rule as a result of this comment.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the

department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

2 CSR 70-14.100 Requirements for Production, Manufacture, Storage, Transportation, and Testing of Hemp and Hemp Extract

(2) Storage.

(A) Licensed cultivation and production facility and cannabidiol oil care centers shall—

1. Not produce or maintain hemp in excess of the quantity

required for normal, efficient operation;

- 2. Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security for the production and manufacture of hemp or hemp extract;
- 3. Maintain a separate secure area for hemp and hemp extract that is outdated, adulterated, damaged, deteriorated, misbranded, unusable, or whose sealed containers or packaging have been broken or opened, until such material is disposed;
- 4. Keep all safes, vaults, or any other equipment or areas used for cultivation, production, harvesting, processing, manufacturing, or storage of hemp and hemp extract, securely locked and protected from entry by unauthorized individuals;
- 5. Store all hemp extract in an approved safe or approved vault and in such a manner as to prevent diversion, theft, or loss;
- 6. Store all hemp in a secure area, room, or location within the facility accessible only to authorized facility personnel, the director or designated representative, or law enforcement;
- 7. Have a sign posted at all entries to storage areas of the facility containing hemp or hemp extract stating: "Do Not Enter Access Limited to Authorized Personnel Only";
 - 8. Be maintained in a clean and orderly manner;
- 9. Be free from infestation of pests, including insects, rodents, birds, vermin, and mold; and
- 10. Ensure all areas of the cultivation and production facility and cannabidiol oil care centers are compartmentalized based on function, and that access shall be restricted between compartments.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.110 Hemp Monitoring System Records to be Maintained for Manufacture, Storage, Testing, and Distribution of Hemp and Hemp Extract **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1751–1752). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Agriculture (MDA) received one (1) comment on the proposed rule.

COMMENT: R. Smith, RPh, commented on 2 CSR 70-14.110(2) Produce Records in ten (10) days. This allows people to "cook the books" and hide fraud. Most manufacturers and distributors and dispensers of drugs have to produce their controlled drug records in three (3) business days.

RESPONSE: The ten (10) working days is in reference to requests in writing. All records and hemp monitoring system data shall be available for inspection and auditing at a reasonable time during regular business hours. No change has been made to the rule as a result of this comment.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith. RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.120 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1753–1754). The section with changes is reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Agriculture (MDA) received three (3) comments on the proposed rule. One (1) comment received from R. Smith, RPh, and two (2) comments from Bradley L. Schlaggar, M.D., Ph.D., and K. Scott Gronowski, R.Ph., JD, representing Washington University School of Medicine and BJC HealthCare (hereinafter "BJC HealthCare").

COMMENT #1: R. Smith, RPh, commented on 2 CSR 70-14.120-Packaging and Labeling of Products. This packaging and labeling rule proposed does not provide any of the following information for a patient that is standard on all other drug products:

- Dosing level and instructions;
- How to store the drug, in light or not, and at what temperature;
- Are there foods I should not mix it with?
- Are there any drugs I should not mix it with?
- Poison control contact number information;
- Dosing level for adults as well as children;
- What if the patient is an infant?
- What if the patient is pregnant?

I did not notice a tamper proof seal/membrane as a requirement to show that the drug product has not been tampered with.

RESPONSE AND EXPLANATION OF CHANGE: The neurologist is responsible for determining the treatment and guidance for use. As a result, MDA will remove subsection (3)(E) "Medicating instructions."

COMMENT #2: BJC HealthCare commented on Labeling: The marijuana plant contains eighty-five (85) cannabinoids, many of which could have effects (harmful or desirable) on a patient's treatment. The rule should require a manufacturer to state on the label and all cannabinoids that are contained in the product.

RESPONSE: The rule mirrors 195.207.2.(3)(b), RSMo. No change has been made to the rule as a result of this comment.

COMMENT #3: BJC HealthCare commented on the manufacturer's role in communicating with patients: The rule is unclear as to which individual or entity is responsible for determining the dosage of hemp required by the patient, as well as ensuring proper usage of the hemp product by the patient. 19 CSR 20-51.010, as proposed by the Department Health and Senior Services, only requires the neurologist to recommend cannabidiol (CBD) oil treatment, but this rule and rules by the Department of Agriculture presumably leave dosage determination, as well as communication about dosage and possible side effects, to the manufacturer and dispensing facility.

RESPONSE: The neurologist is responsible for determining the treatment and guidance for use. No change has been made to the rule as a result of this comment.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address mar-

ijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

2 CSR 70-14.120 Packaging and Labeling of Hemp and Hemp Extract

- (3) All hemp extract must be labeled with—
- (E) A statement, "Keep out of reach of children", in bold capital letters; and
 - (F) Net weight or measure of the container's net content.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section

263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.130 Cultivation and Production Facility and Cannabidiol Oil Care Center Security Measures, Reportable Events, and Records to be Maintained **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1755–1756). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that

would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.140 Waste Disposal of Unusable Hemp and Hemp Extract is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1757–1758). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Agriculture (MDA) received one (1) comment on the proposed rule.

COMMENT: R. Smith, RPh, commented on 2 CSR 70-14.140(2)(C) Disposal of Unwanted Hemp Waste. This subsection is in violation of state and federal laws, and it will cause researchers to be in violation of state and federal laws.

- Researchers must be registered with the DEA;
- Researchers may only receive controlled drugs from other authorized registrants who have DEA numbers. Hemp manufacturers won't have DEA numbers, so researchers cannot legally accept any controlled drug waste product from them;
- The researchers won't be able to have any legitimate use for the hemp waste. Hemp waste will not be consistently made, so no reliable research can take place.

RESPONSE: 261.265.9., RSMo provides for hemp waste to be donated to an institution of higher education for research purposes as does Section 7606 of the Agricultural Act of 2014. No change has been made to the rule as a result of this comment.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The

rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.150 Pesticide Record Keeping Requirements is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1759–1760). No changes have been made in the text of the

proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith. RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government

would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.160 Inspection of Premises and Facility of License Holder, Samples Collected for Analysis, Issuance of Search Warrant, and Powers of Director During Investigation or Hearing, When the Director May Report Violations to Prosecuting Attorney for Action is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1761–1763). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a

result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.170 Stop Sale, Use, or Removal Orders is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1764–1765). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims

when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.180 Revocation, Suspension, or Modification of a Cultivation and Production Facility License **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1766–1768). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the application of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 2—DEPARTMENT OF AGRICULTURE Division 70—Plant Industries Chapter 14—Missouri Cannabidiol Oil Rules

ORDER OF RULEMAKING

By the authority vested in the Department of Agriculture under section 263.040, RSMo 2000, the director adopts a rule as follows:

2 CSR 70-14.190 Penalty for Violations of the Act or Any Regulation Issued Thereunder is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on November 3, 2014 (39 MoReg 1769–1771). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF GENERAL COMMENTS: The Department of Agriculture (MDA) received five (5) general comments from R. Smith, RPh.

COMMENT #1: The bill that was passed clearly states in multiple places that the manufacturing and dispensing of hemp extract must be in compliance with existing state and federal laws. How does the department plan on implementing these proposed rules when they clearly do not comply with existing federal laws? Drug manufacturers are required to have a license from the U.S. FDA and the DEA. The bill requires these. How can the department ignore what the statute requires? Please explain to avoid an injunction.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #2: Insurance companies do not have to pay claims when a person is clearly violating laws and committing a criminal act. How will drug manufacturers be able to get insurance? No insurance company will have to pay since these manufacturers and dispensers will clearly be violating Missouri and federal laws?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #3: The department is going to authorize and license someone to make a drug. The drug will be manufactured, packaged, labeled, and dispensed for use to treat children. How can the department allow a licensee to take on this incredible responsibility, without any requirement to have any liability insurance? Legitimate drug companies all have recalls from bad batches and mold and other problems. Why don't you make it a requirement that manufacturers and dispensers carry liability/malpractice insurance?

RESPONSE: The General Assembly did not address insurance requirements in 261.265, RSMo. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

COMMENT #4: Labeling. State law section 195.100, RSMo states that no manufacturer shall manufacture and dispense any controlled substance without labeling the controlled substance with the appropriate Drug Schedule insignia, i.e., Cl, C2, C3, C4, C5. I did not see this in your rules.

RESPONSE: The proposed rules reflect the authority given by the General Assembly to MDA. The rules do not preclude the applica-

tion of other state laws and regulations. No changes have been made to the rules as a result of this comment.

COMMENT #5: How can the department authorize the commission of felonies by department regulations? During this past session, the Missouri legislature enacted this statute to authorize the creation of some hemp oil extract. Simultaneously, they passed SB491 that would still make hemp a Schedule One controlled substance. It is illegal to possess and illegal to manufacture, and if a person has *more* than 36 grams of this hemp oil extract, their business can be deemed a "public nuisance." The legislature enacted two separate pieces of legislation that clearly conflict. The legislature did not remove hemp oil from the state's list of illegal controlled substances.

RESPONSE: A 2013 Department of Justice memo clarified the government's prosecutorial priorities and stated that the federal government would rely on state and local law enforcement to address marijuana activity through enforcement of their own narcotics laws. The rules mirror the requirements of 261.265, RSMo. No changes have been made to the rules as a result of this comment.

Title 5—DEPARTMENT OF ELEMENTARY AND SECONDARY EDUCATION Division 10—Commissioner of Education Chapter 2—Education Scholarships

ORDER OF RULEMAKING

By the authority vested in the State Board of Education under sections 161.092 and 161.825.12, RSMo Supp. 2014, the board hereby amends a rule as follows:

5 CSR 10-2.010 Scholarship Granting Organizations is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1932). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 5—DEPARTMENT OF ELEMENTARY AND SECONDARY EDUCATION Division 10—Commissioner of Education Chapter 2—Education Scholarships

ORDER OF RULEMAKING

By the authority vested in the State Board of Education under sections 161.092 and 161.825.12, RSMo Supp. 2014, the board hereby amends a rule as follows:

5 CSR 10-2.020 Scholarships is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1932). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 5—DEPARTMENT OF ELEMENTARY AND SECONDARY EDUCATION

Division 10—Commissioner of Education Chapter 2—Education Scholarships

ORDER OF RULEMAKING

By the authority vested in the State Board of Education under sections 161.092 and 161.825.12, RSMo Supp. 2014, the board hereby amends a rule as follows:

5 CSR 10-2.030 Eligibility for Scholarships is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1932–1933). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION

Division 200—Insurance Solvency and Company Regulation Chapter 12—Missouri and Extended Missouri Mutual Companies

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Insurance, Financial Institutions and Professional Registration under section 374.045, RSMo Supp. 2014, and sections 380.471 and 380.561, RSMo 2000, the director amends a rule as follows:

20 CSR 200-12.020 Extended Missouri Mutual Companies' Approved Investments is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 15, 2014 (39 MoReg 2140). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The public comment period on this proposed amendment ended January 14, 2015, and a public hearing was held January 16, 2015. At the public hearing, three (3) comments were made in support of the proposed amendment.

COMMENT: John Rehagen, with the Division of Insurance Company Regulation in the Department of Insurance, Financial Institutions and Professional Registration, Brent Butler, with the Missouri Insurance Coalition and the Missouri Association of Mutual Insurance Companies, and Mark Johnston, with the National Association of Mutual Insurance Companies, each testified at the public hearing in support of the proposed amendment with no suggested changes. Mr. Johnston additionally submitted written comments in support of the proposed amendment with no suggested changes.

RESPONSE: No changes have been made to the rule as a result of these comments.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION

Division 2220—State Board of Pharmacy Chapter 5—Drug Distributor

ORDER OF RULEMAKING

By the authority vested in the State Board of Pharmacy under sections 338.340 and 338.350, RSMo 2000, and sections 338.140.1, 338.315, 338.330, 338.333, 338.335, and 338.337, RSMo Supp. 2014, the board amends a rule as follows:

20 CSR 2220-5.020 Drug Distributor Licensing Requirements **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1964–1966). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.010 Definitions is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1967–1970). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.020 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1970–1980). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received four (4) comments on the proposed amendment.

COMMENT #1: MCHCP staff commented regarding a grammatical error under paragraph (2)(C)1.

RESPONSE: The language in the December 1, 2014 *Missouri Register* was printed correctly. No changes were made to the rule based on this comment.

COMMENT #2: MCHCP staff commented under subsection (5)(B), to clarify that the order of placement is proof of eligibility for addition of a foster child(ren). The words "papers in a subscriber's care" are unnecessary.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, subsection (5)(B) has been amended to remove "papers in a subscriber's care."

COMMENT #3: MCHCP staff commented under subparagraph (5)(G)1.A., to clarify the proof of eligibility requirements for a disabled child.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, subparagraph (5)(G)1.A. was amended to add that evidence that a permanently disabled child was entitled to and receiving disability benefits prior to turning age twenty-six (26) years as documentation for enrolling or continuing coverage as a disabled dependent.

COMMENT #4: MCHCP staff commented under paragraph (7)(A)5., to clarify the events that cause a termination of coverage to occur.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, the language in paragraph (7)(A)5. regarding when a child reaches age twenty-six (26) was removed because it is duplicative of the language regarding when a dependent is no longer eligible for coverage.

22 CSR 10-2.020 General Membership Provisions

- (5) Proof of Eligibility. Proof of eligibility documentation is required for all dependents and subscribers, as necessary. Enrollment is not complete until proof of eligibility is received by MCHCP. A subscriber must include his/her MCHCPid or Social Security number on the documentation. If proof of eligibility is not received, MCHCP will send a letter requesting it from the subscriber. Except for open enrollment, documentation must be received within thirty-one (31) days of the letter date, or coverage will not take effect for those individuals whose proof of eligibility was not received. MCHCP reserves the right to request that such proof of eligibility be provided at any time upon request. If such proof is not received or is unacceptable as determined by MCHCP, coverage will terminate or never take effect. If enrolling during open enrollment, proof of eligibility must be received by November 20, or coverage will not take effect the following January 1 for those individuals whose proof of eligibility was not received.
- (B) Acceptable forms of proof of eligibility are included in the following chart:

(G) Disabled Dependent.

- 1. A new employee may enroll his/her permanently disabled child or an enrolled permanently disabled dependent turning age twenty-six (26) years may continue coverage beyond age twenty-six (26) years, provided the following documentation is submitted to the plan prior to the dependent's twenty-sixth birthday for the enrolled permanently disabled dependent or within thirty-one (31) days of enrollment of a new employee and his/her permanently disabled child:
- A. Evidence that the permanently disabled dependent or child was entitled to and receiving disability benefits prior to turning age twenty-six (26) years. Evidence could be from the Social Security Administration, representation from the dependent's or child's physician, or by sworn statement from the subscriber;
- B. A letter from the dependent's or child's physician describing the current disability and verifying that the disability predates the dependent's or child's twenty-sixth birthday and the disability is permanent; and
- C. A benefit verification letter dated within the last twelve (12) months from the Social Security Administration (SSA) confirming the child is still considered disabled by SSA.
- 2. If a disabled dependent or child over the age of twenty-six (26) years is determined to be no longer disabled by the SSA, coverage will terminate the last day of the month in which the disability ends or will never take effect for new enrollment requests.
- 3. Once the disabled dependent's coverage is cancelled or terminated, s/he will not be able to enroll at a later date.

(7) Termination.

- (A) Unless stated otherwise, termination of coverage shall occur on the last day of the calendar month coinciding with or after any of the following events, whichever occurs first:
- 1. Failure to make any required contribution toward the cost of coverage. If MCHCP has not received payment of premium at the end of the thirty-one- (31-) day grace period, the subscriber and his/her dependents will be retroactively terminated to the date covered by his/her last paid premium. The subscriber will be responsible for the value of services rendered after the retroactive termination date, including, but not limited to, the grace period;
 - 2. Entry into the armed forces of any country;
- 3. With respect to active employee(s) and his/her dependents, termination of employment in a position covered by the MCHCP, except as expressly specified otherwise in this rule;
- 4. With respect to active employee(s) and his/her dependents, the employer has determined that the active employee is no longer an eligible variable-hour employee;
- 5. With respect to dependents, upon divorce or legal separation from the subscriber or when a dependent is no longer eligible for coverage. A subscriber must terminate coverage for his/her enrolled ex-spouse and stepchild(ren) at the time his/her divorce is final.
- A. When a subscriber drops dependent coverage after a divorce, s/he must submit a completed form, a copy of the divorce decree, and current addresses of all affected dependents. Coverage ends on the last day of the month in which the divorce decree and completed form are received by MCHCP or MCHCP otherwise receives credible evidence of a final divorce that results in loss of member eligibility under the plan;
- 6. Death of dependent. The dependent's coverage ends on the date of death. The subscriber must submit completed form and a copy of the death certificate within thirty-one (31) days of death;
- 7. A member's act, practice, or omission that constitutes fraud or intentional misrepresentation of material fact;
- 8. A member's threatening conduct or perpetrating violent acts against MCHCP or an employee of MCHCP; or
 - 9. A member otherwise loses benefit eligibility.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.030 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1981–1983). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment

COMMENT #1: MCHCP staff commented to consider removing the "of" before the deleted words "employee coverage."

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, the word "of" has been removed from section (1). MCHCP intended to remove this word from the proposed rule in the original submission.

22 CSR 10-2.030 Contributions

(1) Total premium costs for various levels are based on employment status, retiree status, eligibility for Medicare, and various classifications of dependent participation as established by the plan administrator.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.045 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1983–1984). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan received three (3) comments on the proposed amendment.

COMMENT #1: UMR believes that MCHCP intended to remove the prior authorization requirement for procedure codes ending in "T". RESPONSE: MCHCP intended to prior authorize all procedure codes ending in "T". These are Category III procedures and many are investigational, some are not. Just as in prior years, the prior authorization should continue on these types of procedures so a proper determination can be made prior to service delivery. No changes have been made to the rule as a result of this comment.

COMMENT #2: UMR suggests an addition that states prior authorization for services outside the country are not required. UMR is not prior authorizing services from outside the country, as the providers are not contracted, and obtaining clinical information prior to services being delivered is problematic.

RESPONSE: No changes have been made to the rule as a result of this comment.

COMMENT #3: MCHCP staff commented to clarify the extent to which MCHCP will cover dental care from the direct result of cancer. RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, MCHCP has clarified section (1) to add prior authorization requirements for dental care.

22 CSR 10-2.045 Plan Utilization Review Policy

- (1) Clinical Management—Certain benefits are subject to a utilization review (UR) program. The program has the following components:
- (A) Prior Authorization of Services—The claims administrator must authorize some services in advance. Without prior authorization, any claim that requires prior authorization will be denied for payment. Members who have another primary carrier, including Medicare, are not subject to this provision except for those services that are not covered by the other primary carrier, but are otherwise subject to prior authorization under this rule. Prior authorization does not verify eligibility or payment. Prior authorizations found to have a material misrepresentation or intentional or negligent omission about the person's health condition or the cause of the condition may be rescinded.
- 1. The following medical services are subject to prior authorization:
- A. Ambulance services for non-emergent use, whether air or ground;
- B. Anesthesia and hospital charges for dental care for children younger than five (5) years, the severely disabled, or a person with a medical or behavioral condition that requires hospitalization;
 - C. Applied behavior analysis for autism at initial service;
 - D. Auditory brainstem implant (ABI);
 - E. Bariatric surgery;
- F. Cardiac rehabilitation after thirty-six (36) visits within a twelve- (12-) week period;
 - G. Chiropractic services after twenty-six (26) visits annually;
 - H. Cochlear implant device;
 - I. Chelation therapy;
 - J. Dental care;
- K. Durable medical equipment (DME) over one thousand five hundred dollars (\$1,500) or DME rentals over five hundred dollars (\$500) per month;
 - L. Genetic testing or counseling;
 - M. Hearing Aids;
 - N. Home health care;
 - O. Hospice care and palliative services;
 - P. Hospital inpatient services;
- Q. Imaging (diagnostic non-emergent outpatient), including magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), positron emission tomography (PET), computerized tomography scan (CT), computerized tomography angiography (CTA), electron-beam computed tomography (EBCT), and nuclear cardiology;
- R. Maternity coverage for maternity hospital stays longer than forty-eight (48) hours for vaginal delivery or ninety-six (96) hours for cesarean delivery;
 - S. Nutritional counseling after six (6) sessions annually;
 - T. Orthognathic surgery;
 - U. Orthotics over one thousand dollars (\$1,000);
- V. Physical, speech, and occupational therapy and rehabilitation services (outpatient) after sixty (60) combined visits per incident;
- W. Procedures with procedure codes ending in "T" (temporary procedure codes used for data collection, experimental, investi-

gational, or unproven procedures);

- X. Prostheses over one thousand dollars (\$1,000);
- Y. Pulmonary rehabilitation after thirty-six (36) visits within a twelve- (12-) week period;
 - Z. Skilled nursing facility;
- AA. Surgery (outpatient)—The following outpatient surgical procedures: cornea transplant, potential cosmetic surgery, sleep apnea surgery, implantable stimulators, stimulators for bone growth, spinal surgery (including, but not limited to, artificial disc replacement, fusions, nonpulsed radiofrequency denervation, vertebroplasty, kyphoplasty, spinal cord stimulator trials, spinal cord stimulator implantation, and any unlisted spinal procedure), and oral surgery (excisions of tumors and cysts of the jaw, cheeks, lips, tongue, roof, and floor of the mouth when such conditions require pathological exams); and
- BB. Transplants, including requests related to covered travel and lodging.
- 2. The following pharmacy services included in the prescription drug plan for non-Medicare primary members are subject to prior authorization:
- A. Second-step therapy medications that skip the first-step medication trial;
 - B. Specialty medications;
- C. Medications that may be prescribed for several conditions, including some for which treatment is not medically necessary;
- D. Medication refill requests that are before the time allowed for refill:
- E. Medications that exceed drug quantity and day supply limitations;
- F. Medications with costs exceeding nine thousand nine hundred ninety-nine dollars and ninety-nine cents (\$9,999.99) at retail or the mail order pharmacy and one hundred forty-nine dollars and ninety-nine cents (\$149.99) for compound medications at retail or the mail order pharmacy; and
 - 3. Prior authorization timeframes.
- A. A benefit determination for non-urgent prior authorization requests will be made within fifteen (15) calendar days of the receipt of the request. The fifteen (15) days may be extended by the claims administrator for up to fifteen (15) calendar days if an extension is needed as a result of matters beyond the claims administrator's control. The claims administrator will notify the member of any necessary extension prior to the expiration of the initial fifteen- (15-) calendar-day period. If a member fails to submit necessary information to make a benefit determination, the member will be given at least ninety (90) calendar days from receipt of the extension notice to respond with additional information.
- B. A benefit determination for urgent prior authorization requests will be made as soon as possible based on the clinical situation, but in no case later than twenty-four (24) hours of the receipt of the request;

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.051 PPO 300 Plan Benefit Provisions and Covered Charges is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1984–1985). No changes have been made in the text

of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment.

COMMENT #1: UMR commented that the language regarding prior authorization requirements provided for in 22 CSR 10-2.045 regarding services received while out of the country should be removed. RESPONSE: No changes have been made to the rule as a result of this comment.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.052 PPO 600 Plan Benefit Provisions and Covered Charges **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1985–1986). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment.

COMMENT #1: UMR commented that the language regarding prior authorization requirements provided for in 22 CSR 10-2.045 regarding services received while out of the country should be removed. RESPONSE: No changes have been made to the rule as a result of this comment.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, and section 103.080.3, RSMo Supp. 2014, the executive director amends a rule as follows:

22 CSR 10-2.053 Health Savings Account Plan Benefit Provisions and Covered Charges is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1986–1988). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment

COMMENT #1: UMR commented that the language regarding prior authorization requirements provided for in 22 CSR 10-2.045 regarding services received while out of the country should be removed. RESPONSE: No changes have been made to the rule as a result of this comment.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.055 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1988–1998). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received eight (8) comments on the proposed amendment.

COMMENT #1: UMR and MCHCP staff both commented that the transition of care language in section (2) be reviewed to ensure it is in alignment with Chapter 354.612, RSMo.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, the amended language has been removed to ensure alignment with Chapter 354.612, RSMo.

COMMENT #2: MCHCP staff commented to clarify the extent to which MCHCP will cover dental care from the direct result of cancer.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, MCHCP has amended paragraph (3)(E)12., to clarify dental care coverage.

COMMENT #3: Ron Fitzwater, with the Missouri Pharmacy Association, commented to ensure pharmacists are included in the definition of certified Diabetes Educator stating this type of patient counseling is permitted under their scope of practice and has yielded results in the MO HealthNet program.

RESPONSE AND EXPLANATION OF CHANGE: Diabetes Education is covered by a certified diabetic educator when provided through the medical network provider. A pharmacist would be included as a certified diabetic educator if s/he has that credential. Language has been added to clarify the service must be provided through a medical network provider.

COMMENT #4: Scott George, B.S., BC-HIS, with the Mid-America Hearing Center and Robert Guison, with the Missouri Hearing Society, both commented the comprehensive exam in part (3)(E)22.A.(I) should be replaced with a preliminary exam.

RESPONSE AND EXPLANATION OF CHANGE: Language has been added to reflect that prior to receiving a hearing aid, a member must have a medical exam as recommended by the Food and Drug Administration (FDA). The purpose of the medical exam is to assure

that all medically treatable conditions that may affect hearing are identified and treated before a hearing aid is provided.

COMMENT #5: Scott George, B.S., BC-HIS, with the Mid-America Hearing Center and Robert Guison, with the Missouri Hearing Society, both commented that part (3)(E)22.A.(II) requires a "comprehensive hearing test to assess the need for hearing aids." This aligns with HCPCS codes V5010 and is appropriate for an evaluation that was performed for the primary purpose of selecting appropriate hearing aid amplification. The comprehensive hearing assessment includes air, bone, speech reception threshold, and speech recognition/speech understanding/word recognition testing, with masking where appropriate. Hearing health care practice protocols require that such testing be done using an audiometer.

RESPONSE AND EXPLANATION OF CHANGE: Language has been added to reflect that prior to receiving a hearing aid, a member must have a medical exam as recommended by the FDA. The purpose of the medical exam is to assure that all medically treatable conditions that may affect hearing are identified and treated before a hearing aid is provided.

COMMENT #6: Scott George, B.S., BC-HIS, with the Mid-America Hearing Center and Robert Guison, with the Missouri Hearing Society both commented with the suggestion that "hearing instrument specialists" be added to the list of providers licensed to perform a comprehensive hearing test.

RESPONSE AND EXPLANATION OF CHANGE: MCHCP has amended language as requested.

COMMENT #7: Scott George, B.S., BC-HIS, with the Mid-America Hearing Center, commented that while everything listed in these rules is in the scope of practice for audiologist and hearing instruments specialists, ASHA (the national association for speech-language pathologists) makes a specific point that only hearing screenings are in their scope of practice. They suggested MCHCP might want to check with the Missouri association (MSHA) regarding rule changes.

RESPONSE AND EXPLANATION OF CHANGE: MCHCP has amended language to reflect this comment.

COMMENT #8: UMR commented that part (3)(E)26.A.(IV) should be clarified to state that inpatient treatment in a network hospital or facility by a non-network provider is covered at the network benefit. RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, part (3)(E)26.A.(IV) has been clarified to specify that inpatient treatment in a network hospital or facility by a non-network provider is covered at the network benefit.

22 CSR 10-2.055 Medical Plan Benefit Provisions and Covered Charges

(2) Transition of Care. A transition of care option is available for members using a hospital or dialysis facility that loses network status during the plan year. A subscriber and his/her dependents using a hospital or dialysis facility that loses network status during the plan year may apply for a ninety- (90-) day transition of care to continue receiving network benefits with that hospital or dialysis facility. The request for consideration must be submitted to the medical plan within forty-five (45) days of the last day the hospital or dialysis facility was a contracted network provider, to be eligible for transition of care benefits. A subscriber and his/her dependents may apply for additional days beyond the ninety- (90-) day transition if care is related to a moderate or high risk pregnancy, if care is during a member's second or third trimester of pregnancy, or up to eight (8) weeks postpartum. The subscriber and his/her dependents must apply for additional transition of care days prior to the end of the initial ninety- (90-) day transition of care period. Most routine services, treatment for stable conditions, minor illnesses, and elective surgeries will not be covered

by transition of care benefits. The rate of payment during the transitional period shall be the fee paid prior to leaving the network. Benefits eligible for transition of care include:

- (3) Covered Charges Applicable to the PPO 300 Plan, PPO 600 Plan, and HSA Plan.
- (E) Plan benefits for the PPO 300 Plan, PPO 600 Plan, and HSA Plan are as follows:
- 1. Allergy Testing and Immunotherapy. No coverage for no provider allergy services or associated expenses relating to an allergic condition, including installation of air filters, air purifiers, or air ventilation system cleaning. Allergy testing and allergy immunotherapy are considered medically necessary for members with clinically significant allergic symptoms. The following tests and treatments are covered:
- A. Epicutaneous (scratch, prick, or puncture) when Immunoglobulan E- (IgE-) mediated reactions occur to any of the following:
 - (I) Foods;
 - (II) Hymenoptera venom (stinging insects);
 - (III) Inhalants; or
- (IV) Specific drugs (penicillins and macromolecular agents);
- B. Intradermal (Intracutaneous) when IgE-mediated reactions occur to any of the following:
 - (I) Foods;
 - (II) Hymenoptera venom (stinging insects);
 - (III) Inhalants; or
- (IV) Specific drugs (penicillins and macromolecular agents);
- C. Skin or Serial Endpoint Titration (SET), also known as intradermal dilutional testing (IDT), for determining the starting dose for immunotherapy for members highly allergic to any of the following:
 - (I) Hymenoptera venom (stinging insects); or
 - (II) Inhalants;
- D. Skin Patch Testing: for diagnosing contact allergic dermatitis:
- E. Photo Patch Testing: for diagnosing photo-allergy (such asphoto-allergic contact dermatitis);
 - F. Photo Tests: for evaluating photo-sensitivity disorders;
- G. Bronchial Challenge Test: for testing with methacholine, histamine, or antigens in defining asthma or airway hyperactivity when either of the following conditions is met:
- (I) Bronchial challenge test is being used to identify new allergens for which skin or blood testing has not been validated; or
 - (II) Skin testing is unreliable;
- H. Exercise Challenge Testing for exercise-induced bronchospasm;
 - I. Ingestion (Oral) Challenge Test for any of the following:
 - (I) Food or other substances; or
 - (II) Drugs when all of the following are met:
 - (a) History of allergy to a particular drug;
 - (b) There is no effective alternative drug; and
 - (c) Treatment with that drug class is essential;
- J. In Vitro IgE Antibody Tests (RAST, MAST, FAST, ELISA, ImmunoCAP) are covered for any of the following:
- (I) Allergic broncho-pulmonary aspergillosis (ABPA) and certain parasitic diseases;
 - (II) Food allergy;
 - (III) Hymenoptera venom allergy (stinging insects);
 - (IV) Inhalant allergy; or
 - (V) Specific drugs;
- K. Total Serum IgE for diagnostic evaluation in members with known or suspected ABPA and/or hyper IgE syndrome;
- L. Lymphocyte transformation tests such as lymphocyte mitogen response test, PHE stimulation test, or lymphocyte antigen

response assay are covered for evaluation of persons with any of the following suspected conditions:

- (I) Sensitivity to beryllium;
- (II) Congenital or acquired immunodeficiency diseases affecting cell-mediated immunity, such as severe combined immunodeficiency, common variable immunodeficiency, X-linked immunodeficiency with hyper IgM, Nijmegen breakage syndrome, reticular dysgenesis, DiGeorge syndrome, Nezelof syndrome, Wiscott-Aldrich syndrome, ataxia telangiectasia, and chronic mucocutaneous candidiasis:
 - (III) Thymoma; and
- (IV) To predict allograft compatibility in the transplant setting;
- M. Allergy Re-testing: routine allergy re-testing is not considered medically necessary;
- N. Allergy immunotherapy is covered for the treatment of any of the following IgE-mediated allergies:
 - (I) Allergic (extrinsic) asthma;
 - (II) Dust mite atopic dermatitis;
- (III) Hymenoptera (bees, hornets, wasps, fire ants) sensitive individuals;
 - (IV) Mold-induced allergic rhinitis;
 - (V) Perennial rhinitis;
- (VI) Seasonal allergic rhinitis or conjunctivitis when one (1) of the following conditions are met:
- (a) Member has symptoms of allergic rhinitis or asthma after natural exposure to the allergen;
- (b) Member has a life-threatening allergy to insect stings; or
- (c) Member has skin test or serologic evidence of IgE mediated antibody to a potent extract of the allergen; and
- (VII) Avoidance or pharmacologic therapy cannot control allergic symptoms or member has unacceptable side effects with pharmacologic therapy;
- O. Other treatments: the following other treatments are covered:
- (I) Rapid, rush, cluster, or acute desensitization for members with any of the following conditions:
- (a) IgE antibodies to a particular drug that cannot be treated effectively with alternative medications;
- (b) Insect sting (e.g., wasps, hornets, bees, fire ants) hypersensitivity (hymenoptera); or
- (c) Members with moderate to severe allergic rhinitis who need treatment during or immediately before the season of the affecting allergy;
- (II) Rapid desensitization is considered experimental and investigational for other indications;
- P. Epinephrine kits, Ana-Kit, and Epi-Pen kits to prevent anaphylactic shock for members who have had life-threatening reactions to insect stings, foods, drugs, or other allergens; have severe asthma or if needed during immunotherapy;
- 2. Ambulance service. The following ambulance transport services are covered:
- A. By ground to the nearest appropriate facility when other means of transportation would be contraindicated;
- B. By air to the nearest appropriate facility when the member's medical condition is such that transportation by either basic or advanced life support ground ambulance is not appropriate or contraindicated;
- 3. Applied Behavior Analysis (ABA) for Autism is covered for children younger than age nineteen (19) years;
- 4. Bariatric surgery. Bariatric surgery is covered when all of the following requirements have been met:
- A. The surgery is performed at a facility accredited by one (1) of the following accreditation programs:
- (I) American College of Surgeons Bariatric Surgery Center Network (ACS BSCN);

- (II) American Society for Metabolic and Bariatric Surgery Bariatric Surgery Centers of Excellence (ASMBS BSCOE); or
- (III) Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP);
- B. The following open or laparoscopic bariatric surgery procedures are covered:
 - (I) Roux-en-Y gastric bypass;
 - (II) Sleeve gastrectomy;
- (III) Biliopancreatic diversion with duodenal switch for individuals with a body mass index (BMI) greater than fifty (50);
- (IV) Adjustable silicone gastric banding and adjustments of a silicone gastric banding to control the rate of weight loss and/or treat symptoms secondary to gastric restriction following an adjustable silicone gastric banding procedure;
- (V) Surgical reversal of bariatric surgery when complications of the original surgery (e.g., stricture, pouch dilatation, erosion, or band slippage) cause abdominal pain, inability to eat or drink, or cause vomiting of prescribed meals;
- (VI) Revision of a previous bariatric surgical procedure or conversion to another procedure due to inadequate weight loss when one (1) of the following specific criteria has been met:
- (a) There is evidence of full compliance with the previously prescribed post-operative dietary and exercise program; or
- (b) There is documented clinical testing demonstrating technical failure of the original bariatric surgical procedure which caused the individual to fail achieving adequate weight loss of at least fifty percent (50%) of excess body weight or failure to achieve body weight to within thirty percent (30%) of ideal body weight at least two (2) years following the original surgery;
 - C. All of the following criteria have been met:
- (I) The member is eighteen (18) years or older or has reached full skeletal growth, and has evidence of one (1) of the following:
 - (a) BMI greater than forty (40); or
- (b) BMI between thirty-five (35) and thirty-nine and nine tenths (39.9) and one (1) or more of the following:
 - I. Type II diabetes;
- II. Cardiovascular disease such as stroke, myocardial infarction, stable or unstable angina pectoris, hypertension, or coronary artery bypass; or
- III. Life-threatening cardiopulmonary problems such as severe sleep apnea, Pickwickian syndrome, or obesity-related cardiomyopathy; and
- (II) Demonstration that dietary attempts at weight control have been ineffective through completion of a structured diet program. Commercial weight loss programs are acceptable if completed under the direction of a provider or registered dietitian and documentation of participation is available for review. One (1) structured diet program for six (6) consecutive months or two (2) structured diet programs for three (3) consecutive months each within a two- (2-) year period prior to the request for the surgical treatment of morbid obesity are sufficient. Provider-supervised programs consisting exclusively of pharmacological management are not sufficient; and
- (III) A thorough multidisciplinary evaluation within the previous twelve (12) months, which include all of the following:
- (a) An evaluation by a bariatric surgeon recommending surgical treatment, including a description of the proposed procedure and all of the associated current procedural terminology codes;
- (b) A separate medical evaluation from a provider other than the surgeon recommending surgery that includes a medical clearance for bariatric surgery;
- (c) Completion of a psychological examination from a mental health provider evaluating the member's readiness and fitness for surgery and the necessary post-operative lifestyle changes. After the evaluation, the mental health provider must provide clearance for bariatric surgery; and
- (d) A nutritional evaluation by a provider or registered dietitian;

- 5. Contraception and Sterilization. All Food and Drug Administration- (FDA-) approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity. The following contraceptive devices and injections are covered when administered in a provider's office:
 - A. Available under the medical plan only-
 - (I) Tubal ligation;
 - B. Available under the prescription or medical plan-
 - (I) Cervical cap;
 - (II) Diaphragm;
 - (III) Implants, such as an intrauterine device (IUD);
 - (IV) Injection; and
 - (V) Vaginal ring;
- 6. Blood storage. Storage of whole blood, blood plasma, and blood products is covered in conjunction with medical treatment that requires immediate blood transfusion support;
- 7. Cardiac rehabilitation. An electrocardiographically-monitored program of outpatient cardiac rehabilitation (Phase II) is covered for specific criteria when it is individually prescribed by a provider and a formal exercise stress test is completed following the event and prior to the initiation of the program. Cardiac rehabilitation is covered for members who meet one (1) of the following criteria:
- A. Acute myocardial infarction (MI) (heart attack in the last twelve (12) months);
 - B. Coronary artery bypass grafting (CABG);
 - C. Stable angina pectoris;
 - D. Percutaneous coronary vessel remodeling;
 - E. Valve replacement or repair;
 - F. Heart transplant;
- G. Coronary artery disease (CAD) associated with chronic stable angina that has failed to respond adequately to pharmacotherapy and is interfering with the ability to perform age-related activities of daily living and/or impairing functional abilities; or
- H. Heart failure that has failed to respond adequately to pharmacotherapy and is interfering with the ability to perform age-related activities of daily living and/or impairing functional abilities;
- 8. Chelation therapy. The administration of FDA-approved chelating agents is covered for any of the following conditions:
 - A. Genetic or hereditary hemochromatosis;
- B. Lead overload in cases of acute or long-term lead exposure;
- C. Secondary hemochromatosis due to chronic iron overload due to transfusion-dependent anemias (e.g., Thalassemias, Cooley's anemia, sickle cell anemia, sideroblastic anemia);
 - D. Copper overload in patients with Wilson's disease;
- E. Arsenic, mercury, iron, copper, or gold poisoning when long-term exposure to and toxicity has been confirmed through lab results or clinical findings consistent with metal toxicity;
 - F. Aluminum overload in chronic hemodialysis patients;
 - G. Emergency treatment of hypercalcemia;
 - H. Prophylaxis against doxorubicin-induced cardiomyopathy;
 - I. Internal plutonium, americium, or curium contamination;
 - J. Cystinuria;

or

- 9. Chiropractic services. Chiropractic manipulation and adjunct therapeutic procedures/modalities (e.g., mobilization, therapeutic exercise, traction) are covered when all of the following conditions are met:
- A. A neuromusculoskeletal condition is diagnosed that may be relieved by standard chiropractic treatment in order to restore optimal function;
- B. Chiropractic care is being performed by a licensed doctor of chiropractic who is practicing within the scope of his/her license as defined by state law;
- C. The individual is involved in a treatment program that clearly documents all of the following:

- (I) A prescribed treatment program that is expected to result in significant therapeutic improvement over a clearly defined period of time;
 - (II) The symptoms being treated;
 - (III) Diagnostic procedures and results;
- (IV) Frequency, duration, and results of planned treatment modalities;
- (V) Anticipated length of treatment plan with identification of quantifiable, attainable short-term and long-term goals; and
- (VI) Demonstrated progress toward significant functional gains and/or improved activity tolerances;
- D. Following previous successful treatment with chiropractic care, acute exacerbation or re-injury are covered when all of the following criteria are met:
- (I) The member reached maximal therapeutic benefit with prior chiropractic treatment;
- (II) The member was compliant with a self-directed homecare program;
- (III) Significant therapeutic improvement is expected with continued treatment; and
- (IV) The anticipated length of treatment is expected to be short-term (e.g., no more than six (6) visits within a three- (3-) week period):
- 10. Clinical trials. Routine member care costs incurred as the result of a Phase I, II, III, or IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition are covered when—
- A. The study or investigation is conducted under an investigational new drug application reviewed by the FDA; or
- B. Is a drug trial that is exempt from having such an investigational new drug application. Life-threatening condition means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted; and
- C. Routine member care costs include all items and services consistent with the coverage provided in plan benefits that would otherwise be covered for a member not enrolled in a clinical trial. Routine patient care costs do not include the investigational item, device, or service itself; items and services that are provided solely to satisfy data collection and analysis needs and are not used in the direct clinical management of the member; or a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis;
- D. The member must be eligible to participate in the clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition; and
- E. The clinical trial must be approved or funded by one (1) of the following:
 - (I) National Institutes of Health (NIH);
 - (II) Centers for Disease Control and Prevention (CDC);
 - (III) Agency for Health Care Research and Quality;
 - (IV) Centers for Medicare & Medicaid Services (CMS);
- (V) A cooperative group or center of any of the previously named agencies or the Department of Defense or the Department of Veterans Affairs;
- (VI) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; or
- (VII) A study or investigation that is conducted by the Department of Veterans Affairs, the Department of Defense, or the Department of Energy and has been reviewed and approved to be comparable to the system of peer review of studies and investigations used by the NIH and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review;
- 11. Cochlear implant device. Uniaural (monaural) or binaural (bilateral) cochlear implantation and necessary replacement batteries are covered for a member with bilateral, pre- or post-linguistic, sensorineural, moderate-to-profound hearing impairment when there is

reasonable expectation that a significant benefit will be achieved from the device and when the following age-specific criteria are met:

- A. Auditory brainstem implant. Auditory brainstem implant (ABI) covered for the diagnosis of neurofibromatosis type II, von Recklinghausen's disease, or when a member is undergoing bilateral removal of tumors of the auditory nerves, and it is anticipated that the member will become completely deaf as a result of the surgery, or the member had bilateral auditory nerve tumors removed and is now bilaterally deaf;
- (I) For an adult (age eighteen (18) years or older) with BOTH of the following:
- (a) Bilateral, severe to profound sensorineural hearing loss determined by a pure-tone average of seventy (70) decibels (dB) hearing loss or greater at five hundred (500) hertz (Hz), one thousand (1000) Hz and two thousand (2000) Hz; and
- (b) Member has limited benefit from appropriately fitted binaural hearing aids. Limited benefit from amplification is defined by test scores of forty percent (40%) correct or less in best-aided listening condition on open-set sentence cognition (e.g., Central Institute for the Deaf (CID) sentences, Hearing in Noise Test (HINT) sentences, and Consonant-Nucleus-Consonant (CNC) test);
- (II) For a child age twelve (12) months to seventeen (17) years, eleven (11) months with both of the following:
- (a) Profound, bilateral sensorineural hearing loss with thresholds of ninety (90) dB or greater at one thousand (1000) Hz; and
- (b) Limited or no benefit from a three- (3-) month trial of appropriately fitted binaural hearing aids;
- (III) For children four (4) years of age or younger, with one (1) of the following:
- (a) Failure to reach developmentally appropriate auditory milestones measured using the Infant-Toddler Meaningful Auditory Integration Scale, the Meaningful Auditory Integration Scale, or the Early Speech Perception test; or
- (b) Less than twenty percent (20%) correct on open-set word recognition test Multisyllabic Lexical Neighborhood Test (MLNT) in conjunction with appropriate amplification and participation in intensive aural habilitation over a three- (3-) to six- (6-) month period;
- (IV) For children older than four (4) years of age with one (1) of the following:
- (a) Less than twelve percent (12%) correct on the Phonetically Balanced-Kindergarten Test; or
- (b) Less than thirty percent (30%) correct on the HINT for children, the open-set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending on the child's cognitive ability and linguistic skills; and
- (V) A three- (3-) to six- (6-) month hearing aid trial has been undertaken by a child without previous experience with hearing aids;
 - B. Radiologic evidence of cochlear ossification;
- C. The following additional medical necessity criteria must also be met for uniaural (monaural) or binaural (bilateral) cochlear implantation in adults and children:
- (I) Member must be enrolled in an educational program that supports listening and speaking with aided hearing;
- (II) Member must have had an assessment by an audiologist and from an otolaryngologist experienced in this procedure indicating the likelihood of success with this device;
- (III) Member must have no medical contraindications to cochlear implantation (e.g., cochlear aplasia, active middle ear infection); and
- (IV) Member must have arrangements for appropriate follow-up care, including the speech therapy required to take full advantage of this device;
- D. A second cochlear implant is covered in the contralateral (opposite) ear as medically necessary in an individual with an exist-

ing unilateral cochlear implant when the hearing aid in the contralateral ear produces limited or no benefit;

- E. The replacement of an existing cochlear implant is covered when either of the following criteria is met:
- (I) Currently used component is no longer functional and cannot be repaired; or
- (II) Currently used component renders the implant recipient unable to adequately and/or safely perform his/her age-appropriate activities of daily living; and
- F. Post-cochlear or ABI rehabilitation program (aural rehabilitation) is covered to achieve benefit from a covered device;
 - 12. Dental care.
 - A. Dental care is covered for the following:
- (I) Treatment to reduce trauma and restorative services limited to dental implants only when the result of accidental injury to sound natural teeth and tissue that are viable, functional, and free of disease; and
- (II) Restorative services limited to dental implants when needed as a result of cancerous or non-cancerous tumors and cysts, cancer and post-surgical sequelae.
- B. The administration of general anesthesia, monitored anesthesia care, and hospital charges for dental care are covered for children younger than five (5) years, the severely disabled, or a person with a medical or behavioral condition that requires hospitalization when provided in a network or non-network hospital or surgical center:
- 13. Diabetic Education when prescribed by a provider and taught by a Certified Diabetes Educator through a medical network provider.
- 14. Durable medical equipment (DME) is covered when ordered by a provider to treat an injury or illness. DME includes, but is not limited to, the following:
 - A. Insulin pumps;
 - B. Oxygen;
 - C. Augmentative communication devices;
 - D. Manual and powered mobility devices;
- E. Disposable supplies that do not withstand prolonged use and are periodically replaced, including, but not limited to, the following:
 - (I) Colostomy and ureterostomy bags;
- (II) Prescription compression stockings limited to two (2) pairs or four (4) individual stockings per plan year;
- F. Non-reusable disposable supplies, including, but not limited to:
 - (I) Bandages;
 - (II) Wraps;
 - (III) Tape;
 - (IV) Disposable sheets and bags;
 - (V) Fabric supports;
 - (VI) Surgical face masks;
 - (VII) Incontinence pads;
 - (VIII) Irrigating kits;
 - (IX) Pressure leotards; and
- (X) Surgical leggings and support hose, over-the-counter medications and supplies, including oral appliances, are not covered;
- G. Repair and replacement of DME is covered when any of the following criteria are met:
- (I) Repairs, including the replacement of essential accessories, which are necessary to make the item or device serviceable;
- (II) Routine wear and tear of the equipment renders it nonfunctional and the member still requires the equipment; or
- (III) The provider has documented that the condition of the member changes or if growth-related;
- 15. Emergency room services. Coverage is for emergency medical conditions. If a member is admitted to the hospital, s/he may be required to transfer to network facility for maximum benefit. Hospital and ancillary charges are paid as a network benefit;

- 16. Eye glasses and contact lenses. Coverage limited to charges incurred in connection with the fitting of eye glasses or contact lenses for initial placement immediately following cataract surgery;
- 17. Foot care (trimming of nails, corns, or calluses). Foot care is considered routine in nature and not covered in the absence of systemic disease that has resulted in severe circulatory insufficiency or areas of desensitization in the lower extremities. Foot care services are covered when administered by a provider and—
- A. When associated with systemic conditions that are significant enough to result in severe circulatory insufficiency or areas of desensitization in the lower extremities including, but not limited to, any of the following:
 - (I) Diabetes mellitus;
 - (II) Peripheral vascular disease; or
 - (III) Peripheral neuropathy.
- (IV) Evaluation/debridement of mycotic nails, in the absence of a systemic condition, when both of the following conditions are met:
- (a) Pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate; and
- (b) If the member is ambulatory, pain markedly limits ambulation:
- 18. Genetic counseling. Pre-test and post-test genetic counseling with a provider or a licensed or certified genetic counselor are covered when a member is recommended for covered heritable genetic testing.
- A. Genetic counseling in connection with pregnancy management is covered only for evaluation of any of the following:
- (I) Couples who are closely related genetically (e.g., consanguinity, incest);
 - (II) Familial cancer disorders:
- (III) Individuals from ethnic groups recognized to be at increased risk for specific genetic disorders (e.g., African Americans for sickle cell anemia, Ashkenazi (eastern European) Jews for Tay-Sachs disease);
- (IV) Infertility cases where either parent is known to have a chromosomal abnormality;
- (V) Primary amenorrhea, azospermia, abnormal sexual development, or failure in developing secondary sexual characteristics;
- (VI) Mother is a known, or presumed carrier of an X linked recessive disorder;
- (VII) One (1) or both parents are known carriers of anautosomal recessive disorder;
- (VIII) Parents of a child born with a genetic disorder, birth defect, inborn error of metabolism, or chromosome abnormality;
- (IX) Parents of a child with mental retardation, autism, developmental delays, or learning disabilities;
- (X) Pregnant women who, based on prenatal ultrasound tests or an abnormal multiple marker screening test, maternal serum alpha-fetoprotein (AFP) test, test for sickle cell anemia, or tests for other genetic abnormalities have been told their pregnancy may be at increased risk for complications or birth defects;
- (XI) Pregnant women age thirty-five (35) years or older at delivery;
- (XII) Pregnant women, or women planning pregnancy, exposed to potentially teratogenic, mutagenic, or carcinogenic agents such as chemicals, drugs, infections, or radiation;
- (XIII) Previous unexplained stillbirth or repeated (three (3) or more; two (2) or more among infertile couples) first-trimester miscarriages, where there is suspicion of parental or fetal chromosome abnormalities; or
- (XIV) When contemplating pregnancy, either parent affected with an autosomal dominant disorder;
- 19. Genetic testing. No coverage for testing based on family history alone, except for testing for the breast cancer susceptibility gene (BRCA). Genetic testing is covered to establish a molecular diagnosis of an inheritable disease when all of the following criteria are met:

- A. The member displays clinical features or is at direct risk of inheriting the mutation in question (pre-symptomatic);
- B. The result of the test will directly impact the treatment being delivered to the member:
- C. The testing method is considered scientifically valid for identification of a genetically-linked heritable disease; and
- D. After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain;
- 20. Hair analysis. Chemical hair analysis is covered for the diagnosis of suspected chronic arsenic poisoning. Other purposes are considered experimental and investigational;
- 21. Hair prostheses. Prostheses and expenses for scalp hair prostheses worn for hair loss are covered for alopecia areata or alopecia totalis for children eighteen (18) years of age or younger. The annual maximum is two hundred dollars (\$200), and the lifetime maximum is three thousand two hundred dollars (\$3,200);
- 22. Hearing aids (per ear). Hearing aids covered for conductive hearing loss unresponsive to medical or surgical interventions, sensorineural hearing loss, and mixed hearing loss.
 - A. Prior to receiving a hearing aid members must receive—
- (I) A medical exam by a physician or other qualified provider to identify any medically treatable conditions that may affect hearing; and
- (II) A comprehensive hearing test to assess the need for hearing aids conducted by a certified audiologist, hearing instrument specialist, or other provider licensed or certified to administer this test
- B. Covered once every two (2) years. If the cost of one (1) hearing aid exceeds the amount listed below, member is also responsible for charges over that amount.
 - (I) Conventional: one thousand dollars (\$1,000).
 - (II) Programmable: two thousand dollars (\$2,000).
 - (III) Digital: two thousand five hundred dollars (\$2,500).
- (IV) Bone Anchoring Hearing Aid (BAHA): three thousand five hundred dollars (\$3,500);
- 23. Hearing testing. One (1) hearing test per year. Additional hearing tests are covered if recommended by provider;
- 24. Home health care. Skilled home health nursing care is covered for members who are homebound because of injury or illness (i.e., the member leaves home only with considerable and taxing effort, and absences from home are infrequent or of short duration, or to receive medical care). Services must be performed by a registered nurse or licensed practical nurse, licensed therapist, or a registered dietitian. Covered services include:
- A. Home visits instead of visits to the provider's office that do not exceed the usual and customary charge to perform the same service in a provider's office;
- B. Intermittent nurse services. Benefits are paid for only one (1) nurse at any one (1) time, not to exceed four (4) hours per twenty-four- (24-) hour period;
- C. Nutrition counseling provided by or under the supervision of a registered dietitian;
- D. Physical, occupational, respiratory, and speech therapy provided by or under the supervision of a licensed therapist;
- E. Medical supplies, drugs or medication prescribed by provider, and laboratory services to the extent that the plan would have covered them under this plan if the covered person had been in a hospital;
 - F. A home health care visit is defined as-
- (I) A visit by a nurse providing intermittent nurse services (each visit includes up to a four- (4-) hour consecutive visit in a twenty-four- (24-) hour period if clinical eligibility for coverage is met) or a single visit by a therapist or a registered dietitian; and
 - G. Benefits cannot be provided for any of the following:
 - (I) Homemaker or housekeeping services;
- (II) Supportive environment materials such as handrails, ramps, air conditioners, and telephones;

- (III) Services performed by family members or volunteer workers;
 - (IV) "Meals on Wheels" or similar food service;
- (V) Separate charges for records, reports, or transportation;
- (VI) Expenses for the normal necessities of living such as food, clothing, and household supplies; and
- (VII) Legal and financial counseling services, unless otherwise covered under this plan;
- 25. Hospice care and palliative services (inpatient or outpatient). Includes bereavement and respite care. Hospice care services, including pre-hospice evaluation or consultation, are covered when the individual is terminally ill and expected to live six (6) months or less, potentially curative treatment for the terminal illness is not part of the prescribed plan of care, the individual or appointed designee has formally consented to hospice care (i.e., care directed mostly toward palliative care and symptom management), and the hospice services are provided by a certified/accredited hospice agency with care available twenty-four (24) hours per day, seven (7) days per week.
- A. When the above criteria are met, the following hospice care services are covered:
- (I) Assessment of the medical and social needs of the terminally ill person, and a description of the care to meet those needs;
- (II) Inpatient care in a facility when needed for pain control and other acute and chronic symptom management, psychological and dietary counseling, physical or occupational therapy, and part-time home health care services;
- (III) Outpatient care for other services as related to the terminal illness, which include services of a physician, physical or occupational therapy, and nutrition counseling provided by or under the supervision of a registered dietitian; and
- (IV) Bereavement counseling benefits which are received by a member's close relative when directly connected to the member's death and bundled with other hospice charges. The services must be furnished within six (6) months of death;
- 26. Hospital (includes inpatient, outpatient, and surgical centers).
 - A. The following benefits are covered:
- (I) Semi-private room and board. For network charges, this rate is based on network repricing. For non-network charges, any charge over a semi-private room charge will be a covered expense only when clinical eligibility for coverage is met. If the hospital has no semi-private rooms, the plan will allow the private room rate subject to usual, customary, and reasonable charges or the network rate, whichever is applicable;
 - (II) Intensive care unit room and board;
- (III) Surgery, therapies, and ancillary services including, but not limited to:
 - (a) Cornea transplant;
- (b) Coverage for breast reconstruction surgery or prostheses following mastectomy and lumpectomy is available to both females and males. A diagnosis of breast cancer is not required for breast reconstruction services to be covered, and the timing of reconstructive services is not a factor in coverage;
- (c) Sterilization for the purpose of birth control is covered;
- (d) Cosmetic/reconstructive surgery is covered to repair a functional disorder caused by disease or injury;
- (e) Cosmetic/reconstructive surgery is covered to repair a congenital defect or abnormality for a member younger than nineteen (19) years; and
- (f) Blood, blood plasma, and plasma expanders are covered, when not available without charge;
- (IV) Inpatient mental health services are covered when authorized by a physician for treatment of a mental health disorder. Inpatient mental health services are covered, subject to all of the following:

- (a) Member must be ill in more than one (1) area of daily living to such an extent that s/he is rendered dysfunctional and requires the intensity of an inpatient setting for treatment. Without such inpatient treatment, the member's condition would deteriorate;
- (b) The member's mental health disorder must be treatable in an inpatient facility;
- (c) The member's mental health disorder must meet diagnostic criteria as described in the most recent edition of the American Psychiatric Association Diagnostic and Statistical Manual (DSM). If outside of the United States, the member's mental health disorder must meet diagnostic criteria established and commonly recognized by the medical community in that region;
- (d) The attending provider must be a psychiatrist. If the admitting provider is not a psychiatrist, a psychiatrist must be attending to the member within twenty-four (24) hours of admittance. Such psychiatrist must be United States board-eligible or board-certified. If outside of the United States, inpatient services must be provided by an individual who has received a diploma from a medical school recognized by the government agency in the country where the medical school is located. The attending provider must meet the requirements, if any, set out by the foreign government or regionally-recognized licensing body for treatment of mental health disorders;
- (e) Day treatment (partial hospitalization) for mental health services means a day treatment program that offers intensive, multidisciplinary services not otherwise offered in an outpatient setting. The treatment program is generally a minimum of twenty (20) hours of scheduled programming extended over a minimum of five (5) days per week. The program is designed to treat patients with serious mental or nervous disorders and offers major diagnostic, psychosocial, and prevocational modalities. Such programs must be a less-restrictive alternative to inpatient treatment; and
- (f) Mental health services received in a residential treatment facility that is licensed by the state in which it operates and provides treatment for mental health disorders is covered. This does not include services provided at a group home. If outside of the United States, the residential treatment facility must be licensed or approved by the foreign government or an accreditation or licensing body working in that foreign country;
- (V) Outpatient mental health services are covered if the member is at a therapeutic medical or mental health facility and treatment includes measurable goals and continued progress toward functional behavior and termination of treatment. Continued coverage may be denied when positive response to treatment is not evident. Treatment must be provided by one (1) of the following:
- (a) A United States board-eligible or board-certified psychiatrist licensed in the state where the treatment is provided;
- (b) A therapist with a doctorate or master's degree that denotes a specialty in psychiatry (Psy.D.);
 - (c) A state-licensed psychologist;
- (d) A state-licensed or certified social worker practicing within the scope of his or her license or certification; or
 - (e) Licensed professional counselor; and
- (VI) Inpatient treatment in a network hospital or facility by a non-network provider. Inpatient treatment received in a network hospital or facility by a non-network provider is covered at the network benefit;
- 27. Injections and infusions. Injections and infusions are covered. See preventive services for coverage of immunizations. See contraception and sterilization for coverage of birth control injections. Medications (specialty and non-specialty) that can be safely obtained through a pharmacy and which may be self-administered, including injectables, are not a medical plan benefit but are covered as part of the pharmacy benefit.
 - A. B12 injections are covered for the following conditions:
 - (I) Pernicious anemia;
 - (II) Crohn's disease;
 - (III) Ulcerative colitis;
 - (IV) Inflammatory bowel disease;

- (V) Intestinal malabsorption;
- (VI) Fish tapeworm anemia;
- (VII) Vitamin B12 deficiency;
- (VIII) Other vitamin B12 deficiency anemia;
- (IX) Macrocytic anemia;
- (X) Other specified megaloblastic anemias;
- (XI) Megaloblastic anemia;
- (XII) Malnutrition of alcoholism;
- (XIII) Thrombocytopenia, unspecified;
- (XIV) Dementia in conditions classified elsewhere;
- (XV) Polyneuropathy in diseases classified elsewhere;
- (XVI) Alcoholic polyneuropathy;
- (XVII) Regional enteritis of small intestine;
- (XVIII) Postgastric surgery syndromes;
- (XIX) Other prophylactic chemo-therapy;
- (XX) Intestinal bypass or anastamosis status;
- (XXI) Acquired absence of stomach;
- (XXII) Pancreatic insufficiency; and
- (XXIII) Ideopathic progressive polyneuropathy;
- 28. Lab, X-ray, and other diagnostic procedures. Outpatient diagnostic services are covered when tests or procedures are performed for a specific symptom and to detect or monitor a condition. Professional charges for automated lab services performed by an out-of-network provider are not covered;
- 29. Maternity coverage. Prenatal and postnatal care is covered. Routine prenatal office visits and screenings recommended by the Health Resources and Services Administration are covered at one hundred percent (100%). Other care is subject to the deductible and coinsurance. Newborns and their mothers are allowed hospital stays of at least forty-eight (48) hours after vaginal birth and ninety-six (96) hours after cesarean section birth. If discharge occurs earlier than specific time periods, the plan shall provide coverage for post discharge care that shall consist of a two- (2-) visit minimum, at least one (1) in the home.
- 30. Nutritional counseling. Individualized nutritional evaluation and counseling for the management of any medical condition for which appropriate diet and eating habits are essential to the overall treatment program is covered when ordered by a physician or physician extender and provided by a licensed health-care professional (e.g., a registered dietitian);
 - 31. Nutrition therapy.
- A. Nutrition therapy is covered only when the following cri-
- (I) Nutrition therapy is the sole source of nutrients or a significant percentage of the daily caloric intake;
- (II) Nutrition therapy is used in the treatment of, or in association with, a demonstrable disease, condition, or disorder;
 - (III) Nutrition therapy is necessary to sustain life or health;
 - (IV) Nutrition therapy is prescribed by a provider; and
- (V) Nutrition therapy is managed, monitored, and evaluated on an on-going basis, by a provider.
 - B. Only the following types of nutrition therapy are covered:
- (I) Enteral Nutrition (EN). EN is the provision of nutritional requirements via the gastrointestinal tract. EN can be taken orally or through a tube into the stomach or small intestine.
- (II) Parenteral Nutrition Therapy (PN) and Total Parenteral Nutrition (TPN). PN is liquid nutrition administered through a vein to provide part of daily nutritional requirements. TPN is a type of PN that provides all daily nutrient needs. PN or TPN are covered when the member's nutritional status cannot be adequately maintained on oral or enteral feedings.
- (III) Intradialytic Parenteral Nutrition (IDPN). IDPN is a type of PN that is administered to members on chronic hemodialysis during dialysis sessions to provide most nutrient needs. IDPN is covered when the member is on chronic hemodialysis and nutritional status cannot be adequately maintained on oral or enteral feedings;
- 32. Office visit. Member encounter with a provider for health care, mental health, or substance abuse disorder in an office, clinic,

- or ambulatory care facility is covered based on the service, procedure, or related treatment plan;
- 33. Oral surgery is covered for injury, tumors, or cysts. Oral surgery includes, but is not limited to, reduction of fractures and dislocation of the jaws; external incision and drainage of cellulites; incision of accessory sinuses, salivary glands, or ducts; excision of exostosis of jaws and hard palate; and frenectomy. Treatment must be initiated within sixty (60) days of accident. No coverage for dental care, including oral surgery, as a result of poor dental hygiene. Extractions of bony or partial bony impactions are excluded;
- 34. Orthognathic or Jaw Surgery. Orthognathic or jaw surgery is covered when one (1) of the following conditions is documented and diagnosed:
 - A. Acute traumatic injury, and post-surgical sequela;
- B. Cancerous or non-cancerous tumors and cysts, cancer and post-surgical sequela;
 - C. Cleft lip/palate (for cleft lip/palate related jaw surgery); or
- D. Physical or physiological abnormality when one (1) of the following criteria is met:
 - (I) Anteroposterior Discrepancies—
- (a) Maxillary/Mandibular incisor relationship: over jet of 5mm or more, or a 0 to a negative value (norm 2mm);
- (b) Maxillary/Mandibular anteroposterior molar relationship discrepancy of 4mm or more (norm 0 to 1mm); or
- (c) These values represent two (2) or more standard deviation from published norms;
 - (II) Vertical Discrepancies—
- (a) Presence of a vertical facial skeletal deformity which is two (2) or more standard deviations from published norms for accepted skeletal landmarks;
- (b) Open bite with no vertical overlap of anterior teeth or unilateral or bilateral posterior open bite greater than 2mm;
- (c) Deep overbite with impingement or irritation of buccal or lingual soft tissues of the opposing arch; or
- (d) Supraeruption of a dentoalveolar segment due to lack of occlusion;
 - (III) Transverse Discrepancies—
- (a) Presence of a transverse skeletal discrepancy which is two (2) or more standard deviations from published norms; or
- (b) Total bilateral maxillary palatal cusp to mandibularfossa discrepancy of 4mm or greater, or a unilateral discrepancy of 3mm or greater, given normal axial inclination of the posterior teeth; or
 - (IV) Asymmetries—
- (a) Anteroposterior, transverse, or lateral asymmetries greater than 3mm with concomitant occlusal asymmetry;
- (V) Masticatory (chewing) and swallowing dysfunction due to malocclusion (e.g., inability to incise or chew solid foods, choking on incompletely masticated solid foods, damage to soft tissue during mastication, malnutrition);
 - (VI) Speech impairment; or
 - (VII) Obstructive sleep apnea or airway dysfunction;
 - 35. Orthotics.
- A. Ankle-Foot Orthosis (AFO) and Knee-Ankle-Foot Orthosis (KAFO).
- (I) Basic coverage criteria for AFO and KAFO used during ambulation are as follows:
- (a) AFO is covered when used in ambulation for members with weakness or deformity of the foot and ankle, which require stabilization for medical reasons, and have the potential to benefit functionally;
- (b) KAFO is covered when used in ambulation for members when the following criteria are met:
 - I. Member is covered for AFO; and
 - II. Additional knee stability is required; and
- (c) AFO and KAFO that are molded-to-patient-model, or custom-fabricated, are covered when used in ambulation, only

AFO:

when the basic coverage criteria and one (1) of the following criteria are met:

- I. The member could not be fit with a prefabricated
- II. AFO or KAFO is expected to be permanent or for more than six (6) months duration;
- III. Knee, ankle, or foot must be controlled in more than one (1) plane;
- IV. There is documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; or
- V. The member has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.
 - (II) AFO and KAFO Not Used During Ambulation.
- (a) AFO and KAFO not used in ambulation are covered if the following criteria are met:
- I. Passive range of motion test was measured with agoniometer and documented in the medical record;
- II. Documentation of an appropriate stretching program administered under the care of provider or caregiver;
- III. Plantar flexion contracture of the ankle with dorsiflexion on passive range of motion testing of at least ten degrees (10°) (i.e., a non-fixed contracture);
- IV. Reasonable expectation of the ability to correct the contracture:
- V. Contracture is interfering or expected to interfere significantly with the patient's functional abilities; and
- VI. Used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons; or VII. Member has plantar fasciitis.
- (b) Replacement interface for AFO or KAFO is covered only if member continues to meet coverage criteria and is limited to a maximum of one (1) per six (6) months.
- B. Cast Boot, Post-Operative Sandal or Shoe, or Healing Shoe. A cast boot, post-operative sandal or shoe, or healing shoe is covered for one (1) of the following indications:
- (I) To protect a cast from damage during weight-bearing activities following injury or surgery;
- (II) To provide appropriate support and/or weight-bearing surface to a foot following surgery;
- (III) To promote good wound care and/or healing via appropriate weight distribution and foot protection; or
- (IV) When the patient is currently receiving treatment for lymphedema and the foot cannot be fitted into conventional footwear.
- C. Cranial Orthoses. Cranial orthosis is covered for Synostotic and Non-Synostotic Plagiocephaly. Plagiocephaly is an asymmetrically shaped head. Synostotic Plagiocephaly is due to premature closure of cranial sutures. Non-Synostotic Plagiocephaly is from positioning or deformation of the head. Cranial orthosis is the use of a special helmet or band on the head which aids in molding the shape of the cranium to normal. Initial reimbursement shall cover any subsequent revisions.
- D. Elastic Supports. Elastic supports are covered when prescribed for one (1) of the following indications:
- (I) Severe or incapacitating vascular problems, such as acute thrombophlebitis, massive venous stasis, or pulmonary embolism;
 - (II) Venous insufficiency;
 - (III) Varicose veins;
 - (IV) Edema of lower extremities;
 - (V) Edema during pregnancy; or
 - (VI) Lymphedema.
- E. Footwear Incorporated Into a Brace for Members with Skeletally Mature Feet. Footwear incorporated into a brace must be billed by the same supplier billing for the brace. The following types of footwear incorporated into a brace are covered:
 - (I) Orthopedic footwear;

- (II) Other footwear such as high top, depth inlay, or custom;
- (III) Heel replacements, sole replacements, and shoe transfers involving shoes on a brace;
- (IV) Inserts for a shoe that is an integral part of a brace and are required for the proper functioning of the brace; or
- (V) Other shoe modifications if they are on a shoe that is an integral part of a brace and are required for the proper functioning of the brace.
- F. Foot Orthoses. Custom, removable foot orthoses are covered for members who meet the following criteria:
- (I) Member with skeletally mature feet who has any of the following conditions:
 - (a) Acute plantar fasciitis;
- (b) Acute sport-related injuries with diagnoses related to inflammatory problems such as bursitis or tendonitis;
 - (c) Calcaneal bursitis (acute or chronic);
 - (d) Calcaneal spurs (heel spurs);
 - (e) Conditions related to diabetes;
- (f) Inflammatory conditions (e.g., sesamoiditis, submetatarsal bursitis, synovitis, tenosynovitis, synovial cyst, osteomyelitis, and plantar fascial fibromatosis);
 - (g) Medial osteoarthritis of the knee;
- (h) Musculoskeletal/arthropathic deformities including deformities of the joint or skeleton that impairs walking in a normal shoe (e.g., bunions, hallux valgus, talipes deformities, pes deformities, or anomalies of toes);
- (i) Neurologically impaired feet including neuroma, tarsal tunnel syndrome, ganglionic cyst;
- (j) Neuropathies involving the feet, including those associated with peripheral vascular disease, diabetes, carcinoma, drugs, toxins, and chronic renal disease; or
- (k) Vascular conditions including ulceration, poor circulation, peripheral vascular disease, Buerger's disease (thromboangiitis obliterans), and chronic thrombophlebitis;
- (II) Member with skeletally immature feet who has any of the following conditions:
 - (a) Hallux valgus deformities;
 - (b) In-toe or out-toe gait;

planus;

- (c) Musculoskeletal weakness such as pronation or pes
 - (d) Structural deformities such as tarsal coalitions; or
- (e) Torsional conditions such as metatarsus adductus, tibial torsion, or femoral torsion.
- G. Helmets. Helmets are covered when cranial protection is required due to a documented medical condition that makes the member susceptible to injury during activities of daily living.
- H. Hip Orthosis. Hip orthosis is covered for one (1) of the following indications:
 - (I) To reduce pain by restricting mobility of the hip;
- (II) To facilitate healing following an injury to the hip or related soft tissues;
- (III) To facilitate healing following a surgical procedure of the hip or related soft tissue; or
- (IV) To otherwise support weak hip muscles or a hip deformity.
- I. Knee Orthosis. Knee orthosis is covered for one (1) of the following indications:
 - (I) To reduce pain by restricting mobility of the knee;
- (II) To facilitate healing following an injury to the knee or related soft tissues;
- (III) To facilitate healing following a surgical procedure on the knee or related soft tissue; or
- (IV) To otherwise support weak knee muscles or a knee deformity.
 - J. Orthopedic Footwear for Diabetic Members.

- (I) Orthopedic footwear, therapeutic shoes, inserts, or modifications to therapeutic shoes are covered for diabetic members if any following criteria are met:
- (a) Previous amputation of the other foot or part of either foot;
 - (b) History of previous foot ulceration of either foot;
 - (c) History of pre-ulcerative calluses of either foot;
- (d) Peripheral neuropathy with evidence of callus formation of either foot;
 - (e) Foot deformity of either foot; or
 - (f) Poor circulation in either foot.
- (II) Coverage is limited to one (1) of the following within one (1) year:
- (a) One (1) pair of custom molded shoes (which includes inserts provided with these shoes) and two (2) additional pairs of inserts;
- (b) One (1) pair of depth shoes and three (3) pairs of inserts (not including the non-customized removable inserts provided with such shoes); or
- (c) Up to three (3) pairs of inserts not dispensed with diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which the insert can be placed.
- K. Orthotic-Related Supplies. Orthotic-related supplies are covered when necessary for the function of the covered orthotic device.
- L. Spinal Orthoses. A thoracic-lumbar-sacral orthosis, lumbar orthosis, lumbar-sacral orthosis, and cervical orthosis are covered for the following indications:
 - (I) To reduce pain by restricting mobility of the trunk;
- (II) To facilitate healing following an injury to the spine or related soft tissues;
- (III) To facilitate healing following a surgical procedure of the spine or related soft tissue; or
- (IV) To otherwise support weak spinal muscles or a deformed spine.
- M. Trusses. Trusses are covered when a hernia is reducible with the application of a truss.
- N. Upper Limb Orthosis. Upper limb orthosis is covered for the following indications:
 - (I) To reduce pain by restricting mobility of the joint(s);
- (II) To facilitate healing following an injury to the joint(s) or related soft tissues: or
- (III) To facilitate healing following a surgical procedure of the joint(s) or related soft tissue.
- O. Orthotic Device Replacement. When repairing an item that is no longer cost-effective and is out of warranty, the plan will consider replacing the item subject to review of medical necessity and life expectancy of the device;
 - 36. Preventive services.
- A. Services recommended by the U.S. Preventive Services Task Force (categories A and B).
- B. Immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.
- C. Preventive care and screenings for infants, children, and adolescents supported by the Health Resources and Services Administration.
- D. Preventive care and screenings for women supported by the Health Resources and Services Administration.
- E. Annual physical exams and routine lab and X-ray services ordered as part of the annual exam. One (1) exam per calendar year is covered. Additional visits as needed to obtain all necessary preventive services are covered for women depending on a woman's health status, health needs, and other risk factors. For benefits to be covered as preventive, including X-rays and lab services, they must be coded by your physician as routine, without indication of an injury or illness.
 - F. Cancer screenings—

- (I) Mammograms—one (1) exam per year, no age limit;
- (II) Pap smears—one (1) per year, no age limit;
- (III) Prostate—one (1) per year, no age limit; and
- (IV) Colorectal screening—One (1) flexible sigmoidoscopy, colonoscopy, or double contrast barium enema per year covered as preventive even if the primary diagnosis is not a preventive code provided a preventive code is included in connection with the screening. Virtual colonoscopy covered as diagnostic only. Additional colorectal screenings covered as diagnostic unless otherwise specified
- G. Zoster vaccination (shingles)—The zoster vaccine is covered for members age fifty (50) years and older;
- 37. Prostheses (prosthetic devices). Basic equipment that meets medical needs. Repair and replacement is covered due to normal wear and tear, if there is a change in medical condition, or if growth-related:
- 38. Pulmonary rehabilitation. Comprehensive, individualized, goal-directed outpatient pulmonary rehabilitation covered for preand post-operative intervention for lung transplantation and lung volume reduction surgery (LVRS) or when all of the following apply:
- A. Member has a reduction of exercise tolerance that restricts the ability to perform activities of daily living (ADL) or work;
- B. Member has chronic pulmonary disease (including asthma, emphysema, chronic bronchitis, chronic airflow obstruction, cystic fibrosis, alpha-1 antitrypsin deficiency, pneumoconiosis, asbestosis, radiation pneumonitis, pulmonary fibrosis, pulmonary alveolar proteinosis, pulmonary hemosiderosis, fibrosing alveolitis), or other conditions that affect pulmonary function such as ankylosing spondylitis, scoliosis, myasthenia gravis, muscular dystrophy, Guillain-Barré syndrome, or other infective polyneuritis, sarcoidosis, paralysis of diaphragm, or bronchopulmonary dysplasia; and
- C. Member has a moderate to moderately severe functional pulmonary disability, as evidenced by either of the following, and does not have any concomitant medical condition that would otherwise imminently contribute to deterioration of pulmonary status or undermine the expected benefits of the program (e.g., symptomatic coronary artery disease, congestive heart failure, myocardial infarction within the last six (6) months, dysrhythmia, active joint disease, claudication, malignancy):
- (I) A maximal pulmonary exercise stress test under optimal bronchodilatory treatment which demonstrates a respiratory limitation to exercise with a maximal oxygen uptake (VO_2 max) equal to or less than twenty milliliters per kilogram per minute (20 ml/kg/min), or about five (5) metabolic equivalents (METS); or
- (II) Pulmonary function tests showing that either the Forced Expiratory Volume in One Second (FEV1), Forced Vital Capacity (FVC), FEV1/FVC, or Diffusing Capacity of the Lung for Carbon Monoxide (DLCO) is less than sixty percent (60%) of that predicted;
- 39. Skilled Nursing Facility. Skilled nursing facility services are covered up to one hundred twenty (120) days per calendar year;
- 40. Bone Growth Stimulators. Implantable bone growth stimulators are covered as an outpatient surgery benefit. The following nonimplantable bone growth stimulators are covered as a durable medical equipment benefit:
- A. Ultrasonic osteogenesis stimulator (e.g., the Sonic Accelerated Fracture Healing System (SAFHS)) to accelerate healing of fresh fractures, fusions, or delayed unions at either of the following high-risk sites:
- (I) Fresh fractures, fusions, or delayed unions of the shaft (diaphysis) of the tibia that are open or segmental; or
- (II) Fresh fractures, fusions, or delayed unions of the scaphoid (carpal navicular);
- B. Ultrasonic osteogenesis stimulator for non-unions, failed arthrodesis, and congenital pseudarthrosis (pseudoarthrosis) of the appendicular skeleton if there has been no progression of healing for three (3) or more months despite appropriate fracture care; or

- C. Direct current electrical bone-growth stimulator is covered for the following indications:
- (I) Delayed unions of fractures or failed arthrodesis at highrisk sites (i.e., open or segmental tibial fractures, carpal navicular fractures);
- (II) Non-unions, failed fusions, and congenital pseudarthrosis where there is no evidence of progression of healing for three (3) or more months despite appropriate fracture care; or
- (III) Members who are at high risk for spinal fusion failure when any of the following criteria is met:
- (a) A multiple-level fusion entailing three (3) or more vertebrae (e.g., L3 to L5, L4 to S1, etc.);
 - (b) Grade II or worse spondylolisthesis; or
 - (c) One (1) or more failed fusions.
- 41. Telehealth Services. Telehealth services are covered for the diagnosis, consultation, or treatment of a member on the same basis that the service would be covered when it is delivered in person;
- 42. Therapy. Physical, occupational, and speech therapy are covered when prescribed by a provider and subject to the provisions below:
 - A. Physical therapy.
 - (I) Physical therapy must meet the following criteria:
- (a) The program is designed to improve lost or impaired physical function or reduce pain resulting from illness, injury, congenital defect, or surgery;
- (b) The program is expected to result in significant therapeutic improvement over a clearly defined period of time; and
- (c) The program is individualized, and there is documentation outlining quantifiable, attainable treatment goals;
 - B. Occupational therapy must meet the following criteria:
- (I) The program is designed to improve or compensate for lost or impaired physical functions, particularly those affecting activities of daily living, resulting from illness, injury, congenital defect, or surgery;
- (II) The program is expected to result in significant therapeutic improvement over a clearly defined period of time; and
- (III) The program is individualized, and there is documentation outlining quantifiable, attainable treatment goals;
 - C. Speech therapy.
- (I) All of the following criteria must be met for coverage of speech therapy:
- (a) The therapy requires one-to-one intervention and supervision of a speech-language pathologist;
- (b) The therapy plan includes specific tests and measures that will be used to document significant progress every two (2) weeks;
 - (c) Meaningful improvement is expected;
- (d) The therapy includes a transition from one-to-one supervision to a self- or caregiver- provided maintenance program upon discharge; and
 - (e) One (1) of the following:
- I. Member has severe impairment of speech-language; and an evaluation has been completed by a certified speech-language pathologist that includes age-appropriate standardized tests to measure the extent of the impairment, performance deviation, and language and pragmatic skill assessment levels; or
- II. Member has a significant voice disorder that is the result of anatomic abnormality, neurological condition, or injury (e.g., vocal nodules or polyps, vocal cord paresis or paralysis, post-operative vocal cord surgery);
- 43. Transplants. Stem cell, kidney, liver, heart, lung, pancreas, small bowel, or any combination are covered. Includes services related to organ procurement and donor expenses if not covered under another plan. Member must contact medical plan for arrangements.
- A. Network includes travel and lodging allowance for the transplant recipient and an immediate family travel companion when the transplant facility is more than fifty (50) miles from the recipient's residence. If the recipient is younger than age nineteen (19) years travel and lodging is covered for both parents. The transplant

- recipient must be with the travel companion or parents(s) for the travel companion's or parent(s)' travel expense to be reimbursable. Combined travel and lodging expenses are limited to a ten thousand dollar (\$10,000) maximum per transplant.
- (I) Lodging—maximum lodging expenses shall not exceed the per diem rates as established annually by U.S. General Services Administration (GSA) for a specific city or county. Go to www.gsa.gov for per diem rates.
- (II) Travel—IRS standard medical mileage rates (same as flexible spending account (FSA) reimbursement).
 - (III) Meals—not covered.
- B. Non-network. Charges above the maximum for services rendered at a non-network facility are the member's responsibility and do not apply to the member's deductible or out-of-pocket maximum. Travel, lodging, and meals are not covered. Non-network facility charges and payments for transplants are limited to the following maximums:
 - (I) Stem cell transplant—
- (a) Allogeneic related—one hundred fifty-three thousand dollars (\$153,000);
- (b) Allogeneic unrelated—one hundred seventy-nine thousand dollars (\$179,000); and
- (c) Autologous stem cell transplant—one hundred five thousand dollars (\$105,000);
- (II) Heart—one hundred eighty-five thousand dollars (\$185,000);
- (III) Heart and lung—two hundred sixty-one thousand three hundred sixty-one dollars (\$261,361);
- (IV) Lung—one hundred forty-two thousand eight hundred seventeen dollars (\$142,817);
 - (V) Kidney—eighty thousand dollars (\$80,000);
- (VI) Kidney and pancreas—one hundred thirty thousand dollars (\$130,000);
- (VII) Liver—one hundred seventy-five thousand nine hundred dollars (\$175,900);
- (VIII) Pancreas—ninety-five thousand dollars (\$95,000); and
- (IX) Small bowel—two hundred seventy-five thousand dollars (\$275,000);
- 44. Urgent care. Care for an illness, injury, or condition serious enough that a reasonable person would seek care right away, but not so severe as to require emergency room care; and
- 45. Vision. One (1) routine exam and refractions is covered per calendar year.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, and section 103.080.3, RSMo Supp. 2014, the executive director amends a rule as follows:

22 CSR 10-2.060 PPO 300 Plan, PPO 600 Plan, and Health Savings Account Plan Limitations **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1998–1999). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, and section 103.089, RSMo Supp. 2014, the executive director amends a rule as follows:

22 CSR 10-2.070 Coordination of Benefits is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 1999–2000). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan received one (1) comment on the proposed amendment.

COMMENT #1: UMR suggested clarifying the coordination of benefits when MCHCP is secondary to Medicare by adding that all claims where Medicare is primary will be considered at the network benefit level when MCHCP coordinates benefits.

RESPONSE: No clarification is needed. No changes were made to the rule as a result of this comment.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.075 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2000–2003). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment.

COMMENT #1: UMR commented to clarify the time period needed to review an appeal of a first and second level appeal.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, subparts (3)(B)2.B.(II)(a) and (3)(B)2.B.(IV)(a) were added to clarify that the vendor may extend the time period for the appeal of a first and second level appeal because of reasons outside the vendor's control and the time frames that the vendor must follow.

22 CSR 10-2.075 Review and Appeals Procedure

- (3) Appeal Process for Medical and Pharmacy Determinations.
 (B) Internal Appeals.
- 1. Eligibility, termination for failure to pay, or rescission. Adverse benefit determinations denying or terminating an individ-

ual's coverage under the plan based on a determination of the individual's eligibility to participate in the plan or the failure to pay premiums, or any rescission of coverage based on fraud or intentional misrepresentation of a member or authorized representative of a member are appealable exclusively to the Missouri Consolidated Health Care Plan (MCHCP) Board of Trustees (board).

- A. The internal review process for appeals relating to eligibility, termination for failure to pay, or rescission shall consist of one (1) level of review by the board.
- B. Adverse benefit determination appeals to the board must identify the eligibility, termination, or rescission decision being appealed and the reason the claimant believes the MCHCP staff decision should be overturned. The member should include with his/her appeal any information or documentation to support his/her appeal request.
- C. The appeal will be reviewed by the board in a meeting closed pursuant to section 610.021, RSMo, and the appeal will be responded to in writing to the claimant within sixty (60) days from the date the board received the written appeal.
- D. Determinations made by the board constitute final internal adverse benefit determinations and are not eligible for external review except as specifically provided in 22 CSR 10-32.075(4)(A)4.
- 2. Medical and pharmacy services. Members may request internal review of any adverse benefit determination relating to urgent care, pre-service claims, and post-service claims made by the plan's medical and pharmacy vendors.
- A. Appeals of adverse benefit determinations shall be submitted in writing to the vendor that issued the original determination giving rise to the appeal at the applicable address set forth in this rule.
- B. The internal review process for adverse benefit determinations relating to medical services consists of two (2) levels of internal review provided by the medical vendor that issued the adverse benefit determination.
- (I) First level appeals must identify the decision being appealed and the reason the member believes the original claim decision should be overturned. The member should include with his/her appeal any additional information or documentation to support the reason the original claim decision should be overturned.
- (II) First level appeals will be reviewed by the vendor by someone who was not involved in the original decision and will consult with a qualified medical professional if a medical judgment is involved. First level medical appeals will be responded to in writing to the member within thirty (30) days for post-service claims and fifteen (15) days for pre-service claims from the date the vendor received the first level appeal request.
- (a) If, because of reasons beyond the vendor's control, more time is needed to review the appeal, the vendor may extend the time period up to an additional fifteen (15) days. The vendor must notify the member prior to the expiration of the first fifteen- (15-) day period, explain the reason for the delay, and request any additional information. If more information is requested, the member has at least forty-five (45) days to provide the information to the vendor. The vendor then must decide the claim no later than fifteen (15) days after the additional information is supplied or after the period of time allowed to supply it ends, whichever is first.
- (III) An expedited appeal of an adverse benefit determination may be requested when a decision is related to a pre-service claim for urgent care. Expedited appeals will be reviewed by the vendor by someone who was not involved in the original decision and will consult with a qualified medical professional if a medical judgment is involved. Expedited appeals will be responded to within seventy-two (72) hours after receiving a request for an expedited review with written confirmation of the decision to the member within three (3) working days of providing notification of the determination.
- (IV) Second level appeals must be submitted in writing within sixty (60) days of the date of the first level appeal decision letter that upholds the original adverse benefit determination. Second level appeals should include any additional information or documentation to support the reason the member believes the first level appeal

decision should be overturned. Second level appeals will be reviewed by the vendor by someone who was not involved in the original decision or first level appeal and will include consultation with a qualified medical professional if a medical judgment is involved. Second level medical appeals shall be responded to in writing to the member within thirty (30) days for post-service claims and within fifteen (15) days for pre-service claims from the date the vendor received the second level appeal request.

- (a) If, because of reasons beyond the vendor's control, more time is needed to review the appeal, the vendor may extend the time period up to an additional fifteen (15) days. The vendor must notify the member prior to the expiration of the first fifteen- (15-) day period, explain the reason for the delay, and request any additional information. If more information is requested, the member has at least forty-five (45) days to provide the information to the vendor. The vendor then must decide the claim no later than fifteen (15) days after the additional information is supplied or after the period of time allowed to supply it ends, whichever is first.
 - (V) For members with medical coverage through UMR—
- (a) First and second level pre-service and concurrent claim appeals must be submitted in writing to—

UMR Appeals PO Box 400046 San Antonio, TX 78229 or by fax to (888) 615-6584

(b) First and second level post-service appeals must be sent in writing to—

UMR Claims Appeal Unit PO Box 30546 Salt Lake City, UT 84130-0546 or by fax to (877) 291-3248

- (c) Expedited pre-service appeals must be communicated by calling (800) 808-4424, ext. 15227 or by submitting a written fax to (888) 615-6584, Attention: Appeals Unit.
- (VI) For members with medical coverage through Coventry Health Care of Kansas, Inc.—
- (a) First and second level appeals must be submitted in writing to—

Coventry Health Care of Kansas, Inc. Attn: Appeals Department 9401 Indian Creek Parkway, Suite 1300 Overland Park, KS 66210 or by fax to (866) 769-2408

- (b) Expedited appeals must be communicated by calling (913) 202-5000 or by submitting a written fax to (866) 769-2408.
- C. The internal review process for adverse benefit determinations relating to pharmacy and the Pharmacy Lock-In Program consists of one (1) level of internal review provided by the pharmacy vendor.
- (I) Pharmacy appeals. Pharmacy appeals and Pharmacy Lock-In Program appeals must identify the matter being appealed and should include the member's (and dependent's, if applicable) name, the date the member attempted to fill the prescription, the prescribing physician's name, the drug name and quantity, the cost of the prescription, if applicable, and any applicable reason(s) relevant to the appeal including: the reason(s) the member believes the claim should be paid, the reason(s) the member believes s/he should not be included in the Pharmacy Lock-In Program, and any other written documentation to support the member's belief that the original decision should be overturned.
- (II) All pharmacy appeals must be submitted in writing to-

Express Scripts
Attn: Clinical Appeals Department
PO Box 66588
St. Louis, MO 63116-6588
or by fax to (877) 852-4070

(III) All Pharmacy Lock-In Program appeals must be submitted in writing to— $\,$

Express Scripts Drug Utilization Review Program 100 Parsons Pond Dr. Franklin Lakes, NJ 07417-2603

- (IV) Pharmacy appeals will be reviewed by someone who was not involved in the original decision and the reviewer will consult with a qualified medical professional if a medical judgment is involved. Pharmacy appeals will be responded to in writing to the member within sixty (60) days for post-service claims and thirty (30) days for pre-service claims from the date the vendor received the appeal request.
- (V) The Pharmacy Benefit Manager will respond to Pharmacy Lock-In Program appeals in writing to the member within thirty (30) days from the date the Pharmacy Benefit Manager received the appeal request.
- D. Members may seek external review only after they have exhausted all applicable levels of internal review or received a final internal adverse benefit determination.
- (I) A claimant or authorized representative may file a written request for an external review within four (4) months after the date of receipt of a final internal adverse benefit determination.
- (II) The claimant can submit an external review request in writing to—

HHS Federal Request
MAXIMUS Federal Services
3750 Monroe Ave., Suite 705
Pittsford, NY 14534
or by fax to (888) 866-6190
or to request a review online at
http://www.externalappeal.com/

- (III) The claimant may call the toll-free number (888) 866-6205 with any questions or concerns during the external review process and can submit additional written comments to the external reviewer at the mailing address above.
- (IV) The external review decision will be made as expeditiously as possible and within forty-five (45) days after receipt of the request for the external review.
- (V) A claimant may make a written or oral request for an expedited external review if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant; or would jeopardize the claimant's ability to regain maximum function; or if the final internal adverse benefit determination involves an admission, availability of care, continued stay, or health care item or service for which the claimant received services, but has not been discharged from a facility.
- 3. For all internal appeals of adverse benefit determinations, the plan or the vendor reviewing the appeal will provide the member, free of charge, with any new or additional evidence or rationale considered, relied upon, or generated by the plan or the vendor in connection with reviewing the claim or the appeal and will give the member an opportunity to respond to such new evidence or rationale before issuing a final internal adverse determination.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.080 Miscellaneous Provisions is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2003–2004). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.089 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2004–2005). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment.

COMMENT #1: MCHCP staff commented under paragraph (1)(I)4., to clarify that formulary brand contraception is covered at one hundred percent (100%) when a generic is not medically appropriate or a generic version is not available.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, paragraph (1)(I)4., has been amended to clarify that formulary brand contraception is covered at one hundred percent (100%) when a generic is not medically appropriate or a generic version is not available.

22 CSR 10-2.089 Pharmacy Employer Group Waiver Plan for Medicare Primary Members

- (1) The pharmacy benefit for Medicare primary members is provided through a Pharmacy Employer Group Waiver Plan (EGWP) as regulated by the Centers for Medicare and Medicaid Services herein after referred to as the Medicare Prescription Drug Plan.
- (I) Prescription drugs and prescribed over-the-counter drugs as recommended by the U.S Preventive Services Task Force (categories A and B) are covered at one hundred percent (100%) when filled at a network pharmacy. The following are also covered at one hundred percent (100%) when filled at a network pharmacy:

- 1. Prescribed Vitamin D for all ages:
- A. The dosage range for preventive Vitamin D at or below 1000 IU of Vitamin D_2 or D_3 per dose;
- 2. Zoster (shingles) vaccine and administration for members age fifty (50) years and older;
- 3. Influenza vaccine and administration as recommend by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention; and
- 4. Formulary brand contraception and non-formulary contraception when the provider determines a generic is not medically appropriate or a generic version is not available.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.090 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2005–2008). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment.

COMMENT #1: MCHCP staff commented to clarify that Hepatitis C specialty drugs may not be filled through a retail pharmacy in addition to those select drugs that have been included in the specialty split-fill program.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, part (1)(A)1.D.(II), has been amended to clarify that Hepatitis C specialty drugs may not be filled through a retail pharmacy

22 CSR 10-2.090 Pharmacy Benefit Summary

- (1) The pharmacy benefit provides coverage for prescription drugs. Vitamin and nutrient coverage is limited to prenatal agents, therapeutic agents for specific deficiencies and conditions, and hematopoietic agents as prescribed by a provider to non-Medicare primary members.
 - (A) PPO 300 and PPO 600.
 - 1. Network:
- A. Generic copayment: Eight dollars (\$8) for up to a thirty-one- (31-) day supply; sixteen dollars (\$16) for up to a sixty- (60-) day supply; and twenty-four dollars (\$24) for up to a ninety- (90-) day supply for a generic drug on the formulary;
- B. Brand copayment: Thirty-five dollars (\$35) for up to a thirty-one- (31-) day supply; seventy dollars (\$70) for up to a sixty- (60-) day supply; and one hundred and five dollars (\$105) for up to a ninety- (90-) day supply for a brand drug on the formulary;
- C. Non-formulary copayment: One hundred dollars (\$100) for up to a thirty-one- (31-) day supply; two hundred dollars (\$200) for up to a sixty- (60-) day supply; and three hundred dollars (\$300) for up to a ninety- (90-) day supply for a drug not on the formulary;
 - D. Home delivery program.

- (I) Maintenance prescriptions may be filled through the home delivery program.
- (a) Generic copayments: Eight dollars (\$8) for up to a thirty-one- (31-) day supply; sixteen dollars (\$16) for up to a sixty-(60-) day supply; and twenty dollars (\$20) for up to a ninety- (90-) day supply for a generic drug on the formulary;
- (b) Brand copayments: Thirty-five dollars (\$35) for up to a thirty-one- (31-) day supply; seventy dollars (\$70) for up to a sixty- (60-) day supply; and eighty-seven dollars and fifty cents (\$87.50) for up to a ninety- (90-) day supply for a brand drug on the formulary;
- (c) Non-formulary copayments: One hundred dollars (\$100) for up to a thirty-one- (31-) day supply; two hundred dollars (\$200) for up to a sixty- (60-) day supply; and two hundred fifty dollars (\$250) for up to a ninety- (90-) day supply for a drug not on the formulary;
- (d) A member must choose how maintenance prescriptions will be filled by notifying the pharmacy benefit manager (PBM) of his/her decision to fill a maintenance prescription through home delivery or retail pharmacy;
- I. If the member chooses to fill his/her maintenance prescription at a retail pharmacy and the member does not notify the PBM of his/her decision, the first two (2) maintenance prescription orders may be filled by the retail pharmacy. After the first two (2) orders are filled at the retail pharmacy, the member must notify the PBM of his/her decision to continue to fill the maintenance prescription at the retail pharmacy. If a member does not make a decision after the first two (2) orders are filled at the retail pharmacy, s/he will be charged the full discounted cost of the drug until the PBM has been notified of the decision and the amount charged will not apply to the out-of-pocket maximum; and
- II. Once a member makes his/her delivery decision, the member can modify the decision by contacting the PBM; and
- (II) Specialty drugs are covered only through the specialty home delivery network for up to a thirty-one- (31-) day supply unless the PBM has determined that the specialty drug is eligible for up to a ninety- (90-) day supply. The first specialty prescription order may be filled through a retail pharmacy, except for Hepatitis C specialty drugs and those select drugs that have been included in the specialty split-fill program.
- (a) Generic copayment: Eight dollars (\$8) for a generic drug on the formulary list.
- (b) Brand copayment: Thirty-five dollars (\$35) for a brand drug on the formulary.
- (c) Non-formulary copayment: One hundred dollars (\$100) for a drug not on the formulary;
- (III) Specialty split-fill program—The specialty split-fill program applies to select specialty drugs as determined by the PBM. For the first three (3) months, members will be shipped a fifteen- (15-) day supply and charged a prorated copayment. If the member is able to continue with the medication, the remaining supply will be shipped and the member will be charged the remaining portion of the copayment. Starting with the fourth month, an up to thirty-one- (31-) day supply will be shipped if the member continues on treatment.
- E. Only one (1) copayment is charged if a combination of different manufactured dosage amounts must be dispensed in order to fill a prescribed single dosage amount;
- F. The copayment for a compound drug is based on the primary drug in the compound. The primary drug in a compound is the most expensive prescription drug in the mix. If any ingredient in the compound is excluded by the plan, the compound will be denied;
- G. If the copayment amount is more than the cost of the drug, the member is only responsible for the cost of the drug;
- H. If the physician allows for generic substitution and the member chooses a brand-name drug, the member is responsible for the generic copayment and the cost difference between the brand name and generic drug which shall not apply to the out-of-pocket maximum; and

- I. Prescription drugs and prescribed over-the-counter drugs as recommended by the U.S. Preventive Services Task Force (categories A and B) and, for women, by the Health Resources and Services Administration are covered at one hundred percent (100%) when filled at a network pharmacy. The following are also covered at one hundred percent (100%) when filled at a network pharmacy:
 - (I) Prescribed Vitamin D for all ages;
- (a) The dosage range for preventive Vitamin D at or below 1000 IU of Vitamin D_2 or D_3 per dose;
- (II) Zoster (shingles) vaccine and administration for members age fifty (50) years and older; and
- (III) Influenza vaccine and administration as recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention; and
- (IV) Generic Tamoxifen, generic Raloxifene, and brand Soltamox for prevention of breast cancer.
- 2. Non-network: If a member chooses to use a non-network pharmacy for non-specialty prescriptions, s/he will be required to pay the full cost of the prescription and then file a claim with the PBM. The PBM will reimburse the cost of the drug based on the network discounted amount as determined by the PBM, less the applicable network copayment.
 - 3. Out-of-pocket maximum.
- A. Network and non-network out-of-pocket maximums are separate;
- B. The family out-of-pocket maximum is an aggregate of applicable charges received by all covered family members of the plan. Any combination of covered family member applicable charges may be used to meet the family out-of-pocket maximum. Applicable charges received by one (1) family member may only meet the individual out-of-pocket maximum amount;
 - C. Individual—five thousand one hundred dollars (\$5,100);
 - D. Family—ten thousand two hundred dollars (\$10,200).

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.095 TRICARE Supplement Plan is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2008). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, and section 103.078, RSMo Supp. 2014, the executive director amends a rule as follows:

22 CSR 10-2.110 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2008–2012). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received three (3) comments on the proposed amendment.

COMMENT #1: MCHCP staff commented that under paragraph (3)(C)5., the language regarding dependent and spouse/child(ren) be reviewed to ensure it is in alignment with the definitions in 22 CSR 10-2 010

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, the amended language regarding spouse/child(ren) in paragraph (3)(C)5. was removed and replaced with dependents.

COMMENT #2: MCHCP staff commented that under paragraph (5)(D)1., the language regarding dependent and child be reviewed to ensure it is in alignment with the definitions in 22 CSR 10-2.010. RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, the amended language regarding documentation for a permanently disabled spouse/child(ren) in paragraph (5)(D)1. was replaced with dependents.

COMMENT #3: MCHCP staff commented that under paragraph (6)(A)3., the events be clarified that cause a termination of coverage to occur.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, clarification was made under paragraph (6)(A)3. that termination occurs when a dependent is no longer eligible for coverage.

22 CSR 10-2.110 General Foster Parent Membership Provisions

- (3) Enrollment Procedures.
- (C) An eligible foster parent may apply for coverage for himself/herself and/or for his/her spouse/child(ren) if one (1) of the following occurs:
- 1. Occurrence of a life event, which includes marriage, birth, adoption, and placement of children. A special enrollment period of thirty-one (31) days shall be available beginning with the date of the life event. It is the eligible foster parent's responsibility to notify MCHCP of the life event;
- A. If paternity is necessary to establish the life event and was not established at birth, the date that paternity is established shall be the date of the life event; or
- 2. Employer-sponsored group coverage loss. An eligible foster parent and his/her spouse/child(ren) may enroll within sixty (60) days if s/he involuntarily loses employer-sponsored coverage under one (1) of the following circumstances:
- A. Employer-sponsored medical, dental, or vision plan terminates:
 - B. Eligibility for employer-sponsored coverage ends;
 - C. Employer contributions toward the premiums end; or
- $\label{eq:D.Consolidated Omnibus Budget Reconciliation Act (COBRA)} Coverage ends; or$
- 3. If an eligible foster parent or his/her spouse/child(ren) loses MO HealthNet or Medicaid status, s/he may enroll in an MCHCP plan within sixty (60) days of the date of loss; or
- 4. If an eligible foster parent or eligible foster parent's spouse receives a court order stating s/he is responsible for coverage of a child, the eligible foster parent may enroll the child in an MCHCP plan within sixty (60) days of the court order; or
- 5. If an eligible foster parent is enrolled and does not complete enrollment during the open enrollment period, the foster parent and

his/her dependents will be enrolled at the same level of coverage in the PPO 600 Plan provided through the vendor the foster parent is enrolled in, effective the first day of the next calendar year; or

- 6. If an eligible foster parent submits an Open Enrollment Worksheet or an Enroll/Change/Cancel form that is incomplete or contains obvious errors, MCHCP will notify the foster parent of such by mail, phone, or secure message. The foster parent must submit a corrected form to MCHCP by the date enrollment was originally due to MCHCP or ten (10) business days from the date MCHCP notifies the foster parent, whichever is later.
- (5) Proof of Eligibility. Proof of eligibility documentation is required for all dependents and subscribers, as necessary. Enrollment is not complete until proof of eligibility is received by MCHCP. A subscriber must include his/her MCHCPid or Social Security number on the documentation. If proof of eligibility is not received, MCHCP will send a letter requesting it from the subscriber. Except for open enrollment, documentation must be received within thirty-one (31) days of the letter date, or coverage will not take effect for those individuals whose proof of eligibility was not received. MCHCP reserves the right to request that such proof of eligibility be provided at any time upon request. If such proof is not received or is unacceptable as determined by MCHCP, coverage will terminate or never take effect. If enrolling during open enrollment, proof of eligibility must be received by November 20, or coverage will not take effect the following January 1 for those individuals whose proof of eligibility was not received.

(D) Disabled Dependent.

- 1. A newly eligible foster parent may enroll his/her permanently disabled child or an enrolled permanently disabled dependent turning age twenty-six (26) years, may continue coverage beyond age twenty-six (26) years, provided the following documentation is submitted to the plan prior to the dependent's twenty-sixth birthday for the enrolled permanently disabled dependent or within thirty-one (31) days of enrollment of a new foster parent and his/her permanently disabled child:
- A. Evidence that the permanently disabled dependent or child was entitled to and receiving disability benefits prior to turning age twenty-six (26). Evidence could be from the Social Security Administration (SSA), representation from the dependent's or child's physician, or by sworn statement from the subscriber;
- B. A letter from the dependent's or child's physician describing the current disability and verifying that the disability predates the dependent's or child's twenty-sixth birthday and the disability is permanent; and
- C. A benefit verification letter dated within the last twelve (12) months from the SSA confirming the child is still considered disabled by SSA.
- 2. If a disabled dependent over the age of twenty-six (26) years is determined to be no longer disabled by the SSA, coverage will terminate the last day of the month in which the disability ends or never take effect for new enrollment requests.
- 3. Once the disabled child's coverage is cancelled or terminated, s/he will not be able to enroll at a later date.

(6) Termination.

- (A) Unless stated otherwise, termination of coverage shall occur on the last day of the calendar month coinciding with or after any of the following events, whichever occurs first:
- 1. Failure to make premium payment for the cost of coverage. If MCHCP has not received payment of premium at the end of the thirty-one- (31-) day grace period, the subscriber and his/her dependents will be retroactively terminated to the date covered by his/her last paid premium. The subscriber will be responsible for the value of services rendered after the retroactive termination date, including, but not limited to, the grace period;
- 2. Loss of foster parent licensure as determined by the Department of Social Services;

- 3. With respect to dependents, upon divorce or legal separation from the subscriber or when a dependent is no longer eligible for coverage. A subscriber must terminate coverage for his/her enrolled ex-spouse and stepchild(ren) at the time his/her divorce is final.
- A. When a subscriber drops dependent coverage after a divorce, s/he must submit a completed form, a copy of the divorce decree, and current addresses of all affected dependents. Coverage ends on the last day of the month in which the divorce decree and completed form are received by MCHCP or MCHCP otherwise receives credible evidence of a final divorce that results in loss of member eligibility under the plan;
- 4. Death of dependent. The dependent's coverage ends on the date of death. The subscriber must submit a completed form and a copy of the death certificate within thirty-one (31) days of death;
- 5. A member's act, practice, or omission that constitutes fraud or intentional misrepresentation of material fact;
- 6. A member's threatening conduct or perpetrating violent acts against MCHCP or an employee of MCHCP;
- 7. A subscriber has obtained access to other health insurance coverage through an employer or spouse's employer; or
 - 8. A member otherwise loses benefit eligibility.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-2.140 Strive for Wellness® Health Center Provisions, Charges, and Services **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2012–2013). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director adopts a rule as follows:

22 CSR 10-2.150 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2013–2014). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed rule.

COMMENT #1: MCHCP staff commented that paragraph (2)(C)2. be removed as the oncology disease management program is duplicative of case management provided by the medical TPA.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, paragraph (2)(C)2. has been removed as it is duplicative of case management services provided by the medical TPA.

22 CSR 10-2.150 Disease Management Services Provisions and Limitations

(2) Disease Management.

- (C) An eligible member may participate in a DM program appropriate for managing a chronic condition if s/he meets the relevant age criterion and has one (1) or more of the following chronic conditions:
 - 1. Asthma—open to those aged six (6) and over;
- 2. Chronic obstructive pulmonary disease—open to those aged eighteen (18) and over;
- 3. Congestive heart failure—open to those aged eighteen (18) and over:
- 4. Coronary artery disease—open to those aged eighteen (18) and over;
 - 5. Depression—open to those aged eighteen (18) and over;
 - 6. Diabetes—open to those aged six (6) and over;
- 7. Musculoskeletal/chronic pain (including low back pain)—open to those aged eighteen (18) and over;
- 8. Obesity (Body Mass Index \geq 30)—open to those aged eighteen (18) and over; or
- 9. Hypertension as a co-morbid condition to any of the chronic conditions listed herein—open to those aged eighteen (18) and over.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 2—State Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director adopts a rule as follows:

22 CSR 10-2.160 Pharmacy Lock-in Program is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2014–2015). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-3.010 Definitions is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2015–2018). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-3.020 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2018–2024). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received five (5) comments on the proposed amendment.

COMMENT #1: MCHCP staff commented that paragraph (2)(B)1. be clarified so that in addition to the employee and his/her dependents, spouse/child(ren) may enroll or continue coverage at retirement.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, paragraph (2)(B)1. has been clarified that to enroll in coverage at the time of retirement, the employee's spouse/child(ren) must submit the required documentation outlined in the rule.

COMMENT #2: Under paragraph (2)(E)1., MCHCP staff commented to consider removing the words "and his/her spouse/child(ren)" as the employee is the individual that is eligible to elect or continue coverage.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, the suggested language under paragraph (2)(E)1. has been removed

COMMENT #3: Under part (2)(G)2.A.(VIII), MCHCP staff commented to consider adding the words "or child" after the words "newborn of a dependent," as they were inadvertently omitted from the proposed changes.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, the suggested language was added to part (2)(G)2.A.(VIII).

COMMENT #4: Under subparagraph (5)(F)1.A., MCHCP staff commented to clarify the proof of eligibility requirements for a disabled child.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, subparagraph (5)(F)1.A. has been clarified that evidence of being entitled to and receiving disability benefits applies to a permanently disabled dependent or child.

COMMENT #5: Under paragraph (7)(A)4., MCHCP staff commented to clarify the events that cause a termination of coverage to occur.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, the language in paragraph (7)(A)4. regarding when a child reaches age twenty-six (26) was removed because it is duplicative of the language regarding when a dependent is no longer eligible for coverage.

22 CSR 10-3.020 General Membership Provisions

- (2) Eligibility Requirements.
 - (B) Retiree Coverage.
- 1. An employee may participate in an MCHCP plan when s/he retires if s/he is fully vested in the retirement plan upon termination and the public entity remains with MCHCP. The public entity must make the benefits available to all retirees, past and future, who meet the vesting requirements. The employee may elect coverage for him/herself and dependents and his/her spouse/child(ren), provided the employee and his/her spouse/child(ren) have been continuously covered for health care benefits—
- A. Through MCHCP since the effective date of the last open enrollment period;
 - B. Through MCHCP since the initial date of eligibility; or
- C. Through group or individual medical coverage for the six (6) months immediately prior to retirement. Proof of prior group or individual coverage (letter from previous insurance carrier or former employer with dates of effective coverage and list of persons covered) is required.
- 2. If the retiree's spouse is an active public entity employee or retiree and enrolled in MCHCP, both spouses may transfer to coverage under the plan in which his/her spouse is enrolled or from his/her spouse's coverage to his/her coverage at any time as long as both spouses are eligible for MCHCP coverage and their coverage is continuous.
- 3. If a retiree who is eligible for coverage elects not to be continuously covered for him/herself and his/her spouse/child(ren) with MCHCP from the date first eligible, or does not apply for coverage for him/herself and his/her spouse/child(ren) within thirty-one (31) days of his/her eligibility date, the retiree and his/her spouse/child(ren) shall not thereafter be eligible for coverage unless specified elsewhere herein.
 - (E) Long-Term Disability Coverage.
- 1. An employee is eligible for long-term disability coverage if the employee is eligible for long-term disability benefits from the public entity and the employee may elect or continue coverage if the employee with long-term disability coverage and his/her spouse/child(ren) had coverage—
- A. Through MCHCP since the effective date of the last open enrollment period;
 - B. Through MCHCP since the initial date of eligibility; or
- C. Through group or individual medical coverage for the six (6) months immediately prior to becoming eligible for long-term disability benefits. Proof of prior group or individual coverage (letter from previous insurance carrier or former employer with dates of effective coverage and list of persons covered) is required.
- 2. If an enrolled, vested, long-term disability subscriber becomes ineligible for disability benefits, the long-term disability subscriber and his/her dependents will have continuous coverage as a terminated vested subscriber. If an enrolled long-term disability subscriber is not vested and becomes ineligible for disability benefits, coverage is terminated and the subscriber and his/her dependents are offered COBRA benefits. If an enrolled long-term disability subscriber becomes ineligible for disability benefits and returns to work, the subscriber is considered a new employee and must submit a form to enroll. If the employee's spouse is an active state employee or retiree, s/he may transfer coverage under the plan in which his/her spouse is enrolled. If the employee wishes to be covered individually at a later date, s/he can make the change, as long as coverage is continuous.
 - (G) Dependent Coverage. Eligible dependents include:

1. Spouse.

- A. Active Employee Coverage of a Spouse.
- (I) If both spouses have access to MCHCP benefits through two (2) different public entities, the employee and his/her spouse may elect to enroll in coverage separately through his/her respective employer or together through one (1) of the employers. The employee cannot have coverage through both public entities.
- (II) If both spouses are employed by the same public entity with access to MCHCP benefits, the employee and spouse may elect coverage either as individuals or under the spouse (if allowed by the employer).
 - B. Retiree Coverage of a Spouse.
- (I) A public entity retiree may enroll as a spouse under a public entity employee's coverage or elect coverage as a retiree.
 - 2. Children.
- A. Children may be covered through the end of the month in which they turn twenty-six (26) years old if they meet one (1) of the following criteria:
 - (I) Natural child of subscriber or spouse;
 - (II) Legally-adopted child of subscriber or spouse;
- (III) Child legally placed for adoption of subscriber or spouse;
- (IV) Stepchild of subscriber. Such child will continue to be considered a dependent after the stepchild relationship ends due to the death of the child's natural parent and subscriber's spouse;
- (V) Foster child of subscriber or spouse. Such child will continue to be considered a dependent child after the foster child relationship ends by operation of law when the child ages out if the foster child relationship between the subscriber or spouse and the child was in effect the day before the child ages out;
- (VI) Grandchild for whom the subscriber or spouse has legal guardianship or legal custody;
- (VII) A child for whom the subscriber or spouse is the court-ordered legal guardian under a guardianship of a minor. Such child will continue to be considered a dependent child after the guardianship ends by operation of law when the child becomes eighteen (18) years old if the guardianship of a minor relationship between the subscriber or spouse and the child was in effect the day before the child became eighteen (18) years old;
- (VIII) Newborn of a dependent or child of a dependent when paternity by the dependent is established after birth so long as the parent continues to be covered as a dependent of the subscriber;
- (IX) Child for whom the subscriber or spouse is required to provide coverage under a Qualified Medical Child Support Order (OMCSO): or
- (X) A child under twenty-six (26) years, who is eligible for MCHCP coverage as a subscriber, may be covered as a dependent of a public entity employee.
- B. A child who is twenty-six (26) years old or older and is permanently disabled in accordance with subsection (5)(F), may be covered only if such child was disabled the day before the child turned twenty-six (26) years old and has remained continuously disabled.
- C. A child may only be covered by one (1) parent if his/her parents are married to each other and are both covered under an MCHCP medical plan.
- D. A child may have dual coverage if the child's parents are divorced or have never married, and both have coverage under an MCHCP medical plan. MCHCP will only pay for a service once, regardless of whether the claim for the child's care is filed under multiple subscribers' coverage. If a child has coverage under two (2) subscribers, the child will have a separate deductible, copayment, and coinsurance under each subscriber. The claims administrator will process the claim and apply applicable cost-sharing using the coverage of the subscriber who files the claim first. The second claim for the same services will not be covered. If a provider files a claim simultaneously under both subscribers' coverage, the claim will be processed under the subscriber whose birthday is first in the calendar

- year. If both subscribers have the same birthday, the claim will be processed under the subscriber whose coverage has been in effect for the longest period of time; or
- 3. Changes in dependent status. If a dependent loses his/her eligibility, the subscriber must notify MCHCP within thirty one (31) days of the loss of eligibility. Coverage will end on the last day of the month that the completed form is received by MCHCP or the last day of the month MCHCP otherwise receives credible evidence of loss of eligibility under the plan.

(5) Proof of Eligibility.

- (F) Disabled dependent.
- 1. A new employee may enroll his/her permanently disabled child or an enrolled permanently disabled dependent turning age twenty-six (26) years and may continue coverage beyond age twenty-six (26) years, provided the following documentation is submitted to the plan prior to the dependent's twenty-sixth birthday for the enrolled permanently disabled dependent or within thirty-one (31) days of enrollment of a new employee and his/her permanently disabled child:
- A. Evidence that the permanently disabled dependent or child was entitled to and receiving disability benefits prior to turning age twenty-six (26) years. Evidence could be from the Social Security Administration, representation from the dependent's or child's physician, or by sworn statement from the subscriber;
- B. A letter from the dependent's or child's physician describing the current disability and verifying that the disability predates the dependent's or child's twenty-sixth birthday and the disability is permanent; and
- C. A benefit verification letter dated within the last twelve (12) months from the Social Security Administration (SSA) confirming the child is still considered disabled by SSA.
- 2. If a disabled dependent or child over the age of twenty-six (26) years is determined to be no longer disabled by the SSA, coverage will terminate the last day of the month in which the disability ends or never take effect for new enrollment requests.
- 3. Once the disabled dependent's coverage is cancelled or terminated, s/he will not be able to enroll at a later date.

(7) Termination.

- (A) Unless stated otherwise, termination of coverage shall occur on the last day of the calendar month coinciding with, or after the happening of, any of the following events, whichever shall occur first:
- 1. Failure to make any required contribution toward the cost of coverage;
 - 2. Entry into the armed forces of any country;
- 3. With respect to active employee(s) and his/her dependents, termination of employment in a position covered by the MCHCP, except as expressly specified otherwise in this rule;
- 4. With respect to dependents, upon divorce or legal separation from the subscriber or when a dependent is no longer eligible for coverage. A subscriber must terminate coverage for his/her enrolled ex-spouse and stepchild(ren) at the time his/her divorce is final;
- A. The public entity shall notify MCHCP when any of subscriber's dependents cease to be a dependent as defined in this chapter
- B. When a subscriber drops dependent coverage after a divorce, s/he must submit a completed form, a copy of the divorce decree, and current addresses of all affected dependents. Coverage ends on the last day of the month in which the divorce decree and completed form are received by MCHCP or MCHCP otherwise receives credible evidence of a final divorce that results in loss of member eligibility under the plan;
- 5. Death of dependent. The dependent's coverage ends on the date of death;
- A. The public entity shall notify MCHCP of a dependent's death;

- A member's act, practice, or omission that constitutes fraud or the member makes an intentional misrepresentation of material fact;
- 7. A member's threatening conduct or perpetrating violent acts against MCHCP or an employee of MCHCP; or
 - 8. A member otherwise loses benefit eligibility.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-3.045 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2024–2025). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan received three (3) comments on the proposed amendment.

COMMENT #1: UMR believes that MCHCP intended to remove the prior authorization requirement for procedure codes ending in "T". RESPONSE: MCHCP intended to prior authorize all procedure codes ending in "T". These are Category III procedures and many are investigational, some are not. Just as in prior years, the prior authorization should continue on these types of procedures so a proper determination can be made prior to service delivery. No changes have been made to the rule as a result of this comment.

COMMENT #2: UMR suggests an addition that states prior authorization for services outside the country are not required. UMR is not prior authorizing services from outside the country, as the providers are not contracted, and obtaining clinical information prior to services being delivered is problematic.

RESPONSE: No changes have been made as a result of this comment.

COMMENT #3: MCHCP staff commented to clarify the extent to which MCHCP will cover dental care from the direct result of cancer

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, MCHCP has clarified section (1) regarding prior authorization requirements for dental care.

22 CSR 10-3.045 Plan Utilization Review Policy

- (1) Clinical Management—Certain benefits are subject to a utilization review (UR) program. The program has the following components:
- (A) Prior Authorization of Services—The claims administrator must authorize some services in advance. Without prior authorization, any claim that requires prior authorization will be denied for payment. Members who have another primary carrier, including Medicare, are not subject to this provision except for those services that are not covered by the other primary carrier, but are otherwise subject to prior authorization under this rule. Prior authorization does not verify eligibility or payment. Prior authorizations found to have a material misrepresentation or intentional or negligent omis-

sion about the person's health condition or the cause of the condition may be rescinded.

- 1. The following medical services are subject to prior authoriza-
- A. Ambulance services for non-emergent use, whether air or ground;
- B. Anesthesia and hospital charges for dental care for children younger than five (5) years, the severely disabled, or a person with a medical or behavioral condition that requires hospitalization;
 - C. Applied behavior analysis for autism at initial service;
 - D. Auditory brainstem implant (ABI);
 - E. Bariatric surgery;
- F. Cardiac rehabilitation after thirty-six (36) visits within a twelve- (12-) week period;
 - G. Chiropractic services after twenty-six (26) visits annually;
 - H. Cochlear implant device;
 - I. Chelation therapy;
 - J. Dental care;
- K. Durable medical equipment (DME) over one thousand five hundred dollars (\$1,500) or DME rentals over five hundred dollars (\$500) per month;
 - L. Genetic testing or counseling;
 - M. Hearing Aids;
 - N. Home health care;
 - O. Hospice care and palliative services;
 - P. Hospital inpatient services;
- Q. Imaging (diagnostic non-emergent outpatient), including magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), positron emission tomography (PET), computerized tomography scan (CT), computerized tomography angiography (CTA), electron-beam computed tomography (EBCT), and nuclear cardiology;
- R. Maternity coverage for maternity hospital stays longer than forty-eight (48) hours for vaginal delivery or ninety-six (96) hours for cesarean delivery;
 - S. Nutritional counseling after six (6) sessions annually;
 - T. Orthognathic surgery;
 - U. Orthotics over one thousand dollars (\$1,000);
- V. Physical, speech, and occupational therapy and rehabilitation services (outpatient) after sixty (60) combined visits per incident:
- W. Procedures with procedure codes ending in "T" (temporary procedure codes used for data collection, experimental, investigational, or unproven procedures);
 - X. Prostheses over one thousand dollars (\$1,000);
- Y. Pulmonary rehabilitation after thirty-six (36) visits within a twelve- (12-) week period;
 - Z. Skilled nursing facility;
- AA. Surgery (outpatient)—The following outpatient surgical procedures: cornea transplant, potential cosmetic surgery, sleep apnea surgery, implantable stimulators, stimulators for bone growth, spinal surgery (including, but not limited to, artificial disc replacement, fusions, nonpulsed radiofrequency denervation, vertebroplasty, kyphoplasty, spinal cord stimulator trials, spinal cord stimulator implantation, and any unlisted spinal procedure), and oral surgery (excisions of tumors and cysts of the jaw, cheeks, lips, tongue, roof, and floor of the mouth when such conditions require pathological exams); and
- BB. Transplants, including requests related to covered travel and lodging.
- 2. The following pharmacy services included in the prescription drug plan for non-Medicare primary members are subject to prior authorization:
- A. Second-step therapy medications that skip the first-step medication trial;
 - B. Specialty medications;
- C. Medications that may be prescribed for several conditions, including some for which treatment is not medically necessary;

- D. Medication refill requests that are before the time allowed for refill;
- E. Medications that exceed drug quantity and day supply limitations;
- F. Medications with costs exceeding nine thousand nine hundred ninety-nine dollars and ninety-nine cents (\$9,999.99) at retail or the mail order pharmacy and one hundred forty-nine dollars and ninety-nine cents (\$149.99) for compound medications at retail or the mail order pharmacy; and
 - 3. Prior authorization timeframes.
- A. A benefit determination for non-urgent prior authorization requests will be made within fifteen (15) calendar days of the receipt of the request. The fifteen (15) days may be extended by the claims administrator for up to fifteen (15) calendar days if an extension is needed as a result of matters beyond the claims administrator's control. The claims administrator will notify the member of any necessary extension prior to the expiration of the initial fifteen- (15-) calendar-day period. If a member fails to submit necessary information to make a benefit determination, the member will be given at least ninety (90) calendar days from receipt of the extension notice to respond with additional information.
- B. A benefit determination for urgent prior authorization requests will be made as soon as possible based on the clinical situation, but in no case later than twenty-four (24) hours of the receipt of the request;

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-3.053 PPO 1000 Plan Benefit Provisions and Covered Charges **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2025–2026). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment.

COMMENT #1: UMR commented that the language regarding prior authorization requirements provided for in 22 CSR 10-3.045 regarding services received while out of the country should be removed.

RESPONSE: No changes have been made as a result of this comment.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, and section 103.080.3, RSMo Supp. 2014, the executive director amends a rule as follows:

22 CSR 10-3.055 Health Savings Account Plan Benefit Provisions and Covered Charges is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2026–2027). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment

COMMENT #1: UMR commented that the language regarding prior authorization requirements provided for in 22 CSR 10-3.045 regarding services received while out of the country should be removed. RESPONSE: No changes have been made as a result of this comment

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-3.056 PPO 600 Plan Benefit Provisions and Covered Charges is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2027–2028). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment.

COMMENT #1: UMR commented that the language regarding prior authorization requirements provided for in 22 CSR 10-3.045 regarding services received while out of the country should be removed. RESPONSE: No changes have been made as a result of this comment.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-3.057 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1,

2014 (39 MoReg 2028–2038). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received eight (8) comments on the proposed amendment.

COMMENT #1: UMR and MCHCP staff both commented that the transition of care language in section (2) be reviewed to ensure it is in alignment with section 354.612, RSMo.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, the amended language has been removed to ensure alignment with section 354.612, RSMo.

COMMENT #2: MCHCP staff commented to clarify the extent to which MCHCP will cover dental care from the direct result of cancer.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, MCHCP has amended paragraph (3)(E)12., to clarify dental care coverage.

COMMENT #3: Ron Fitzwater, with the Missouri Pharmacy Association, commented to ensure pharmacists are included in the definition of certified Diabetes Educator stating this type of patient counseling is permitted under their scope of practice and has yielded results in the MO HealthNet program.

RESPONSE AND EXPLANATION OF CHANGE: Diabetes Education is covered by a certified diabetic educator when provided through the medical network provider. A pharmacist would be included as a certified diabetic educator if s/he has that credential. Language has been added to clarify the service must be provided through a medical network provider.

COMMENT #4: Scott George, B.S., BC-HIS, with the Mid-America Hearing Center and Robert Guison, with the Missouri Hearing Society, both commented the comprehensive exam in part (3)(E)22.A.(I) should be replaced with a preliminary exam.

RESPONSE AND EXPLANATION OF CHANGE: Language has been added to reflect that prior to receiving a hearing aid a member must have a medical exam as recommended by the Food and Drug Administration (FDA). The purpose of the medical exam is to assure that all medically treatable conditions that may affect hearing are identified and treated before a hearing aid is provided.

COMMENT #5: Scott George, B.S., BC-HIS, with the Mid-America Hearing Center and Robert Guison, with the Missouri Hearing Society, both commented that part (3)(E)22.A.(II), requires a "comprehensive hearing test to assess the need for hearing aids". This aligns with HCPCS codes V5010 and is appropriate for an evaluation that was performed for the primary purpose of selecting appropriate hearing aid amplification. The comprehensive hearing assessment includes air, bone, speech reception threshold, and speech recognition/speech understanding/word recognition testing, with masking where appropriate. Hearing health care practice protocols require that such testing be done using an audiometer.

RESPONSE AND EXPLANATION OF CHANGE: Language has been added to reflect that prior to receiving a hearing aid a member must have a medical exam as recommended by the FDA. The purpose of the medical exam is to assure that all medically treatable conditions that may affect hearing are identified and treated before a hearing aid is provided.

COMMENT #6: Scott George, B.S., BC-HIS, with the Mid-America Hearing Center and Robert Guison with the Missouri Hearing Society both commented with the suggestion that "hearing instrument specialists" be added to the list of providers licensed to perform a comprehensive hearing test.

RESPONSE AND EXPLANATION OF CHANGE: MCHCP has amended language as requested.

COMMENT #7: Scott George, B.S., BC-HIS, with the Mid-America Hearing Center, commented that while everything listed in these rules is in the scope of practice for audiologist and hearing instruments specialists, ASHA (the national association for speech-language pathologists) makes a specific point that only hearing screenings are in their scope of practice. They suggested MCHCP might want to check with the Missouri association (MSHA) regarding rule changes.

RESPONSE AND EXPLANATION OF CHANGE: MCHCP has amended language to reflect this comment.

COMMENT #8: UMR commented that part (3)(E)26.A.(IV) should be clarified to state that inpatient treatment in a network hospital or facility by a non-network provider is covered at the network benefit. RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, part (3)(E)26.A.(IV) has been clarified to specify that inpatient treatment in a network hospital or facility by a non-network provider is covered at the network benefit.

22 CSR 10-3.057 Medical Plan Benefit Provisions and Covered Charges

- (2) Transition of Care. A transition of care option is available for members using a hospital or dialysis facility that loses network status during the plan year. A subscriber and his/her dependents using a hospital or dialysis facility that loses network status during the plan year may apply for a ninety- (90-) day transition of care to continue receiving network benefits with that hospital or dialysis facility. The request for consideration must be submitted to the medical plan within forty-five (45) days of the last day the hospital or dialysis facility was a contracted network provider to be eligible for transition of care benefits. A subscriber and his/her dependents may apply for additional days beyond the ninety- (90-) day transition if care is related to a moderate or high risk pregnancy, if care is during a member's second or third trimester of pregnancy, or up to eight (8) weeks postpartum. The subscriber and his/her dependents must apply for additional transition of care days prior to the end of the initial ninety- (90-) day transition of care period. Most routine services, treatment for stable conditions, minor illnesses, and elective surgeries will not be covered by transition of care benefits. The rate of payment during the transitional period shall be the same fee as paid prior to leaving the network. Benefits eligible for transition of care include:
- (3) Covered Charges Applicable to the PPO 600 Plan, PPO 1000, and HSA Plan.
- (E) Plan benefits for the PPO 600 Plan, PPO 1000, and HSA Plan are as follows:
- 1. Allergy Testing and Immunotherapy. No coverage for no provider allergy services or associated expenses relating to an allergic condition, including installation of air filters, air purifiers, or air ventilation system cleaning. Allergy testing and allergy immunotherapy are considered medically necessary for members with clinically significant allergic symptoms. The following tests and treatments are covered:
- A. Epicutaneous (scratch, prick, or puncture) when Immunoglobulan E- (IgE-) mediated reactions occur to any of the following:
 - (I) Foods:
 - (II) Hymenoptera venom (stinging insects);
 - (III) Inhalants; or
- (IV) Specific drugs (penicillins and macromolecular agents);
- B. Intradermal (Intracutaneous) when IgE-mediated reactions occur to any of the following:
 - (I) Foods:

- (II) Hymenoptera venom (stinging insects);
- (III) Inhalants; or
- (IV) Specific drugs (penicillins and macromolecular agents);
- C. Skin or Serial Endpoint Titration (SET), also known as intradermal dilutional testing (IDT), for determining the starting dose for immunotherapy for members highly allergic to any of the following:
 - (I) Hymenoptera venom (stinging insects); or
 - (II) Inhalants;
- D. Skin Patch Testing: for diagnosing contact allergic dermatitis;
- E. Photo Patch Testing: for diagnosing photo-allergy (such as photo-allergic contact dermatitis);
 - F. Photo Tests: for evaluating photo-sensitivity disorders;
- G. Bronchial Challenge Test: for testing with methacholine, histamine, or antigens in defining asthma or airway hyperactivity when either of the following conditions is met:
- (I) Bronchial challenge test is being used to identify new allergens for which skin or blood testing has not been validated; or
 - (II) Skin testing is unreliable;
- H. Exercise Challenge Testing for exercise-induced bronchospasm;
 - I. Ingestion (Oral) Challenge Test for any of the following:
 - (I) Food or other substances; or
 - (II) Drugs when all of the following are met:
 - (a) History of allergy to a particular drug;
 - (b) There is no effective alternative drug; and
 - (c) Treatment with that drug class is essential;
- J. In Vitro IgE Antibody Tests (RAST, MAST, FAST, ELISA, ImmunoCAP) are covered for any of the following:
- (I) Allergic broncho-pulmonary aspergillosis (ABPA) and certain parasitic diseases;
 - (II) Food allergy;
 - (III) Hymenoptera venom allergy (stinging insects);
 - (IV) Inhalant allergy; or
 - (V) Specific drugs;
- K. Total Serum IgE for diagnostic evaluation in members with known or suspected ABPA and/or hyper IgE syndrome;
- L. Lymphocyte transformation tests such as lymphocyte mitogen response test, PHE stimulation test, or lymphocyte antigen response assay are covered for evaluation of persons with any of the following suspected conditions:
 - (I) Sensitivity to beryllium;
- (II) Congenital or acquired immunodeficiency diseases affecting cell-mediated immunity, such as severe combined immunodeficiency, common variable immunodeficiency, X-linked immunodeficiency with hyper IgM, Nijmegen breakage syndrome, reticular dysgenesis, DiGeorge syndrome, Nezelof syndrome, Wiscott-Aldrich syndrome, ataxia telangiectasia, and chronic mucocutaneous candidiasis;
 - (III) Thymoma; and
- (IV) To predict allograft compatibility in the transplant setting;
- M. Allergy Re-testing: routine allergy re-testing is not considered medically necessary;
- N. Allergy immunotherapy is covered for the treatment of any of the following IgE-mediated allergies:
 - (I) Allergic (extrinsic) asthma;
 - (II) Dust mite atopic dermatitis;
- (III) Hymenoptera (bees, hornets, wasps, fire ants) sensitive individuals;
 - (IV) Mold-induced allergic rhinitis;
 - (V) Perennial rhinitis;
- (VI) Seasonal allergic rhinitis or conjunctivitis when one (1) of the following conditions are met:
- (a) Member has symptoms of allergic rhinitis or asthma after natural exposure to the allergen;

- (b) Member has a life-threatening allergy to insect stings; or
- (c) Member has skin test or serologic evidence of IgE mediated antibody to a potent extract of the allergen; and
- (VII) Avoidance or pharmacologic therapy cannot control allergic symptoms or member has unacceptable side effects with pharmacologic therapy;
- O. Other treatments: the following other treatments are covered:
- (I) Rapid, rush, cluster, or acute desensitization for members with any of the following conditions:
- (a) IgE antibodies to a particular drug that cannot be treated effectively with alternative medications;
- (b) Insect sting (e.g., wasps, hornets, bees, fire ants) hypersensitivity (hymenoptera); or
- (c) Members with moderate to severe allergic rhinitis who need treatment during or immediately before the season of the affecting allergy;
- (II) Rapid desensitization is considered experimental and investigational for other indications;
- P. Epinephrine kits, Ana-Kit, and Epi-Pen kits to prevent anaphylactic shock for members who have had life-threatening reactions to insect stings, foods, drugs, or other allergens; have severe asthma or if needed during immunotherapy;
- 2. Ambulance service. The following ambulance transport services are covered:
- A. By ground to the nearest appropriate facility when other means of transportation would be contraindicated;
- B. By air to the nearest appropriate facility when the member's medical condition is such that transportation by either basic or advanced life support ground ambulance is not appropriate or contraindicated;
- 3. Applied Behavior Analysis (ABA) for Autism is covered for children younger than age nineteen (19) years;
- 4. Bariatric surgery. Bariatric surgery is covered when all of the following requirements have been met:
- A. The surgery is performed at a facility accredited by one (1) of the following accreditation programs:
- (I) American College of Surgeons Bariatric Surgery Center Network (ACS BSCN);
- (II) American Society for Metabolic and Bariatric Surgery Bariatric Surgery Centers of Excellence (ASMBS BSCOE); or
- (III) Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP);
- B. The following open or laparoscopic bariatric surgery procedures are covered:
 - (I) Roux-en-Y gastric bypass;
 - (II) Sleeve gastrectomy;
- (III) Biliopancreatic diversion with duodenal switch for individuals with a body mass index (BMI) greater than fifty (50);
- (IV) Adjustable silicone gastric banding and adjustments of a silicone gastric banding to control the rate of weight loss and/or treat symptoms secondary to gastric restriction following an adjustable silicone gastric banding procedure;
- (V) Surgical reversal of bariatric surgery when complications of the original surgery (e.g., stricture, pouch dilatation, erosion, or band slippage) cause abdominal pain, inability to eat or drink, or cause vomiting of prescribed meals;
- (VI) Revision of a previous bariatric surgical procedure or conversion to another procedure due to inadequate weight loss when one (1) of the following specific criteria has been met:
- (a) There is evidence of full compliance with the previously prescribed post-operative dietary and exercise program; or
- (b) There is documented clinical testing demonstrating technical failure of the original bariatric surgical procedure which caused the individual to fail achieving adequate weight loss of at least fifty percent (50%) of excess body weight or failure to achieve body

weight to within thirty percent (30%) of ideal body weight at least two (2) years following the original surgery;

- C. All of the following criteria have been met:
- (I) The member is eighteen (18) years or older or has reached full skeletal growth, and has evidence of one (1) of the following:
 - (a) BMI greater than forty (40); or
- (b) BMI between thirty-five (35) and thirty-nine and nine tenths (39.9) and one (1) or more of the following:
 - I. Type II diabetes;
- II. Cardiovascular disease such as stroke, myocardial infarction, stable or unstable angina pectoris, hypertension, or coronary artery bypass; or
- III. Life-threatening cardiopulmonary problems such as severe sleep apnea, Pickwickian syndrome, or obesity-related cardiomyopathy; and
- (II) Demonstration that dietary attempts at weight control have been ineffective through completion of a structured diet program. Commercial weight loss programs are acceptable if completed under the direction of a provider or registered dietitian and documentation of participation is available for review. One (1) structured diet program for six (6) consecutive months or two (2) structured diet programs for three (3) consecutive months each within a two- (2-) year period prior to the request for the surgical treatment of morbid obesity are sufficient. Provider-supervised programs consisting exclusively of pharmacological management are not sufficient; and
- (III) A thorough multidisciplinary evaluation within the previous twelve (12) months, which include all of the following:
- (a) An evaluation by a bariatric surgeon recommending surgical treatment, including a description of the proposed procedure and all of the associated current procedural terminology codes;
- (b) A separate medical evaluation from a provider other than the surgeon recommending surgery that includes a medical clearance for bariatric surgery;
- (c) Completion of a psychological examination from a mental health provider evaluating the member's readiness and fitness for surgery and the necessary post-operative lifestyle changes. After the evaluation, the mental health provider must provide clearance for bariatric surgery; and
- (d) A nutritional evaluation by a provider or registered dietitian;
- 5. Contraception and Sterilization. All Food and Drug Administration- (FDA-) approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity. The following contraceptive devices and injections are covered when administered in a provider's office:
 - A. Available under the medical plan only—
 - (I) Tubal ligation;
 - B. Available under the prescription or medical plan—
 - (I) Cervical cap;
 - (II) Diaphragm;
 - (III) Implants, such as an intrauterine device (IUD);
 - (IV) Injection; and
 - (V) Vaginal ring;
- 6. Blood storage. Storage of whole blood, blood plasma, and blood products is covered in conjunction with medical treatment that requires immediate blood transfusion support;
- 7. Cardiac rehabilitation. An electrocardiographically-monitored program of outpatient cardiac rehabilitation (Phase II) is covered for specific criteria when it is individually prescribed by a provider and a formal exercise stress test is completed following the event and prior to the initiation of the program. Cardiac rehabilitation is covered for members who meet one (1) of the following criteria:
- A. Acute myocardial infarction (MI) (heart attack in the last twelve (12) months);
 - B. Coronary artery bypass grafting (CABG);
 - C. Stable angina pectoris;
 - D. Percutaneous coronary vessel remodeling;

- E. Valve replacement or repair;
- F. Heart transplant;
- G. Coronary artery disease (CAD) associated with chronic stable angina that has failed to respond adequately to pharmacotherapy and is interfering with the ability to perform age-related activities of daily living and/or impairing functional abilities; or
- H. Heart failure that has failed to respond adequately to pharmacotherapy and is interfering with the ability to perform age-related activities of daily living and/or impairing functional abilities;
- 8. Chelation therapy. The administration of FDA-approved chelating agents is covered for any of the following conditions:
 - A. Genetic or hereditary hemochromatosis;
- B. Lead overload in cases of acute or long-term lead exposure:
- C. Secondary hemochromatosis due to chronic iron overload due to transfusion-dependent anemias (e.g., Thalassemias, Cooley's anemia, sickle cell anemia, sideroblastic anemia);
 - D. Copper overload in patients with Wilson's disease;
- E. Arsenic, mercury, iron, copper, or gold poisoning when long-term exposure to and toxicity has been confirmed through lab results or clinical findings consistent with metal toxicity;
 - F. Aluminum overload in chronic hemodialysis patients;
 - G. Emergency treatment of hypercalcemia;
 - H. Prophylaxis against doxorubicin-induced cardiomyopathy;
 - I. Internal plutonium, americium, or curium contamination;
 - J. Cystinuria;

or

- 9. Chiropractic services. Chiropractic manipulation and adjunct therapeutic procedures/modalities (e.g., mobilization, therapeutic exercise, traction) are covered when all of the following conditions are met:
- A. A neuromusculoskeletal condition is diagnosed that maybe relieved by standard chiropractic treatment in order to restore optimal function;
- B. Chiropractic care is being performed by a licensed doctor of chiropractic who is practicing within the scope of his/her license as defined by state law;
- C. The individual is involved in a treatment program that clearly documents all of the following:
- (I) A prescribed treatment program that is expected to result in significant therapeutic improvement over a clearly defined period of time;
 - (II) The symptoms being treated;
 - (III) Diagnostic procedures and results;
- (IV) Frequency, duration, and results of planned treatment modalities;
- (V) Anticipated length of treatment plan with identification of quantifiable, attainable short-term and long-term goals; and
- (VI) Demonstrated progress toward significant functional gains and/or improved activity tolerances;
- D. Following previous successful treatment with chiropractic care, acute exacerbation or re-injury are covered when all of the following criteria are met:
- (I) The member reached maximal therapeutic benefit with prior chiropractic treatment;
- (II) The member was compliant with a self-directed home-care program;
- (III) Significant therapeutic improvement is expected with continued treatment; and
- (IV) The anticipated length of treatment is expected to be short-term (e.g., no more than six (6) visits within a three- (3-) week period);
- 10. Clinical trials. Routine member care costs incurred as the result of a Phase I, II, III, or IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition are covered when—
- A. The study or investigation is conducted under an investigational new drug application reviewed by the FDA; or

- B. Is a drug trial that is exempt from having such an investigational new drug application. Life-threatening condition means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted; and
- C. Routine member care costs include all items and services consistent with the coverage provided in plan benefits that would otherwise be covered for a member not enrolled in a clinical trial. Routine patient care costs do not include the investigational item, device, or service itself; items and services that are provided solely to satisfy data collection and analysis needs and are not used in the direct clinical management of the member; or a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis;
- D. The member must be eligible to participate in the clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition; and
- E. The clinical trial must be approved or funded by one (1) of the following:
 - (I) National Institutes of Health (NIH);
 - (II) Centers for Disease Control and Prevention (CDC);
 - (III) Agency for Health Care Research and Quality;
 - (IV) Centers for Medicare & Medicaid Services (CMS);
- (V) A cooperative group or center of any of the previously named agencies or the Department of Defense or the Department of Veterans Affairs;
- (VI) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants; or
- (VII) A study or investigation that is conducted by the Department of Veterans Affairs, the Department of Defense, or the Department of Energy and has been reviewed and approved to be comparable to the system of peer review of studies and investigations used by the NIH and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review;
- 11. Cochlear implant device. Uniaural (monaural) or binaural (bilateral) cochlear implantation and necessary replacement batteries are covered for a member with bilateral, pre- or post-linguistic, sensorineural, moderate-to-profound hearing impairment when there is reasonable expectation that a significant benefit will be achieved from the device and when the following age-specific criteria are met:
- A. Auditory brainstem implant. Auditory brainstem implant (ABI) covered for the diagnosis of neurofibromatosis type II, von Recklinghausen's disease, or when a member is undergoing bilateral removal of tumors of the auditory nerves, and it is anticipated that the member will become completely deaf as a result of the surgery, or the member had bilateral auditory nerve tumors removed and is now bilaterally deaf;
- (I) For an adult (age eighteen (18) years or older) with BOTH of the following:
- (a) Bilateral, severe to profound sensorineural hearing loss determined by a pure-tone average of seventy (70) decibels (dB) hearing loss or greater at five hundred (500) hertz (Hz), one thousand (1000) Hz and two thousand (2000) Hz; and
- (b) Member has limited benefit from appropriately fitted binaural hearing aids. Limited benefit from amplification is defined by test scores of forty percent (40%) correct or less in best-aided listening condition on open-set sentence cognition (e.g., Central Institute for the Deaf (CID) sentences, Hearing in Noise Test (HINT) sentences, and Consonant-Nucleus-Consonant (CNC) test);
- (II) For a child age twelve (12) months to seventeen (17) years, eleven (11) months with both of the following:
- (a) Profound, bilateral sensorineural hearing loss with thresholds of ninety (90) dB or greater at one thousand (1000) Hz; and
- (b) Limited or no benefit from a three- (3-) month trial of appropriately fitted binaural hearing aids;

- (III) For children four (4) years of age or younger, with one (1) of the following:
- (a) Failure to reach developmentally appropriate auditory milestones measured using the Infant-Toddler Meaningful Auditory Integration Scale, the Meaningful Auditory Integration Scale, or the Early Speech Perception test; or
- (b) Less than twenty percent (20%) correct on open-set word recognition test Multisyllabic Lexical Neighborhood Test (MLNT) in conjunction with appropriate amplification and participation in intensive aural habilitation over a three- (3-) to six- (6-) month period;
- (IV) For children older than four (4) years of age with one (1) of the following:
- (a) Less than twelve percent (12%) correct on the Phonetically Balanced-Kindergarten Test; or
- (b) Less than thirty percent (30%) correct on the HINT for children, the open-set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending on the child's cognitive ability and linguistic skills; and
- (V) A three- (3-) to six- (6-) month hearing aid trial has been undertaken by a child without previous experience with hearing aids:
 - B. Radiologic evidence of cochlear ossification;
- C. The following additional medical necessity criteria must also be met for uniaural (monaural) or binaural (bilateral) cochlear implantation in adults and children:
- (I) Member must be enrolled in an educational program that supports listening and speaking with aided hearing;
- (II) Member must have had an assessment by an audiologist and from an otolaryngologist experienced in this procedure indicating the likelihood of success with this device;
- (III) Member must have no medical contraindications to cochlear implantation (e.g., cochlear aplasia, active middle ear infection); and
- (IV) Member must have arrangements for appropriate follow-up care, including the speech therapy required to take full advantage of this device;
- D. A second cochlear implant is covered in the contralateral (opposite) ear as medically necessary in an individual with an existing unilateral cochlear implant when the hearing aid in the contralateral ear produces limited or no benefit;
- E. The replacement of an existing cochlear implant is covered when either of the following criteria is met:
- (I) Currently used component is no longer functional and cannot be repaired; or
- (II) Currently used component renders the implant recipient unable to adequately and/or safely perform his/her age-appropriate activities of daily living; and
- F. Post-cochlear or ABI rehabilitation program (aural rehabilitation) is covered to achieve benefit from a covered device;
 - 12. Dental care.
- A. Dental care is covered for treatment of trauma to the mouth, jaw, teeth, or contiguous sites, as a result of accidental injury;
- (I) Treatment to reduce trauma and restorative services limited to dental implants only when the result of accidental injury to sound natural teeth and tissue that are viable, functional, and free of disease; and
- (II) Restorative services limited to dental implants when needed as a result of cancerous or non-cancerous tumors and cysts, cancer and post-surgical sequelae; and
- B. The administration of general anesthesia, monitored anesthesia care, and hospital charges for dental care are covered for children younger than five (5) years, the severely disabled, or a person with a medical or behavioral condition that requires hospitalization when provided in a network or non-network hospital or surgical center;

- 13. Diabetic Education when prescribed by a provider and taught by a Certified Diabetes Educator through a medical network provider;
- 14. Durable medical equipment (DME) is covered when ordered by a provider to treat an injury or illness. DME includes, but is not limited to, the following:
 - A. Insulin pumps;
 - B. Oxygen;
 - C. Augmentative communication devices;
 - D. Manual and powered mobility devices;
- E. Disposable supplies that do not withstand prolonged use and are periodically replaced, including, but not limited to, the following:
 - (I) Colostomy and ureterostomy bags;
- (II) Prescription compression stockings limited to two (2) pairs or four (4) individual stockings per plan year;
- F. Non-reusable disposable supplies, including, but not limited to:
 - (I) Bandages;
 - (II) Wraps;
 - (III) Tape;
 - (IV) Disposable sheets and bags;
 - (V) Fabric supports;
 - (VI) Surgical face masks;
 - (VII) Incontinence pads;
 - (VIII) Irrigating kits;
 - (IX) Pressure leotards: and
- (X) Surgical leggings and support hose, over-the-counter medications and supplies, including oral appliances, are not covered;
- G. Repair and replacement of DME is covered when any of the following criteria are met:
- (I) Repairs, including the replacement of essential accessories, which are necessary to make the item or device serviceable;
- (II) Routine wear and tear of the equipment renders it nonfunctional and the member still requires the equipment; or
- (III) The provider has documented that the condition of the member changes or if growth-related;
- 15. Emergency room services. Coverage is for emergency medical conditions. If a member is admitted to the hospital, s/he may be required to transfer to network facility for maximum benefit. Hospital and ancillary charges are paid as a network benefit;
- 16. Eye glasses and contact lenses. Coverage limited to charges incurred in connection with the fitting of eye glasses or contact lenses for initial placement immediately following cataract surgery;
- 17. Foot care (trimming of nails, corns, or calluses). Foot care is considered routine in nature and not covered in the absence of systemic disease that has resulted in severe circulatory insufficiency or areas of desensitization in the lower extremities. Foot care services are covered when administered by a provider and—
- A. When associated with systemic conditions that are significant enough to result in severe circulatory insufficiency or areas of desensitization in the lower extremities including, but not limited to, any of the following:
 - (I) Diabetes mellitus;
 - (II) Peripheral vascular disease; or
 - (III) Peripheral neuropathy.
- (IV) Evaluation/debridement of mycotic nails, in the absence of a systemic condition, when both of the following conditions are met:
- (a) Pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate; and
- (b) If the member is ambulatory, pain markedly limits ambulation;
- 18. Genetic counseling. Pre-test and post-test genetic counseling with a provider or a licensed or certified genetic counselor are covered when a member is recommended for covered heritable genetic testing.

- A. Genetic counseling in connection with pregnancy management is covered only for evaluation of any of the following:
- (I) Couples who are closely related genetically (e.g., consanguinity, incest);
 - (II) Familial cancer disorders;
- (III) Individuals from ethnic groups recognized to be at increased risk for specific genetic disorders (e.g., African Americans for sickle cell anemia, Ashkenazi (eastern European) Jews for Tay-Sachs disease):
- (IV) Infertility cases where either parent is known to have a chromosomal abnormality;
- (V) Primary amenorrhea, azospermia, abnormal sexual development, or failure in developing secondary sexual characteristics;
- (VI) Mother is a known, or presumed carrier of an X linked recessive disorder;
- (VII) One (1) or both parents are known carriers of an autosomal recessive disorder;
- (VIII) Parents of a child born with a genetic disorder, birth defect, inborn error of metabolism, or chromosome abnormality;
- (IX) Parents of a child with mental retardation, autism, developmental delays, or learning disabilities;
- (X) Pregnant women who, based on prenatal ultrasound tests or an abnormal multiple marker screening test, maternal serum alpha-fetoprotein (AFP) test, test for sickle cell anemia, or tests for other genetic abnormalities have been told their pregnancy may be at increased risk for complications or birth defects;
- (XI) Pregnant women age thirty-five (35) years or older at delivery;
- (XII) Pregnant women, or women planning pregnancy, exposed to potentially teratogenic, mutagenic, or carcinogenic agents such as chemicals, drugs, infections, or radiation;
- (XIII) Previous unexplained stillbirth or repeated (three (3) or more; two (2) or more among infertile couples) first-trimester miscarriages, where there is suspicion of parental or fetal chromosome abnormalities: or
- (XIV) When contemplating pregnancy, either parent affected with an autosomal dominant disorder;
- 19. Genetic testing. No coverage for testing based on family history alone, except for testing for the breast cancer susceptibility gene (BRCA). Genetic testing is covered to establish a molecular diagnosis of an inheritable disease when all of the following criteria are met:
- A. The member displays clinical features or is at direct risk of inheriting the mutation in question (pre-symptomatic);
- B. The result of the test will directly impact the treatment being delivered to the member;
- C. The testing method is considered scientifically valid for identification of a genetically-linked heritable disease; and
- D. After history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, a definitive diagnosis remains uncertain;
- 20. Hair analysis. Chemical hair analysis is covered for the diagnosis of suspected chronic arsenic poisoning. Other purposes are considered experimental and investigational;
- 21. Hair prostheses. Prostheses and expenses for scalp hair prostheses worn for hair loss are covered for alopecia areata or alopecia totalis for children eighteen (18) years of age or younger. The annual maximum is two hundred dollars (\$200), and the lifetime maximum is three thousand two hundred dollars (\$3,200);
- 22. Hearing aids (per ear). Hearing aids covered for conductive hearing loss unresponsive to medical or surgical interventions, sensorineural hearing loss, and mixed hearing loss.
 - A. Prior to receiving a hearing aid members must receive—
- (I) A comprehensive medical exam by a physician or other qualified provider to identify any medically treatable conditions that may affect hearing; and
- (II) A comprehensive hearing test to assess the need for hearing aids conducted by a certified audiologist, hearing instrument

specialist, or other provider licensed or certified to administer this test

- B. Covered once every two (2) years. If the cost of one (1) hearing aid exceeds the amount listed below, member is also responsible for charges over that amount.
 - (I) Conventional: one thousand dollars (\$1,000).
 - (II) Programmable: two thousand dollars (\$2,000).
 - (III) Digital: two thousand five hundred dollars (\$2,500).
- (IV) Bone Anchoring Hearing Aid (BAHA): three thousand five hundred dollars (\$3,500);
- 23. Hearing testing. One (1) hearing test per year. Additional hearing tests are covered if recommended by provider;
- 24. Home health care. Skilled home health nursing care is covered for members who are homebound because of injury or illness (i.e., the member leaves home only with considerable and taxing effort, and absences from home are infrequent or of short duration, or to receive medical care). Services must be performed by a registered nurse or licensed practical nurse, licensed therapist, or a registered dietitian. Covered services include:
- A. Home visits instead of visits to the provider's office that do not exceed the usual and customary charge to perform the same service in a provider's office;
- B. Intermittent nurse services. Benefits are paid for only one (1) nurse at any one (1) time, not to exceed four (4) hours per twenty-four- (24-) hour period;
- C. Nutrition counseling provided by, or under the supervision of, a registered dietitian;
- D. Physical, occupational, respiratory, and speech therapy provided by, or under the supervision of, a licensed therapist;
- E. Medical supplies, drugs or medication prescribed by provider, and laboratory services to the extent that the plan would have covered them under this plan if the covered person had been in a hospital;
 - F. A home health care visit is defined as—
- (I) A visit by a nurse providing intermittent nurse services (each visit includes up to a four- (4-) hour consecutive visit in a twenty-four- (24-) hour period if clinical eligibility for coverage is met) or a single visit by a therapist or a registered dietitian; and
 - G. Benefits cannot be provided for any of the following:
 - (I) Homemaker or housekeeping services;
- (II) Supportive environment materials such as handrails, ramps, air conditioners, and telephones;
- (III) Services performed by family members or volunteer workers;
 - (IV) "Meals on Wheels" or similar food service;
- (V) Separate charges for records, reports, or transportation:
- (VI) Expenses for the normal necessities of living such as food, clothing, and household supplies; and
- (VII) Legal and financial counseling services, unless otherwise covered under this plan;
- 25. Hospice care and palliative services (inpatient or outpatient). Includes bereavement and respite care. Hospice care services, including pre-hospice evaluation or consultation, are covered when the individual is terminally ill and expected to live six (6) months or less, potentially curative treatment for the terminal illness is not part of the prescribed plan of care, the individual or appointed designee has formally consented to hospice care (i.e., care directed mostly toward palliative care and symptom management), and the hospice services are provided by a certified/accredited hospice agency with care available twenty-four (24) hours per day, seven (7) days per week.
- A. When the above criteria are met, the following hospice care services are covered:
- (I) Assessment of the medical and social needs of the terminally ill person, and a description of the care to meet those needs;
- (II) Inpatient care in a facility when needed for pain control and other acute and chronic symptom management, psychological

and dietary counseling, physical or occupational therapy, and parttime home health care services;

- (III) Outpatient care for other services as related to the terminal illness, which include services of a physician, physical or occupational therapy, and nutrition counseling provided by, or under the supervision of, a registered dietitian; and
- (IV) Bereavement counseling benefits which are received by a member's close relative when directly connected to the member's death and bundled with other hospice charges. The services must be furnished within six (6) months of death;
- 26. Hospital (includes inpatient, outpatient, and surgical centers).
 - A. The following benefits are covered:
- (I) Semi-private room and board. For network charges, this rate is based on network repricing. For non-network charges, any charge over a semi-private room charge will be a covered expense only when clinical eligibility for coverage is met. If the hospital has no semi-private rooms, the plan will allow the private room rate subject to usual, customary, and reasonable charges or the network rate, whichever is applicable;
 - (II) Intensive care unit room and board;
- (III) Surgery, therapies, and ancillary services including, but not limited to:
 - (a) Cornea transplant;
- (b) Coverage for breast reconstruction surgery or prostheses following mastectomy and lumpectomy is available to both females and males. A diagnosis of breast cancer is not required for breast reconstruction services to be covered, and the timing of reconstructive services is not a factor in coverage;
- (c) Sterilization for the purpose of birth control is covered:
- (d) Cosmetic/reconstructive surgery is covered to repair a functional disorder caused by disease or injury;
- (e) Cosmetic/reconstructive surgery is covered to repair a congenital defect or abnormality for a member younger than nineteen (19) years; and
- (f) Blood, blood plasma, and plasma expanders are covered, when not available without charge;
- (IV) Inpatient mental health services are covered when authorized by a physician for treatment of a mental health disorder. Inpatient mental health services are covered, subject to all of the following:
- (a) Member must be ill in more than one (1) area of daily living to such an extent that s/he is rendered dysfunctional and requires the intensity of an inpatient setting for treatment. Without such inpatient treatment, the member's condition would deteriorate;
- (b) The member's mental health disorder must be treatable in an inpatient facility;
- (c) The member's mental health disorder must meet diagnostic criteria as described in the most recent edition of the American Psychiatric Association Diagnostic and Statistical Manual (DSM). If outside of the United States, the member's mental health disorder must meet diagnostic criteria established and commonly recognized by the medical community in that region;
- (d) The attending provider must be a psychiatrist. If the admitting provider is not a psychiatrist, a psychiatrist must be attending to the member within twenty-four (24) hours of admittance. Such psychiatrist must be United States board-eligible or board-certified. If outside of the United States, inpatient services must be provided by an individual who has received a diploma from a medical school recognized by the government agency in the country where the medical school is located. The attending provider must meet the requirements, if any, set out by the foreign government or regionally-recognized licensing body for treatment of mental health disorders;
- (e) Day treatment (partial hospitalization) for mental health services means a day treatment program that offers intensive, multidisciplinary services not otherwise offered in an outpatient setting. The treatment program is generally a minimum of twenty (20)

hours of scheduled programming extended over a minimum of five (5) days per week. The program is designed to treat patients with serious mental or nervous disorders and offers major diagnostic, psychosocial, and prevocational modalities. Such programs must be a less-restrictive alternative to inpatient treatment; and

- (f) Mental health services received in a residential treatment facility that is licensed by the state in which it operates and provides treatment for mental health disorders is covered. This does not include services provided at a group home. If outside of the United States, the residential treatment facility must be licensed or approved by the foreign government or an accreditation or licensing body working in that foreign country;
- (V) Outpatient mental health services are covered if the member is at a therapeutic medical or mental health facility, and treatment includes measurable goals and continued progress toward functional behavior and termination of treatment. Continued coverage may be denied when positive response to treatment is not evident. Treatment must be provided by one (1) of the following:
- (a) A United States board-eligible or board-certified psychiatrist licensed in the state where the treatment is provided;
- (b) A therapist with a doctorate or master's degree that denotes a specialty in psychiatry (Psy.D.);
 - (c) A state-licensed psychologist;
- (d) A state-licensed or certified social worker practicing within the scope of his or her license or certification; or
 - (e) Licensed professional counselor; and
- (VI) Inpatient treatment in a network hospital or facility by a non-network provider. Inpatient treatment received in a network hospital or facility by a non-network provider is covered at the network benefit;
- 27. Injections and infusions. Injections and infusions are covered. See preventive services for coverage of immunizations. See contraception and sterilization for coverage of birth control injections. Medications (specialty and non-specialty) that can be safely obtained through a pharmacy and which may be self-administered, including injectables, are not a medical plan benefit but are covered as part of the pharmacy benefit.
 - A. B12 injections are covered for the following conditions:
 - (I) Pernicious anemia:
 - (II) Crohn's disease;
 - (III) Ulcerative colitis;
 - (IV) Inflammatory bowel disease;
 - (V) Intestinal malabsorption;
 - (VI) Fish tapeworm anemia;
 - (VII) Vitamin B12 deficiency;
 - (VIII) Other vitamin B12 deficiency anemia;
 - (IX) Macrocytic anemia;
 - (X) Other specified megaloblastic anemias;
 - (XI) Megaloblastic anemia;
 - (XII) Malnutrition of alcoholism;
 - (XIII) Thrombocytopenia, unspecified;
 - (XIV) Dementia in conditions classified elsewhere;
 - (XV) Polyneuropathy in diseases classified elsewhere;
 - (XVI) Alcoholic polyneuropathy;
 - (XVII) Regional enteritis of small intestine;
 - (XVIII) Postgastric surgery syndromes;
 - (XIX) Other prophylactic chemo-therapy;
 - (XX) Intestinal bypass or anastamosis status;
 - (XXI) Acquired absence of stomach;
 - (XXII) Pancreatic insufficiency; and
 - (XXIII) Ideopathic progressive polyneuropathy;
- 28. Lab, X-ray, and other diagnostic procedures. Outpatient diagnostic services are covered when tests or procedures are performed for a specific symptom and to detect or monitor a condition. Professional charges for automated lab services performed by an out-of-network provider are not covered;
- Maternity coverage. Prenatal and postnatal care is covered.Routine prenatal office visits and screenings recommended by the

Health Resources and Services Administration are covered at one hundred percent (100%). Other care is subject to the deductible and coinsurance. Newborns and their mothers are allowed hospital stays of at least forty-eight (48) hours after vaginal birth and ninety-six (96) hours after cesarean section birth. If discharge occurs earlier than specific time periods, the plan shall provide coverage for post discharge care that shall consist of a two- (2-) visit minimum, at least one (1) in the home;

- 30. Nutritional counseling. Individualized nutritional evaluation and counseling for the management of any medical condition for which appropriate diet and eating habits are essential to the overall treatment program is covered when ordered by a physician or physician extender and provided by a licensed health-care professional (e.g., a registered dietitian);
 - 31. Nutrition therapy.
- A. Nutrition therapy is covered only when the following criteria are met:
- (I) Nutrition therapy is the sole source of nutrients or a significant percentage of the daily caloric intake;
- (II) Nutrition therapy is used in the treatment of, or in association with, a demonstrable disease, condition, or disorder;
 - (III) Nutrition therapy is necessary to sustain life or health;
 - (IV) Nutrition therapy is prescribed by a provider; and
- (V) Nutrition therapy is managed, monitored, and evaluated on an on-going basis, by a provider.
 - B. Only the following types of nutrition therapy are covered:
- (I) Enteral Nutrition (EN). EN is the provision of nutritional requirements via the gastrointestinal tract. EN can be taken orally or through a tube into the stomach or small intestine.
- (II) Parenteral Nutrition Therapy (PN) and Total Parenteral Nutrition (TPN). PN is liquid nutrition administered through a vein to provide part of daily nutritional requirements. TPN is a type of PN that provides all daily nutrient needs. PN or TPN are covered when the member's nutritional status cannot be adequately maintained on oral or enteral feedings.
- (III) Intradialytic Parenteral Nutrition (IDPN). IDPN is a type of PN that is administered to members on chronic hemodialysis during dialysis sessions to provide most nutrient needs. IDPN is covered when the member is on chronic hemodialysis and nutritional status cannot be adequately maintained on oral or enteral feedings;
- 32. Office visit. Member encounter with a provider for health care, mental health, or substance abuse disorder in an office, clinic, or ambulatory care facility is covered based on the service, procedure, or related treatment plan;
- 33. Oral surgery is covered for injury, tumors, or cysts. Oral surgery includes, but is not limited to, reduction of fractures and dislocation of the jaws; external incision and drainage of cellulites; incision of accessory sinuses, salivary glands, or ducts; excision of exostosis of jaws and hard palate; and frenectomy. Treatment must be initiated within sixty (60) days of accident. No coverage for dental care, including oral surgery, as a result of poor dental hygiene. Extractions of bony or partial bony impactions are excluded;
- 34. Orthognathic or Jaw Surgery. Orthognathic or jaw surgery is covered when one (1) of the following conditions is documented and diagnosed:
 - A. Acute traumatic injury, and post-surgical sequelae;
- B. Cancerous or non-cancerous tumors and cysts, cancer and post-surgical sequela;
 - C. Cleft lip/palate (for cleft lip/palate related jaw surgery); or
- D. Physical or physiological abnormality when one (1) of the following criteria is met:
 - (I) Anteroposterior Discrepancies—
- (a) Maxillary/Mandibular incisor relationship: over jet of 5mm or more, or a 0 to a negative value (norm 2mm);
- (b) Maxillary/Mandibular anteroposterior molar relationship discrepancy of 4mm or more (norm 0 to 1mm); or
- (c) These values represent two (2) or more standard deviations from published norms;

- (II) Vertical Discrepancies—
- (a) Presence of a vertical facial skeletal deformity which is two (2) or more standard deviations from published norms for accepted skeletal landmarks:
- (b) Open bite with no vertical overlap of anterior teeth or unilateral or bilateral posterior open bite greater than 2mm;
- (c) Deep overbite with impingement or irritation of buccal or lingual soft tissues of the opposing arch; or
- (d) Supraeruption of a dentoalveolar segment due to lack of occlusion;
 - (III) Transverse Discrepancies—
- (a) Presence of a transverse skeletal discrepancy which is two (2) or more standard deviations from published norms; or
- (b) Total bilateral maxillary palatal cusp to mandibularfossa discrepancy of 4mm or greater, or a unilateral discrepancy of 3mm or greater, given normal axial inclination of the posterior teeth; or
 - (IV) Asymmetries—
- (a) Anteroposterior, transverse, or lateral asymmetries greater than 3mm with concomitant occlusal asymmetry;
- (V) Masticatory (chewing) and swallowing dysfunction due to malocclusion (e.g., inability to incise or chew solid foods, choking on incompletely masticated solid foods, damage to soft tissue during mastication, malnutrition);
 - (VI) Speech impairment; or
 - (VII) Obstructive sleep apnea or airway dysfunction;
 - 35. Orthotics.
- A. Ankle-Foot Orthosis (AFO) and Knee-Ankle-Foot Orthosis (KAFO).
- (I) Basic coverage criteria for AFO and KAFO used during ambulation are as follows:
- (a) AFO is covered when used in ambulation for members with weakness or deformity of the foot and ankle, which require stabilization for medical reasons, and have the potential to benefit functionally;
- (b) KAFO is covered when used in ambulation for members when the following criteria are met:
 - I. Member is covered for AFO; and
 - II. Additional knee stability is required; and
- (c) AFO and KAFO that are molded-to-patient-model, or custom-fabricated, are covered when used in ambulation, only when the basic coverage criteria and one (1) of the following criteria are met:
 - I. The member could not be fit with a prefabricated

AFO;

- II. AFO or KAFO is expected to be permanent or for more than $six\ (6)$ months duration;
- III. Knee, ankle, or foot must be controlled in more than one (1) plane;
- IV. There is documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; or
- V. The member has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.
 - (II) AFO and KAFO Not Used During Ambulation.
- (a) AFO and KAFO not used in ambulation are covered if the following criteria are met:
- I. Passive range of motion test was measured with agoniometer and documented in the medical record;
- II. Documentation of an appropriate stretching program administered under the care of provider or caregiver;
- III. Plantar flexion contracture of the ankle with dorsiflexion on passive range of motion testing of at least ten degrees (10°) (i.e., a non-fixed contracture);
- IV. Reasonable expectation of the ability to correct the contracture;
- V. Contracture is interfering, or expected to interfere, significantly with the patient's functional abilities; and

- VI. Used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons; or VII. Member has plantar fasciitis.
- (b) Replacement interface for AFO or KAFO is covered only if member continues to meet coverage criteria and is limited to a maximum of one (1) per six (6) months.
- B. Cast Boot, Post-Operative Sandal or Shoe, or Healing Shoe. A cast boot, post-operative sandal or shoe, or healing shoe is covered for one (1) of the following indications:
- (I) To protect a cast from damage during weight-bearing activities following injury or surgery;
- (II) To provide appropriate support and/or weight-bearing surface to a foot following surgery;
- (III) To promote good wound care and/or healing via appropriate weight distribution and foot protection; or
- (IV) When the patient is currently receiving treatment for lymphedema and the foot cannot be fitted into conventional footwear.
- C. Cranial Orthoses. Cranial orthosis is covered for Synostotic and Non-Synostotic Plagiocephaly. Plagiocephaly is an asymmetrically shaped head. Synostotic Plagiocephaly is due to premature closure of cranial sutures. Non-Synostotic Plagiocephaly is from positioning or deformation of the head. Cranial orthosis is the use of a special helmet or band on the head which aids in molding the shape of the cranium to normal. Initial reimbursement shall cover any subsequent revisions.
- D. Elastic Supports. Elastic supports are covered when prescribed for one (1) of the following indications:
- (I) Severe or incapacitating vascular problems, such as acute thrombophlebitis, massive venous stasis, or pulmonary embolism;
 - (II) Venous insufficiency;
 - (III) Varicose veins;
 - (IV) Edema of lower extremities;
 - (V) Edema during pregnancy; or
 - (VI) Lymphedema.
- E. Footwear Incorporated Into a Brace for Members with Skeletally Mature Feet. Footwear incorporated into a brace must be billed by the same supplier billing for the brace. The following types of footwear incorporated into a brace are covered:
 - (I) Orthopedic footwear;
- (II) Other footwear such as high top, depth inlay, or custom;
- (III) Heel replacements, sole replacements, and shoe transfers involving shoes on a brace;
- (IV) Inserts for a shoe that is an integral part of a brace and are required for the proper functioning of the brace; or
- (V) Other shoe modifications if they are on a shoe that is an integral part of a brace and are required for the proper functioning of the brace
- F. Foot Orthoses. Custom, removable foot orthoses are covered for members who meet the following criteria:
- (I) Member with skeletally mature feet who has any of the following conditions:
 - (a) Acute plantar fasciitis;
- (b) Acute sport-related injuries with diagnoses related to inflammatory problems such as bursitis or tendonitis;
 - (c) Calcaneal bursitis (acute or chronic);
 - (d) Calcaneal spurs (heel spurs);
 - (e) Conditions related to diabetes;
- (f) Inflammatory conditions (e.g., sesamoiditis, submetatarsal bursitis, synovitis, tenosynovitis, synovial cyst, osteomyelitis, and plantar fascial fibromatosis);
 - (g) Medial osteoarthritis of the knee;
- (h) Musculoskeletal/arthropathic deformities including deformities of the joint or skeleton that impairs walking in a normal shoe (e.g., bunions, hallux valgus, talipes deformities, pes deformities, or anomalies of toes);

planus;

- (i) Neurologically impaired feet including neuroma, tarsal tunnel syndrome, ganglionic cyst;
- (j) Neuropathies involving the feet, including those associated with peripheral vascular disease, diabetes, carcinoma, drugs, toxins, and chronic renal disease; or
- (k) Vascular conditions including ulceration, poor circulation, peripheral vascular disease, Buerger's disease (thromboangiitis obliterans), and chronic thrombophlebitis;
- (II) Member with skeletally immature feet who has any of the following conditions:
 - (a) Hallux valgus deformities;
 - (b) In-toe or out-toe gait;
 - (c) Musculoskeletal weakness such as pronation or pes
 - (d) Structural deformities such as tarsal coalitions; or
- (e) Torsional conditions such as metatarsus adductus, tibial torsion, or femoral torsion.
- G. Helmets. Helmets are covered when cranial protection is required due to a documented medical condition that makes the member susceptible to injury during activities of daily living.
- H. Hip Orthosis. Hip orthosis is covered for one (1) of the following indications:
 - (I) To reduce pain by restricting mobility of the hip;
- (II) To facilitate healing following an injury to the hip or related soft tissues;
- (III) To facilitate healing following a surgical procedure of the hip or related soft tissue; or
- (IV) To otherwise support weak hip muscles or a hip deformity.
- I. Knee Orthosis. Knee orthosis is covered for one (1) of the following indications:
 - (I) To reduce pain by restricting mobility of the knee;
- (II) To facilitate healing following an injury to the knee or related soft tissues;
- (III) To facilitate healing following a surgical procedure on the knee or related soft tissue; or
- (IV) To otherwise support weak knee muscles or a knee deformity.
 - J. Orthopedic Footwear for Diabetic Members.
- (I) Orthopedic footwear, therapeutic shoes, inserts, or modifications to therapeutic shoes are covered for diabetic members if any following criteria are met:
- (a) Previous amputation of the other foot or part of either foot;
 - (b) History of previous foot ulceration of either foot;
 - (c) History of pre-ulcerative calluses of either foot;
- (d) Peripheral neuropathy with evidence of callus formation of either foot;
 - (e) Foot deformity of either foot; or
 - (f) Poor circulation in either foot.
- (II) Coverage is limited to one (1) of the following within one (1) year:
- (a) One (1) pair of custom molded shoes (which includes inserts provided with these shoes) and two (2) additional pairs of inserts;
- (b) One (1) pair of depth shoes and three (3) pairs of inserts (not including the non-customized removable inserts provided with such shoes); or
- (c) Up to three (3) pairs of inserts not dispensed with diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which the insert can be placed.
- K. Orthotic-Related Supplies. Orthotic-related supplies are covered when necessary for the function of the covered orthotic device.
- L. Spinal Orthoses. A thoracic-lumbar-sacral orthosis, lumbar orthosis, lumbar-sacral orthosis, and cervical orthosis are covered for the following indications:
 - (I) To reduce pain by restricting mobility of the trunk;

- (II) To facilitate healing following an injury to the spine or related soft tissues;
- (III) To facilitate healing following a surgical procedure of the spine or related soft tissue; or
- (IV) To otherwise support weak spinal muscles or a deformed spine.
- M. Trusses. Trusses are covered when a hernia is reducible with the application of a truss.
- N. Upper Limb Orthosis. Upper limb orthosis is covered for the following indications:
 - (I) To reduce pain by restricting mobility of the joint(s);
- (II) To facilitate healing following an injury to the joint(s) or related soft tissues; or
- (III) To facilitate healing following a surgical procedure of the joint(s) or related soft tissue.
- O. Orthotic Device Replacement. When repairing an item that is no longer cost-effective and is out of warranty, the plan will consider replacing the item subject to review of medical necessity and life expectancy of the device;
 - 36. Preventive services.
- A. Services recommended by the U.S. Preventive Services Task Force (categories A and B).
- B. Immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.
- C. Preventive care and screenings for infants, children, and adolescents supported by the Health Resources and Services Administration.
- D. Preventive care and screenings for women supported by the Health Resources and Services Administration.
- E. Annual physical exams and routine lab and X-ray services ordered as part of the annual exam. One (1) exam per calendar year is covered. Additional visits as needed to obtain all necessary preventive services are covered for women depending on a woman's health status, health needs, and other risk factors. For benefits to be covered as preventive, including X-rays and lab services, they must be coded by your physician as routine, without indication of an injury or illness.
 - F. Cancer screenings-
 - (I) Mammograms—one (1) exam per year, no age limit;
 - (II) Pap smears—one (1) per year, no age limit;
 - (III) Prostate—one (1) per year, no age limit; and
- (IV) Colorectal screening—One (1) flexible sigmoidoscopy, colonoscopy, or double contrast barium enema per year covered as preventive even if the primary diagnosis is not a preventive code provided a preventive code is included in connection with the screening. Virtual colonoscopy covered as diagnostic only. Additional colorectal screenings covered as diagnostic unless otherwise specified
- G. Zoster vaccination (shingles)—The zoster vaccine is covered for members age fifty (50) years and older;
- 37. Prostheses (prosthetic devices). Basic equipment that meets medical needs. Repair and replacement is covered due to normal wear and tear, if there is a change in medical condition, or if growth-related;
- 38. Pulmonary rehabilitation. Comprehensive, individualized, goal-directed outpatient pulmonary rehabilitation covered for preand post-operative intervention for lung transplantation and lung volume reduction surgery (LVRS) or when all of the following apply:
- A. Member has a reduction of exercise tolerance that restricts the ability to perform activities of daily living (ADL) or work;
- B. Member has chronic pulmonary disease (including asthma, emphysema, chronic bronchitis, chronic airflow obstruction, cystic fibrosis, alpha-1 antitrypsin deficiency, pneumoconiosis, asbestosis, radiation pneumonitis, pulmonary fibrosis, pulmonary alveolar proteinosis, pulmonary hemosiderosis, fibrosing alveolitis), or other conditions that affect pulmonary function such as ankylosing spondylitis, scoliosis, myasthenia gravis, muscular dystrophy,

Guillain-Barré syndrome, or other infective polyneuritis, sarcoidosis, paralysis of diaphragm, or bronchopulmonary dysplasia; and

- C. Member has a moderate to moderately severe functional pulmonary disability, as evidenced by either of the following, and does not have any concomitant medical condition that would otherwise imminently contribute to deterioration of pulmonary status or undermine the expected benefits of the program (e.g., symptomatic coronary artery disease, congestive heart failure, myocardial infarction within the last six (6) months, dysrhythmia, active joint disease, claudication, malignancy):
- (I) A maximal pulmonary exercise stress test under optimal bronchodilatory treatment which demonstrates a respiratory limitation to exercise with a maximal oxygen uptake (VO_2 max) equal to or less than twenty milliliters per kilogram per minute (20 ml/kg/min), or about five (5) metabolic equivalents (METS); or
- (II) Pulmonary function tests showing that either the Forced Expiratory Volume in One Second (FEV1), Forced Vital Capacity (FVC), FEV1/FVC, or Diffusing Capacity of the Lung for Carbon Monoxide (DLCO) is less than sixty percent (60%) of that predicted;
- 39. Skilled Nursing Facility. Skilled nursing facility services are covered up to one hundred twenty (120) days per calendar year;
- 40. Bone Growth Stimulators. Implantable bone growth stimulators are covered as an outpatient surgery benefit. The following nonimplantable bone growth stimulators are covered as a durable medical equipment benefit:
- A. Ultrasonic osteogenesis stimulator (e.g., the Sonic Accelerated Fracture Healing System (SAFHS)) to accelerate healing of fresh fractures, fusions, or delayed unions at either of the following high-risk sites:
- (I) Fresh fractures, fusions, or delayed unions of the shaft (diaphysis) of the tibia that are open or segmental; or
- (II) Fresh fractures, fusions, or delayed unions of the scaphoid (carpal navicular);
- B. Ultrasonic osteogenesis stimulator for non-unions, failed arthrodesis, and congenital pseudarthrosis (pseudoarthrosis) of the appendicular skeleton if there has been no progression of healing for three (3) or more months despite appropriate fracture care; or
- C. Direct current electrical bone-growth stimulator is covered for the following indications:
- (I) Delayed unions of fractures or failed arthrodesis at highrisk sites (i.e., open or segmental tibial fractures, carpal navicular fractures);
- (II) Non-unions, failed fusions, and congenital pseudarthrosis where there is no evidence of progression of healing for three (3) or more months despite appropriate fracture care; or
- (III) Members who are at high risk for spinal fusion failure when any of the following criteria is met:
- (a) A multiple-level fusion entailing three (3) or more vertebrae (e.g., L3 to L5, L4 to S1, etc.);
 - (b) Grade II or worse spondylolisthesis; or
 - (c) One (1) or more failed fusions;
- 41. Telehealth Services. Telehealth services are covered for the diagnosis, consultation, or treatment of a member on the same basis that the service would be covered when it is delivered in person;
- 42. Therapy. Physical, occupational, and speech therapy are covered when prescribed by a provider and subject to the provisions below:
 - A. Physical therapy.
 - (I) Physical therapy must meet the following criteria:
- (a) The program is designed to improve lost or impaired physical function or reduce pain resulting from illness, injury, congenital defect, or surgery;
- (b) The program is expected to result in significant therapeutic improvement over a clearly defined period of time; and
- (c) The program is individualized, and there is documentation outlining quantifiable, attainable treatment goals;
 - B. Occupational therapy must meet the following criteria:

- (I) The program is designed to improve or compensate for lost or impaired physical functions, particularly those affecting activities of daily living, resulting from illness, injury, congenital defect, or surgery;
- (II) The program is expected to result in significant therapeutic improvement over a clearly defined period of time; and
- (III) The program is individualized, and there is documentation outlining quantifiable, attainable treatment goals;
 - C. Speech therapy.
- (I) All of the following criteria must be met for coverage of speech therapy:
- (a) The therapy requires one-to-one intervention and supervision of a speech-language pathologist;
- (b) The therapy plan includes specific tests and measures that will be used to document significant progress every two (2) weeks;
 - (c) Meaningful improvement is expected;
- (d) The therapy includes a transition from one-to-one supervision to a self- or caregiver- provided maintenance program upon discharge; and
 - (e) One (1) of the following:
- I. Member has severe impairment of speech-language; and an evaluation has been completed by a certified speech-language pathologist that includes age-appropriate standardized tests to measure the extent of the impairment, performance deviation, and language and pragmatic skill assessment levels; or
- II. Member has a significant voice disorder that is the result of anatomic abnormality, neurological condition, or injury (e.g., vocal nodules or polyps, vocal cord paresis or paralysis, post-operative vocal cord surgery);
- 43. Transplants. Stem cell, kidney, liver, heart, lung, pancreas, small bowel, or any combination are covered. Includes services related to organ procurement and donor expenses if not covered under another plan. Member must contact medical plan for arrangements.
- A. Network includes travel and lodging allowance for the transplant recipient and an immediate family travel companion when the transplant facility is more than fifty (50) miles from the recipient's residence. If the recipient is younger than age nineteen (19) years travel and lodging is covered for both parent(s). The transplant recipient must be with the travel companion or parent(s) for the travel companion's or parent(s)' travel expense to be reimbursable. Combined travel and lodging expenses are limited to a ten thousand dollar (\$10,000) maximum per transplant.
- (I) Lodging—maximum lodging expenses shall not exceed the per diem rates as established annually by U.S. General Services Administration (GSA) for a specific city or county. Go to www.gsa.gov for per diem rates.
- (II) Travel—IRS standard medical mileage rates (same as flexible spending account (FSA) reimbursement).
 - (III) Meals-not covered.
- B. Non-network. Charges above the maximum for services rendered at a non-network facility are the member's responsibility and do not apply to the member's deductible or out-of-pocket maximum. Travel, lodging, and meals are not covered. Non-network facility charges and payments for transplants are limited to the following maximums:
 - (I) Stem cell transplant—
- (a) Allogeneic related—one hundred fifty-three thousand dollars (\$153,000);
- (b) Allogeneic unrelated—one hundred seventy-nine thousand dollars (\$179,000); and
- (c) Autologous stem cell transplant—one hundred five thousand dollars (\$105,000);
- (II) Heart—one hundred eighty-five thousand dollars (\$185,000);
- (III) Heart and lung—two hundred sixty-one thousand three hundred sixty-one dollars (\$261,361);

- (IV) Lung—one hundred forty-two thousand eight hundred seventeen dollars (\$142,817);
 - (V) Kidney—eighty thousand dollars (\$80,000);
- (VI) Kidney and pancreas—one hundred thirty thousand dollars (\$130,000);
- (VII) Liver—one hundred seventy-five thousand nine hundred dollars (\$175,900);
- (VIII) Pancreas—ninety-five thousand dollars (\$95,000); and
- (IX) Small bowel—two hundred seventy-five thousand dollars (\$275,000);
- 44. Urgent care. Care for an illness, injury, or condition serious enough that a reasonable person would seek care right away, but not so severe as to require emergency room care; and
- 45. Vision. One (1) routine exam and refractions is covered per calendar year.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR **10-3.060** PPO 600 Plan, PPO 1000 Plan, and Health Savings Account Plan Limitations **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2038–2039). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, and section 103.089, RSMo Supp. 2014, the executive director amends a rule as follows:

22 CSR 10-3.070 Coordination of Benefits is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2039). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan received one (1) comment on the proposed amendment.

COMMENT #1: UMR suggested clarifying the coordination of benefits when MCHCP is secondary to Medicare by adding that all

claims where Medicare is primary will be considered at the network benefit level when MCHCP coordinates benefits.

RESPONSE: No clarification is needed. No changes were made to the rule as a result of this comment.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-3.075 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2039–2043). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment

COMMENT #1: UMR commented to clarify the time period needed to review an appeal of a first and second level appeal.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, subparts (3)(B)2.B.(II)(a) and (3)(B)2.B.(IV)(a) were added to clarify that the vendor may extend the time period for the appeal of a first and second level appeal because of reasons outside the vendor's control and the time frames that the vendor must follow.

22 CSR 10-3.075 Review and Appeals Procedure

- (3) Appeal Process for Medical and Pharmacy Determinations. (B) Internal Appeals.
- 1. Eligibility, termination for failure to pay, or rescission. Adverse benefit determinations denying or terminating an individual's coverage under the plan based on a determination of the individual's eligibility to participate in the plan or the failure to pay premiums, or any rescission of coverage based on fraud or intentional misrepresentation of a member or authorized representative of a member are appealable exclusively to the Missouri Consolidated Health Care Plan (MCHCP) Board of Trustees (board).
- A. The internal review process for appeals relating to eligibility, termination for failure to pay, or rescission shall consist of one (1) level of review by the board.
- B. Adverse benefit determination appeals to the board must identify the eligibility, termination, or rescission decision being appealed and the reason the claimant believes the MCHCP staff decision should be overturned. The member should include with his/her appeal any information or documentation to support his/her appeal request.
- C. The appeal will be reviewed by the board in a meeting closed pursuant to section 610.021, RSMo, and the appeal will be responded to in writing to the claimant within sixty (60) days from the date the board received the written appeal.
- D. Determinations made by the board constitute final internal adverse benefit determinations and are not eligible for external review, except as specifically provided in 22 CSR 10-32.075(4)(A)4.
- Medical and pharmacy services. Members may request internal review of any adverse benefit determination relating to urgent care, pre-service claims, and post-service claims made by the plan's medical and pharmacy vendors.

- A. Appeals of adverse benefit determinations shall be submitted in writing to the vendor that issued the original determination giving rise to the appeal at the applicable address set forth in this rule.
- B. The internal review process for adverse benefit determinations relating to medical services consists of two (2) levels of internal review provided by the medical vendor that issued the adverse benefit determination.
- (I) First level appeals must identify the decision being appealed and the reason the member believes the original claim decision should be overturned. The member should include with his/her appeal any additional information or documentation to support the reason the original claim decision should be overturned.
- (II) First level appeals will be reviewed by the vendor by someone who was not involved in the original decision and will consult with a qualified medical professional if a medical judgment is involved. First level medical appeals will be responded to in writing to the member within thirty (30) days for post-service claims and fifteen (15) days for pre-service claims from the date the vendor received the first level appeal request.
- (a) If, because of reasons beyond the vendor's control, more time is needed to review the appeal, the vendor may extend the time period up to an additional fifteen (15) days. The vendor must notify the member prior to the expiration of the first fifteen- (15-) day period, explain the reason for the delay, and request any additional information. If more information is requested, the member has at least forty-five (45) days to provide the information to the vendor. The vendor then must decide the claim no later than fifteen (15) days after the additional information is supplied or after the period of time allowed to supply it ends, whichever is first.
- (III) An expedited appeal of an adverse benefit determination may be requested when a decision is related to a pre-service claim for urgent care. Expedited appeals will be reviewed by the vendor by someone who was not involved in the original decision and will consult with a qualified medical professional if a medical judgment is involved. Expedited appeals will be responded to within seventy-two (72) hours after receiving a request for an expedited review with written confirmation of the decision to the member within three (3) working days of providing notification of the determination.
- (IV) Second level appeals must be submitted in writing within sixty (60) days of the date of the first level appeal decision letter that upholds the original adverse benefit determination. Second level appeals should include any additional information or documentation to support the reason the member believes the first level appeal decision should be overturned. Second level appeals will be reviewed by the vendor by someone who was not involved in the original decision or first level appeal and will include consultation with a qualified medical professional if a medical judgment is involved. Second level medical appeals shall be responded to in writing to the member within thirty (30) days for post-service claims and within fifteen (15) days for pre-service claims from the date the vendor received the second level appeal request.
- (a) If, because of reasons beyond the vendor's control, more time is needed to review the appeal, the vendor may extend the time period up to an additional fifteen (15) days. The vendor must notify the member prior to the expiration of the first fifteen- (15-) day period, explain the reason for the delay, and request any additional information. If more information is requested, the member has at least forty-five (45) days to provide the information to the vendor. The vendor then must decide the claim no later than fifteen (15) days after the additional information is supplied or after the period of time allowed to supply it ends, whichever is first.
 - (V) For members with medical coverage through UMR-
- (a) First and second level pre-service and concurrent claim appeals must be submitted in writing to—

UMR Appeals PO Box 400046 San Antonio, TX 78229 or by fax to (888) 615-6584 (b) First and second level post-service appeals must be sent in writing to—

UMR Claims Appeal Unit PO Box 30546 Salt Lake City, UT 84130-0546 or by fax to (877) 291-3248

- (c) Expedited pre-service appeals must be communicated by calling (800) 808-4424, ext. 15227 or by submitting a written fax to (888) 615-6584, Attention: Appeals Unit.
- (VI) For members with medical coverage through Coventry Health Care of Kansas, Inc.—
- (a) First and second level appeals must be submitted in writing to—

Coventry Health Care of Kansas, Inc. Attn: Appeals Department 9401 Indian Creek Parkway, Suite 1300 Overland Park, KS 66210 or by fax to (866) 769-2408

- (b) Expedited appeals must be communicated by calling (913) 202-5000 or by submitting a written fax to (866) 769-2408.
- C. The internal review process for adverse benefit determinations relating to pharmacy and the Pharmacy Lock-In Program consists of one (1) level of internal review provided by the pharmacy vendor.
- (I) Pharmacy appeals. Pharmacy appeals and Pharmacy Lock-In Program appeals must identify the matter being appealed and should include the member's (and dependent's, if applicable) name, the date the member attempted to fill the prescription, the prescribing physician's name, the drug name and quantity, the cost of the prescription, if applicable, and any applicable reason(s) relevant to the appeal including: the reason(s) the member believes the claim should be paid, the reason(s) the member believes s/he should not be included in the Pharmacy Lock-In Program, and any other written documentation to support the member's belief that the original decision should be overturned.
- (II) All pharmacy appeals must be submitted in writing

Express Scripts
Attn: Clinical Appeals Department
PO Box 66588
St. Louis, MO 63116-6588
or by fax to (877) 852-4070

(III) All Pharmacy Lock-In Program appeals must be submitted in writing to—

Express Scripts
Drug Utilization Review Program
100 Parsons Pond Dr.
Franklin Lakes, NJ 07417-2603

- (IV) Pharmacy appeals will be reviewed by someone who was not involved in the original decision and the reviewer will consult with a qualified medical professional if a medical judgment is involved. Pharmacy appeals will be responded to in writing to the member within sixty (60) days for post-service claims and thirty (30) days for pre-service claims from the date the vendor received the appeal request.
- (V) The Pharmacy Benefit Manager will respond to Pharmacy Lock-In Program appeals in writing to the member within thirty (30) days from the date the Pharmacy Benefit Manager received the appeal request.
- D. Members may seek external review only after they have exhausted all applicable levels of internal review or received a final internal adverse benefit determination.

- (I) A claimant or authorized representative may file a written request for an external review within four (4) months after the date of receipt of a final internal adverse benefit determination.
- (II) The claimant can submit an external review request in writing to—

HHS Federal Request MAXIMUS Federal Services 3750 Monroe Ave., Suite 705 Pittsford, NY 14534 or by fax to (888) 866-6190 or to request a review online at http://www.externalappeal.com/

- (III) The claimant may call the toll-free number (888) 866-6205 with any questions or concerns during the external review process and can submit additional written comments to the external reviewer at the mailing address above.
- (IV) The external review decision will be made as expeditiously as possible and within forty-five (45) days after receipt of the request for the external review.
- (V) A claimant may make a written or oral request for an expedited external review if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant; or would jeopardize the claimant's ability to regain maximum function; or if the final internal adverse benefit determination involves an admission, availability of care, continued stay, or health care item or service for which the claimant received services, but has not been discharged from a facility.
- 3. For all internal appeals of adverse benefit determinations, the plan or the vendor reviewing the appeal will provide the member, free of charge, with any new or additional evidence or rationale considered, relied upon, or generated by the plan or the vendor in connection with reviewing the claim or the appeal and will give the member an opportunity to respond to such new evidence or rationale before issuing a final internal adverse determination.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-3.080 Miscellaneous Provisions is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2043). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 22—MISSOURI CONSOLIDATED
HEALTH CARE PLAN
Division 10—Health Care Plan
Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan

under section 103.059, RSMo 2000, the executive director amends a rule as follows:

22 CSR 10-3.090 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2043–2046). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed amendment.

COMMENT #1: MCHCP staff commented to clarify that Hepatitis C specialty drugs may not be filled through a retail pharmacy in addition to those select drugs that have been included in the specialty split-fill program.

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, part (1)(A)1.D.(II), has been amended to clarify that Hepatitis C specialty drugs may not be filled through a retail pharmacy.

22 CSR 10-3.090 Pharmacy Benefit Summary

- (1) The pharmacy benefit provides coverage for prescription drugs. Vitamin and nutrient coverage is limited to prenatal agents, therapeutic agents for specific deficiencies and conditions, and hematopoietic agents as prescribed by a provider.
 - (A) PPO 600 and PPO 1000 Prescription Drug Coverage.
 - 1. Network
- A. Generic copayment: Eight dollars (\$8) for up to a thirty-one-(31-) day supply; sixteen dollars (\$16) for up to a sixty- (60-) day supply; and twenty-four dollars (\$24) for up to a ninety- (90-) day supply for a generic drug on the formulary; formulary generic birth control and tobacco cessation prescriptions covered at one hundred percent (100%).
- B. Brand copayment: Thirty-five dollars (\$35) for up to a thirty-one- (31-) day supply; seventy dollars (\$70) for up to a sixty- (60-) day supply; and one hundred and five dollars (\$105) for up to a nine-ty- (90-) day supply for a brand drug on the formulary; formulary brand birth control and tobacco cessation prescriptions covered at one hundred percent (100%).
- C. Non-formulary copayment: One hundred dollars (\$100) for up to a thirty-one- (31-) day supply; two hundred dollars (\$200) for up to a sixty- (60-) day supply; and three hundred dollars (\$300) for up to a ninety- (90-) day supply for a drug not on the formulary.
 - D. Home delivery program-
- (I) Maintenance prescriptions may be filled through the home delivery program.
- (a) Generic copayments: Eight dollars (\$8) for up to a thirty-one- (31-) day supply; sixteen dollars (\$16) for up to a sixty- (60-) day supply; and twenty dollars (\$20) for up to a ninety- (90-) day supply for a generic drug on the formulary.
- (b) Brand copayments: Thirty-five dollars (\$35) for up to a thirty-one- (31-) day supply; seventy dollars (\$70) for up to a sixty-(60-) day supply; and eighty-seven dollars and fifty-cents (\$87.50) for up to a ninety- (90-) day supply for a brand drug on the formulary.
- (c) Non-formulary copayments: One hundred dollars (\$100) for up to a thirty-one- (31-) day supply; two hundred dollars (\$200) for up to a sixty- (60-) day supply; and two hundred fifty dollars (\$250) for up to a ninety- (90-) day supply for a drug not on the formulary.
- (d) A member must choose how maintenance prescription(s) will be filled by notifying the pharmacy benefit manager

(PBM) of his/her decision to fill a maintenance prescription through home delivery or retail pharmacy.

- (e) If the member chooses to fill his/her maintenance prescription at a retail pharmacy and the member does not notify the PBM of his/her decision, the first two (2) maintenance prescription orders may be filled by the retail pharmacy. After the first two (2) orders are filled at the retail pharmacy, the member must notify the PBM of his/her decision to continue to fill the maintenance prescription at the retail pharmacy. If a member does not make a decision after the first two (2) orders are filled at the retail pharmacy, s/he will be charged the full discounted cost of the drug until the PBM has been notified of the decision and the amount charged will not apply to the out-of-pocket maximum.
- (f) Once a member makes his/her delivery decision, the member can modify the decision by contacting the PBM; and
- (II) Specialty drugs are covered only through the specialty home delivery network for up to a thirty-one- (31-) day supply unless the PBM has determined that the specialty drug is eligible for up to a ninety- (90-) day supply. The first specialty prescription order may be filled through a retail pharmacy, except for Hepatitis C specialty drugs and those select drugs that have been included in the specialty split-fill program.
- (a) Generic copayments: Eight dollars (\$8) for a generic drug on the formulary list.
- (b) Brand copayments: Thirty-five dollars (\$35) for a brand drug on the formulary.
- (c) Non-formulary copayments: One hundred dollars (\$100) for a drug not on the formulary;
- (III) Specialty split-fill program—The specialty split-fill program applies to select specialty drugs as determined by the PBM. For the first three (3) months, members will be shipped a fifteen-(15-) day supply with a prorated copayment. If the member is able to continue with the medication, the remaining supply will be shipped with the remaining portion of the copayment. Starting with the fourth month, and up to thirty-one- (31-) day supply will be shipped if the member continues on treatment.
- E. Only one (1) copayment is charged if a combination of different manufactured dosage amounts must be dispensed in order to fill a prescribed single dosage amount.
- F. The copayment for a compound drug is based on the primary drug in the compound. The primary drug in a compound is the most expensive prescription drug in the mix. If any ingredient in the compound is excluded by the plan, the compound will be denied.
- G. If the copayment amount is more than the cost of the drug, the member is only responsible for the cost of the drug.
- H. If the physician allows for generic substitution and the member chooses a brand-name drug, the member is responsible for the generic copayment and the cost difference between the brand name and generic drug which shall not apply to the out-of-pocket maximum.
- I. Prescription drugs and prescribed over-the-counter drugs as recommended by the U.S. Preventive Services Task Force (categories A and B) and, for women, by the Health Resources and Services Administration are covered at one hundred percent (100%) when filled at a network pharmacy. The following are also covered at one hundred percent (100%) when filled at a network pharmacy:
 - (I) Prescribed Vitamin D for all ages;
- (a) The range for preventive Vitamin D is at or below 1000 IU of Vitamin D_2 or D_3 per dose;
- (II) Zoster (shingles) vaccine and administration for members age fifty (50) years and older;
- (III) Influenza vaccine and administration as recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention; and
- (IV) Generic Tamoxifen, generic Raloxifene, and brand Soltamox for prevention of breast cancer.
- 2. Non-network: If a member chooses to use a non-network pharmacy for non-specialty prescriptions, s/he will be required to

pay the full cost of the prescription and then file a claim with the PBM. The PBM will reimburse the cost of the drug based on the network discounted amount as determined by the PBM, less the applicable network copayment.

- 3. Out-of-pocket maximum.
- A. Network and non-network out-of-pocket maximums are separate.
- B. The family out-of-pocket maximum is an aggregate of applicable charges received by all covered family members of the plan. Any combination of covered family member applicable charges may be used to meet the family out-of-pocket maximum. Applicable charges received by one (1) family member may only meet the individual out-of-pocket maximum amount.
 - C. Individual—five thousand one hundred dollars (\$5,100).
 - D. Family—ten thousand two hundred dollars (\$10,200).

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director adopts a rule as follows:

22 CSR 10-3.150 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2046–2047). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: Missouri Consolidated Health Care Plan (MCHCP) received one (1) comment on the proposed rule.

COMMENT #1: MCHCP staff commented that paragraph (2)(C)2. be removed as the oncology disease management program is duplicative of case management provided by the medical TPA.

RESPONSE AND EXPLANATION OF CHANGE: Based on this

RESPONSE AND EXPLANATION OF CHANGE: Based on this comment, paragraph (2)(C)2. has been removed as it is duplicative of case management services provided by the medical TPA.

22 CSR 10-3.150 Disease Management Services Provisions and Limitations

- (2) Disease Management.
- (C) An eligible member may participate in a DM program appropriate for managing a chronic condition if s/he meets the relevant age criterion and has one (1) or more of the following chronic conditions:
 - 1. Asthma—open to those aged six (6) and over;
- 2. Chronic obstructive pulmonary disease—open to those aged eighteen (18) and over;
- 3. Congestive heart failure—open to those aged eighteen (18) and over;
- 4. Coronary artery disease—open to those aged eighteen (18) and over:
 - 5. Depression—open to those aged eighteen (18) and over;
 - 6. Diabetes—open to those aged six (6) and over;
- 7. Musculoskeletal/chronic pain (including low back pain)—open to those aged eighteen (18) and over;
- 8. Obesity (Body Mass Index \geq 30)—open to those aged eighteen (18) and over; or
- 9. Hypertension as a co-morbid condition to any of the chronic conditions listed herein—open to those aged eighteen (18) and over.

Title 22—MISSOURI CONSOLIDATED HEALTH CARE PLAN Division 10—Health Care Plan Chapter 3—Public Entity Membership

ORDER OF RULEMAKING

By the authority vested in the Missouri Consolidated Health Care Plan under section 103.059, RSMo 2000, the executive director adopts a rule as follows:

22 CSR 10-3.160 Pharmacy Lock-In Program is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on December 1, 2014 (39 MoReg 2047–2048). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

his section may contain notice of hearings, correction notices, public information notices, rule action notices, statements of actual costs, and other items required to be published in the *Missouri Register* by law.

Title 7—DEPARTMENT OF TRANSPORTATION Division 10—Missouri Highways and Transportation Commission Chapter 25—Motor Carrier Operations

IN ADDITION

7 CSR 10-25.010 Skill Performance Evaluation Certificates for Commercial Drivers

PUBLIC NOTICE

Public Notice and Request for Comments on Applications for Issuance of Skill Performance Evaluation Certificates to Intrastate Commercial Drivers with Diabetes Mellitus or Impaired Vision

SUMMARY: This notice publishes MoDOT's receipt of applications for the issuance of Skill Performance Evaluation (SPE) Certificates from individuals who do not meet the physical qualification requirements in the Federal Motor Carrier Safety Regulations for drivers of commercial motor vehicles in Missouri intrastate commerce because of impaired vision or an established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control. If granted, the SPE Certificates will authorize these individuals to qualify as drivers of commercial motor vehicles (CMVs), in intrastate commerce only, without meeting the vision standard prescribed in 49 CFR 391.41(b)(10), if applicable, or the diabetes standard prescribed in 49 CFR 391.41(b)(3).

DATES: Comments must be received at the address stated below, on or before, May 1, 2015.

ADDRESSES: You may submit comments concerning an applicant, identified by the Application Number stated below, by any of the following methods:

- Email: kathy.hatfield@modot.mo.gov
- Mail: PO Box 270, Jefferson City, MO 65102-0270
- Hand Delivery: 830 MoDOT Drive, Jefferson City, MO 65109
- *Instructions:* All comments submitted must include the agency name and Application Number for this public notice. For detailed instructions on submitting comments, see the Public Participation heading of the Supplementary Information section of this notice. All comments received will be open and available for public inspection and MoDOT may publish those comments by any available means.

COMMENTS RECEIVED BECOME MoDOT PUBLIC RECORD

- By submitting any comments to MoDOT, the person authorizes MoDOT to publish those comments by any available means.
- *Docket:* For access to the department's file, to read background documents or comments received, 830 MoDOT Drive, Jefferson City, MO 65109, between 7:30 a.m. and 4:00 p.m., CT, Monday through Friday, except state holidays.

FOR FURTHER INFORMATION CONTACT: Kathy J. Hatfield, Motor Carrier Investigations Specialist, (573) 526-9926, MoDOT Motor Carrier Services Division, PO Box 270, Jefferson City, MO 65102-0270. Office hours are from 7:30 a.m. to 4:00 p.m., CT, Monday through Friday, except state holidays.

SUPPLEMENTARY INFORMATION:

Public Participation

If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard.

Background

The individuals listed in this notice have recently filed applications requesting MoDOT to issue SPE Certificates to exempt them from the physical qualification requirements relating to vision in 49 CFR 391.41(b)(10), or to diabetes in 49 CFR 391.41(b)(3), which otherwise apply to drivers of CMVs in Missouri intrastate commerce.

Under section 622.555, RSMo Supp. 2014, MoDOT may issue an SPE Certificate, for not more than a two- (2-) year period, if it finds that the applicant has the ability, while operating CMVs, to maintain a level of safety that is equivalent to or greater than the driver qualification standards of 49 CFR 391.41. Upon application, MoDOT may renew an exemption upon expiration.

Accordingly, the agency will evaluate the qualifications of each applicant to determine whether issuing an SPE Certificate will comply with the statutory requirements and will achieve the required level of safety. If granted, the SPE Certificate is only applicable to intrastate transportation wholly within Missouri.

Qualifications of Applicants

Application #251

Applicant's Name & Age: David L. Nelson, 37

Relevant Physical Condition: Vision impaired.

Mr. Nelson's best corrected visual acuity in his left eye is 20/20 Snellen and his best corrected visual acuity in his right eye is 20/70 Snellen. David sustained an injury that impaired the vision in his right eye in July 2014.

Relevant Driving Experience: Mr. Nelson is currently employed as a driver for a refuse and recycling business. He currently holds a Class A CDL license, and has approximately four (4) years commercial motor vehicle driving experience. He drives personal vehicle(s) daily.

Doctor's Opinion and Date: Following an examination in January 2015, his ophthalmologist certified his condition would not adversely affect his ability to operate a commercial vehicle safely.

Traffic Accidents and Violations: No accidents or violations on record for the previous three (3) years.

Request for Comments

The Missouri Department of Transportation, Motor Carrier Services Division, pursuant to section 622.555, RSMo, and rule 7 CSR 10-25.010, requests public comment from all interested persons on the applications for issuance of Skill Performance Evaluation Certificates described in this notice. We will consider all comments received before the close of business on the closing date indicated earlier in this notice.

Issued on: February 19, 2015

Scott Marion, Motor Carrier Services Director, Missouri Department of Transportation.

Title 7—DEPARTMENT OF TRANSPORTATION Division 10—Missouri Highways and Transportation Commission Chapter 25—Motor Carrier Operations

IN ADDITION

7 CSR 10-25.010 Skill Performance Evaluation Certificates for Commercial Drivers

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DATES: Comments must be received at the address stated below, on or before, May 1, 2015.

ADDRESSES: You may submit comments concerning an applicant, identified by the Application Number stated below, by any of the following methods:

- Email: kathy.hatfield@modot.mo.gov
- Mail: PO Box 270, Jefferson City, MO 65102-0270
- Hand Delivery: 830 MoDOT Drive, Jefferson City, MO 65109
- *Instructions:* All comments submitted must include the agency name and Application Number for this public notice. For detailed instructions on submitting comments, see the Public Participation heading of the Supplementary Information section of this notice. All comments received will be open and available for public inspection and MoDOT may publish those comments by any available means.

COMMENTS RECEIVED BECOME MoDOT PUBLIC RECORD

- By submitting any comments to MoDOT, the person authorizes MoDOT to publish those comments by any available means.
- *Docket:* For access to the department's file, to read background documents or comments received, 830 MoDOT Drive, Jefferson City, MO 65109, between 7:30 a.m. and 4:00 p.m., CT, Monday through Friday, except state holidays.

FOR FURTHER INFORMATION CONTACT: Kathy J. Hatfield, Motor Carrier Investigations Specialist, (573) 526-9926, MoDOT Motor Carrier Services Division, PO Box 270, Jefferson City, MO 65102-0270. Office hours are from 7:30 a.m. to 4:00 p.m., CT, Monday through Friday, except state holidays.

SUPPLEMENTARY INFORMATION:

Public Participation

If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard.

Background

The individuals listed in this notice have recently filed applications

requesting MoDOT to issue SPE Certificates to exempt them from the physical qualification requirements relating to vision in 49 CFR 391.41(b)(10), or to diabetes in 49 CFR 391.41(b)(3), which otherwise apply to drivers of CMVs in Missouri intrastate commerce.

Under section 622.555, RSMo Supp. 2014, MoDOT may issue an SPE Certificate, for not more than a two- (2-) year period, if it finds that the applicant has the ability, while operating CMVs, to maintain a level of safety that is equivalent to or greater than the driver qualification standards of 49 CFR 391.41. Upon application, MoDOT may renew an exemption upon expiration.

Accordingly, the agency will evaluate the qualifications of each applicant to determine whether issuing an SPE Certificate will comply with the statutory requirements and will achieve the required level of safety. If granted, the SPE Certificate is only applicable to intrastate transportation wholly within Missouri.

Qualifications of Applicants

Application #245

Applicant's Name & Age: Michael B. Wieberg, 31

Relevant Physical Condition: Insulin-treated diabetes mellitus (ITDM). Mr. Wieberg has uncorrected visual acuity of 20/30 Snellen in his right eye, 20/25 Snellen in his left eye, and 10/25 Snellen in both eyes. He has been ITDM since September 2001, with no glycemic reaction to date.

Relevant Driving Experience: Mr. Wieberg has approximately thirteen (13) years of commercial motor vehicle experience. Mr. Wieberg currently has a Class B CDL license. In addition, he has experience driving personal vehicle(s) daily.

Doctor's Opinion & Date: Following an examination, in February 2015, a board-certified endocrinologist certified his condition would not adversely affect his ability to operate a commercial motor vehicle safely.

Traffic Accidents and Violations: Mr. Wieberg has had no tickets or accidents on record for the previous three (3) years.

Request for Comments

The Missouri Department of Transportation, Motor Carrier Services Division, pursuant to section 622.555, RSMo, and rule 7 CSR 10-25.010, requests public comment from all interested persons on the applications for issuance of Skill Performance Evaluation Certificates described in this notice. We will consider all comments received before the close of business on the closing date indicated earlier in this notice.

Issued on: March 2, 2015

Scott Marion, Motor Carrier Services Director, Missouri Department of Transportation.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review
Committee
Chapter 50—Certificate of Need Program

NOTIFICATION OF REVIEW: APPLICATION REVIEW SCHEDULE

The Missouri Health Facilities Review Committee has initiated review of the applications listed below. A decision is tentatively scheduled for April 21, 2015. These applications are available for public inspection at the address shown below:

Date Filed

Project Number: Project Name City (County)
Cost, Description

03/10/15

#5169 HT: Lester E. Cox Medical Center Springfield (Greene County) \$3,010,903, Replace Linear Accelerator

#5148 NT: Meyer Care Center Higginsville (Lafayette County) \$5,225,261, Renovate/Modernize 40-bed ICF

Any person wishing to request a public hearing for the purpose of commenting on these applications must submit a written request to this effect, which must be received by April 9, 2015. All written requests and comments should be sent to—

Chairman

Missouri Health Facilities Review Committee c/o Certificate of Need Program 3418 Knipp Drive, Suite F PO Box 570 Jefferson City, MO 65102

For additional information contact Karla Houchins, (573) 751-6403.

The Secretary of State is required by sections 347.141 and 359.481, RSMo 2000, to publish dissolutions of limited liability companies and limited partnerships. The content requirements for the one-time publishing of these notices are prescribed by statute. This listing is published pursuant to these statutes. We request that documents submitted for publication in this section be submitted in camera ready 8 1/2" x 11" manuscript by email to dissolutions@sos.mo.gov.

Notice of Corporate
Dissolution
To All Creditors of
And Claimants Against
Steven L. Leonard, P.C.

Steven L. Leonard, P.C., a Missouri Professional Corporation, f/k/a Leonard & Lenze, P.C. f/k/a Haller, Leonard & Lenze, P.C. f/k/a Haller, Leonard & Tripp, Inc. filed Articles of Dissolution with the Missouri Secretary of State effective December 31, 2014.

Any claims against the Corporation may be sent to:
Steven L. Leonard, P.O. Box 50011, St. Louis,
Missouri 63105. Claims must include the following:
The name, address and telephone number of the claimant;
the amount claimed; the date on which the claim arose;
the basis for the claim; and documentation in support
of the claim.

All claims will be barred unless a proceeding to enforce the claim is commenced within two (2) years after publication of this notice.

NOTICE OF WINDING UP OF LIMITED LIBAILITY COMPANY TO ALL CREDITORS OF AND CLAIMNTS AGAINST DOUBLE H APARTMENTS, LLC

Double H Apartments, LLC, a Missouri limited liability company (the "Company"), filed a Notice of Winding Up with the Missouri Secretary of State Office on January 11, 2015. The Company requests that all persons or organizations with claims against it present them immediately by mail to: Thomas Herigon, 10805 Route B, Jefferson City, Missouri 65101. All claims must include (1) name, address, and phone number of the claimant; (2) the amount claimed; (3) the basis for the claim; (4) the date(s) on which the event(s) on which the claim is based occurred; and (5) documentation supporting the claim. A claim against the Company will be barred unless a proceeding to enforce the claim is commenced within three years after publication if this notice.

NOTICE OF WINDING UP AND DISSOLUTION OF LIMITED LIABILITY COMPANY TO ALL CREDITORS OF AND CLAIMANTS AGAINST AXIUS FINANCIAL-KANSAS CITY, LLC

Effective February 19, 2015, Axius Financial-Kansas City, LLC, a Missouri limited liability company (the "Company"), filed its Notice of Winding Up and Articles of Termination with the Missouri Secretary of State. The Company requests that all persons and organizations who have claims against the Company present them immediately by letter to Axius Financial, LLC, 2085 Bluestone Drive, St. Charles, MO 63303. All claims <u>must</u> include the name and address of the claimant, the amount claimed, the basis for and a description of the claim, and include copies of any supporting documentation. Any and all claims against the Company will be barred unless a proceeding to enforce such claim is commenced within three (3) years after the publication of this notice.

NOTICE OF WINDING UP AND DISSOLUTION OF LIMITED LIABILITY COMPANY TO ALL CREDITORS OF AND CLAIMANTS AGAINST AXIUS FINANCIAL-CHICAGO, LLC

Effective February 19, 2015, Axius Financial-Chicago, LLC, a Missouri limited liability company (the "Company"), filed its Notice of Winding Up and Articles of Termination with the Missouri Secretary of State. The Company requests that all persons and organizations who have claims against the Company present them immediately by letter to Axius Financial, LLC, 2085 Bluestone Drive, St. Charles, MO 63303. All claims <u>must</u> include the name and address of the claimant, the amount claimed, the basis for and a description of the claim, and include copies of any supporting documentation. Any and all claims against the Company will be barred unless a proceeding to enforce such claim is commenced within three (3) years after the publication of this notice.

April 1, 2015 Vol. 40, No. 7

Rule Changes Since Update to Code of State Regulations

MISSOURI REGISTER

This cumulative table gives you the latest status of rules. It contains citations of rulemakings adopted or proposed after deadline for the monthly Update Service to the *Code of State Regulations*, citations are to volume and page number in the *Missouri Register*, except for material in this issue. The first number in the table cite refers to the volume number or the publication year—39 (2014) and 40 (2015). MoReg refers to *Missouri Register* and the numbers refer to a specific *Register* page, R indicates a rescission, W indicates a withdrawal, S indicates a statement of actual cost, T indicates an order terminating a rule, N.A. indicates not applicable, RAN indicates a rule action notice, RUC indicates a rule under consideration, and F indicates future effective date.

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2 CSR 30-0.020 2 CSR 30-10.010	Animal Health	39 MoReg 1559	39 MoReg 1568	40 MoReg 136	
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2 CSR 70-14.010 2 CSR 70-14.020	Plant Industries	39 MoReg 1639	39 MoReg 1735	This Issue	
2 CSR 70-14.020 2 CSR 70-14.030	Plant Industries Plant Industries	39 MoReg 1640 39 MoReg 1641	39 MoReg 1736 39 MoReg 1739	This Issue This Issue	
2 CSR 70-14.040	Plant Industries	39 MoReg 1642	39 MoReg 1742	This Issue	
2 CSR 70-14.050	Plant Industries	39 MoReg 1643	39 MoReg 1744	This IssueW	
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2 CSR 70-14.090	Plant Industries	39 MoReg 1645	39 MoReg 1745	This Issue	
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2 CSR 70-14.110 2 CSR 70-14.120	Plant Industries Plant Industries	39 MoReg 1648 39 MoReg 1648	39 MoReg 1751 39 MoReg 1753	This Issue This Issue	
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2 CSR 70-14.160 2 CSR 70-14.170	Plant Industries Plant Industries	39 MoReg 1651 39 MoReg 1652	39 MoReg 1761 39 MoReg 1764	This Issue This Issue	
2 CSR 70-14.170	Plant Industries	39 MoReg 1653	39 MoReg 1766	This Issue	
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5 CSR 20-700.100 5 CSR 30-640.200	Division of Learning Services Division of Financial and Administrative Services	4	10 MoReg 227 10 MoReg 228		
5 CSR 30-660.080	Division of Financial and Administrative Services		10 MoReg 55		
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6 CSR 10-2.140	DEPARTMENT OF HIGHER EDUCATION Commissioner of Higher Education	3	39 MoReg 1029		
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1 CSR 10-4.010 1 CSR 10-15.010	Cafeteria Plan				
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2 CSR 70-14.005	Preemption of All Ordinances and Rules of Political Subdivisions	.39 MoReg 1638	Oct. 18, 2014	April 15, 2015	
2 CSR 70-14.010	Definitions				
2 CSR 70-14.020	Application for a Cultivation and Production Facility License	.39 MoReg 1640	Oct. 18, 2014	April 15, 2015	
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2 CSR 70-14.100	Requirements for Production, Manufacture, Storage, Transportation, and Testing of Hemp and Hemp Extract	_		-	
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15-01 Appoints Byron M. Watson to the Ferguson Commission to fill the vacancy created by the resignation of Bethany A. Johnson-Javois. Jan. 2, 2015 40 MoReg 173 14-16 Extends Executive Order 14-07 and further orders that the Disparity Study Oversight Review Committee present its report to the governor and commissioner of administration by January 31, 2015. Dec. 24, 2014 40 MoReg 129 14-15 Establishes the "Ferguson Commission" which shall study and recommend ways to make the St. Louis region a stronger, fairer place for everyone to live by studying the following subjects: 1) citizen-law enforcement interactions and relations; 2) racial and ethnic relations; 3) municipal government organization and the municipal court system; and 4) disparities in substantive areas. Nov. 18, 2014 40 MoReg 5 14-14 Declares a state of emergency exists in the state of Missouri and directs the Missouri State Highway Patrol with the St. Louis County Police Department and the St. Louis Metropolitan Police Department to operate as a Unified command and ensure public safety in the City of Ferguson and the St. Louis Region and further orders the Adjutant General to call and order into service such portions of the organized militia as he deems necessary. Nov. 17, 2014 39 MoReg 1811 14-13 Closes state offices Nov. 28, 2014. Oct. 31, 2014 39 MoReg 1811 14-14 Declares a state of emergency exists in the state of Missouri and directs that the Missouri State Emergency Activation Plan be activated. Oct. 22, 2014 39 MoReg 1801 14-10 Terminates Executive Orders 14-08 and 14-09. Sept. 3, 2014 39 MoReg 1636 14-10 Terminates Executive Orders 14-08 and 14-09. Activates the Office of Community Engagement. Sept. 18, 2014 39 MoReg 1666 14-10 Terminates Executive Orders 14-08 and 14-09. Activates the Disparity Study Oversight Review Committee. July 2, 2014 39 MoReg 1566 14-10 Terminates Executive Orders 14-08 and 14-09. Activates the Disparity Study Oversight Review Committee. July 2, 2014 39 MoReg 1564 14-08 Declares a state of emergency exists	Executive							
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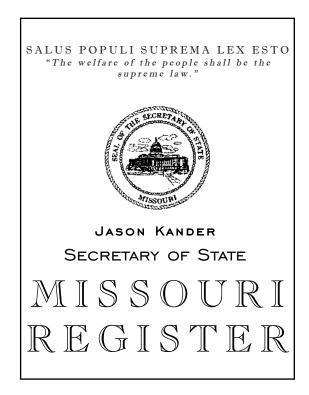
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