KENTUCKY COMMUNITY & TECHNICAL COLLEGE SYSTEM

October 7, 2024

Senator Stephen West
Representative Derek Lewis
Legislative Research Commission
083, Capitol Annex
702 Capitol Avenue
Frankfort, Kentucky 40601

Dear Co-Chairs:

After consideration of the issues raised by 739 KAR 1:060 and 739 KAR 1:070, KCTCS proposes the attached suggested substitutes to these regulations.

Sincerely,

Katherine A. George
Kentucky Community and Technical College System
300 N. Main Street
Versailles, Kentucky 40383

Final – 9/27/2024

SUGGESTED SUBSTITUTE

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM
Board of Regents

739 KAR 1:060. Management of capital construction projects.

RELATES TO: KRS 164A.580
STATUTORY AUTHORITY: KRS 164A.560
NECESSITY, FUNCTION, AND CONFORMITY: KRS 164A.560 ***authorizes[~~permits~~]*** the governing boards of public institutions of higher education to elect to perform financial management functions ***pursuant to[~~per~~]*** KRS 164A.555 ***through[~~to~~]*** 164A.630 by ***[~~issuing~~]*** administrative ***regulation[~~regulations~~]***. This administrative regulation implements the provisions ***established in[~~of~~]*** KRS 164A.580 at the Kentucky Community and Technical College System.

Section 1. Subject to the provisions of KRS 45.750 through 45.800 and 56.870 ***through[~~to~~]*** 56.874, the Kentucky Community and Technical College System Board of Regents elects to adopt the management and administration procedures ***established[~~set forth~~]*** in KRS 164A.580***[~~, Sections 1, 2, 3, 4, 5, 6, 7, and 8~~]***.

CONTACT PERSON: Katie George, Staff Attorney, 300 North Main Street, Versailles, Kentucky 40383, phone 859-256-3242, email katie.george@kctcs.edu.

Final – 9/27/2024

SUGGESTED SUBSTITUTE

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM
Board of Regents

739 KAR 1:070. Contracting for capital construction projects.

RELATES TO: KRS 164A.580, 164A.590, 164A.595, 164A.600
STATUTORY AUTHORITY: KRS 164A.560
NECESSITY, FUNCTION, AND CONFORMITY: KRS 164A.560 ***authorizes[~~permits~~]*** the governing boards of public institutions of higher education to elect to perform financial management functions ***pursuant to[~~per~~]*** KRS 164A.555 ***through[~~to~~]*** 164A.630 by ***[~~issuing~~]*** administrative ***regulation[~~regulations~~]***. This administrative regulation implements the provisions ***established in[~~of~~]*** KRS 164A.580 at the Kentucky Community and Technical College System.

Section 1. ***Subject to the provisions of KRS 164A.560, the[~~The~~]*** Kentucky Community and Technical College System Board of Regents***[~~, under the provisions of KRS 164A.560,~~]*** elects to manage and administer capital construction projects in accordance with ***KRS*** 164A.585 ***through[~~, 164A.590, 164A.595, and~~]*** 164A.600.

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October 11, 2024

Senator Stephen West
Representative Derek Lewis
Legislative Research Commission
083 Capitol Annex
702 Capitol Avenue
Frankfort, KY 40601

Dear Co-Chairs:

After consideration of the issues raised by 806 KAR 17:570, the Department of Insurance proposes the attached suggested substitute to this ordinary regulation.

Sincerely,

Shaun T. Orme, Executive Advisor
Kentucky Department of Insurance
Public Protection Cabinet
500 Mero St, 2 SE 11
Frankfort, KY 40601

Final Version: 10/10/24 at 2:17 p.m.
SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Department of Insurance
Division of Health Life and Managed Care

806 KAR 17:570. Minimum standards for Medicare supplement insurance policies and certificates.

RELATES TO: KRS 304.2-310, 304.2-320, 304.3-240, 304.12-020, 304.14-120, 304.14-500_-_304.14-550, 304.17-311, ***304.17-380, 304.17-383,*** 304.17A-005, 304.18-034, 304.32-275, 304.33-030, 304.38-205, 42***[.]*** C.F.R. 409.87, 45 C.F.R. Part 46, 74 F.R. 18808 (2009), 29 U.S.C. 1002, 42 U.S.C. 426, ***[42 U.S.C.]***1320c-3, 1320d, 1320d-2, ***[42 U.S.C.]***1395_-_1395ggg, ***[42 U.S.C.]***1396, Pub. L. 108-173, 114-10***[, 116-127, 117-328]***

STATUTORY AUTHORITY: KRS 304.2-110(1), 304.14-510, 304.14-525, 304.32-250, 304.38-150

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) authorizes the commissioner of the Department of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code, as ***established[defined]*** in KRS 304.1-010. KRS 304.14-510 authorizes the commissioner of the Department of Insurance to promulgate administrative regulations establishing minimum standards for Medicare supplement insurance policies. KRS 304.32-250 authorizes the commissioner of the Department of Insurance to promulgate administrative regulations necessary for the proper administration of KRS 304.32. KRS 304.38-150 authorizes the commissioner of the Department of Insurance to promulgate administrative regulations necessary for the proper administration of KRS Chapter 304.38. This administrative regulation establishes minimum standards for Medicare supplement insurance policies and certificates.

Section 1. Definitions.

(1) "Applicant" is defined by KRS 304.14-500(1).

(2) "Bankruptcy" means a petition for declaration of bankruptcy filed by or filed against a Medicare Advantage organization that is not an insurer and has ceased doing business in the state.

(3) "Certificate" is defined by KRS 304.14-500(2).

(4) "Certificate form" means the form on which the certificate is delivered or issued for delivery by the insurer.

(5) "Commissioner" means Commissioner of the Department of Insurance.

(6) "Compensation" means monetary or non-monetary remuneration of any kind relating to the sale or renewal of the policy or certificate including bonuses, gifts, prizes, awards, and finder's fees.

(7) "Complaint" means any dissatisfaction expressed by an individual concerning a Medicare Select insurer or its network providers.

(8) "Continuous period of creditable coverage" means the period during which an individual was covered by creditable coverage, if during the period of the coverage the individual had no breaks in coverage greater than sixty-three (63) days.

(9) "Creditable coverage" is defined by KRS 304.17A-005(8).

(10) "Employee welfare benefit plan" means a plan, fund, or program of employee benefits as defined ***by[in]*** 29 U.S.C. Section 1002 of the Employee Retirement Income Security Act.

(11) "Family member" means, with respect to an individual, any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual.

(12) "Genetic information" means, except for information relating to the sex or age:

(a) With respect to any individual:

1. Information about the individual's genetic tests, the genetic tests of family members of the individual, and the manifestation of a disease or disorder in family members of the individual; or

2. Any request for, or receipt of, genetic services, or participation in clinical research ***that[~~which~~]*** includes genetic services, by the individual or any family member of the individual***; and[.]***

(b) Any reference to genetic information concerning an individual or family member of an individual who is a pregnant woman, including:

1. Genetic information of any fetus carried by a pregnant woman; or

2. With respect to an individual or family member utilizing reproductive technology, genetic information of any embryo legally held by an individual or family member.

(13) "Genetic services" means a genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education.

(14) "Genetic test":

(a) Means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detect genotypes, mutations, or chromosomal changes; ***and***

(b) ***Does not mean[~~Except for~~]*** an analysis of proteins or metabolites that:

1. Does not detect genotypes, mutations, or chromosomal changes; or

2.[~~an analysis of proteins or metabolites that~~] Is directly related to a manifested disease, disorder, or pathological condition that ***could[~~may~~]*** reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(15) "Grievance" means dissatisfaction expressed in writing by an individual insured under a Medicare Select policy or certificate with the administration, claims practices, or provision of services concerning a Medicare Select insurer or its network providers.

(16) "Health care expenses" means expenses of health maintenance organizations associated with the delivery of health care services, which expenses are analogous to incurred losses of insurers.

(17) "Insolvency" is defined by KRS 304.33-030(12)[~~(18)~~].

(18) "Insurer" means insurance companies, fraternal benefit societies, health care service plans, health maintenance organizations, and any other entity delivering or issuing for delivery in ***Kentucky.[~~this state~~]*** Medicare supplement policies or certificates.

(19) "Insurer of a Medicare supplement policy or certificate" means an insurer or third-party administrator, or other person acting for or on behalf of the insurer.

(20) "Medicare" is defined by KRS 304.14-500(4).

(21) "Medicare Advantage plan" means a plan of coverage for health benefits under Medicare Part C as defined ***by[~~in~~]*** 42 U.S.C. 1395w-28(b)(1), including:

(a) A coordinated care plan, which provides health care services, including***[~~the following~~]***:

1. A health maintenance organization plan, with or without a point-of-service option;

2. A plan offered by provider-sponsored organization; and

3. A preferred provider organization plan;

(b) A medical savings account plan coupled with a contribution into a Medicare Advantage plan medical savings account; and

(c) A Medicare Advantage private fee-for-service plan.

(22) "Medicare Select insurer" means an insurer offering, or seeking to offer, a Medicare Select policy or certificate.

(23) "Medicare Select policy" or "Medicare Select certificate" means, respectively, a Medicare supplement policy or certificate that contains restricted network provisions.

(24) "Medicare supplement policy" is defined by KRS 304.14-500(3).

(25) "Network provider" means a provider of health care, or a group of providers of health care, that has entered into a written agreement with the insurer to provide benefits insured under a Medicare Select policy.

(26) "Non-age eligible person" is defined by KRS 304.14-525(1)(a).

(27)[~~(26)~~] "Policy form" means the form on which the policy is delivered or issued for delivery by the insurer.

(28)[~~(27)~~] "Pre-standardized Medicare supplement benefit plan[,]", "Pre-Standardized benefit plan[,]", or "Pre-standardized plan" means a group or individual policy of Medicare supplement insurance issued prior to January 1, 1992.

(29)[~~(28)~~] "Restricted network provision" means any provision that conditions the payment of benefits, in whole or in part, on the use of network providers.

(30)[~~(29)~~] "Secretary" means the Secretary of the U.S. Department of Health and Human Services.

(31)[~~(30)~~] "Service area" means the geographic area approved by the commissioner***, as established in Section 12 of this administrative regulation,*** within which an insurer is authorized to offer a Medicare Select policy.

(32)[~~(31)~~] "Structure, language, designation, and format" means style, arrangement, and overall content of a benefit.

(33)[~~(32)~~] "Underwriting purposes" means:

(a) Rules for, or determination of, eligibility, including enrollment and continued eligibility, for benefits under the policy;

(b) The computation of premium or contribution amounts under the policy;

(c) The application of any pre-existing condition exclusion under the policy; and

(d) Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(34) "Weighted average aged premium rate" is defined by KRS 304.14-525(1)(b).

(35)[~~(33)~~] "1990 Standardized Medicare supplement benefit plan[,]", "1990 Standardized benefit plan[,]", or "1990 plan" means a group or individual policy of Medicare supplement insurance issued on or after January 1, 1992, with an effective date for coverage prior to June 1, 2010 including Medicare supplement insurance policies and certificates renewed on or after that date that are not replaced by the insurer at the request of the insured.

(36)[~~(34)~~] "2010 Standardized Medicare supplement benefit plan[,]", "2010 Standardized benefit plan[,]", or "2010 plan" means a group or individual policy of Medicare supplement insurance issued with an effective date for coverage on or after June 1, 2010.

Section 2. Purpose. The purpose of this administrative regulation shall be to:

(1) Provide for the reasonable standardization of coverage and simplification of terms and benefits of Medicare supplement policies;

(2) Facilitate public understanding and comparison of the policies;

(3) Eliminate provisions contained in the policies that may be misleading or confusing in connection with the purchase of the policies or with the settlement of claims; and

(4) Provide for full disclosures in the sale of accident and sickness insurance coverage to persons eligible for Medicare.

Section 3. Applicability and Scope.

(1) Except as provided in Sections 6, 15, 16, 19, and 24, the requirements of this administrative regulation shall apply to:

(a) All Medicare supplement policies delivered or issued for delivery in Kentucky on or after January 4, 2010; and

(b) All certificates issued under group Medicare supplement policies, which certificates have been delivered or issued for delivery in Kentucky.

(2) This administrative regulation shall not apply to a policy or contract:

(a) Of one (1) or more employers or labor organizations, or of the trustees of a fund established by one (1) or more employers or labor organizations, or combination thereof;

(b) For employees or former employees, or a combination thereof; or

(c) For members or former members, or a combination thereof, of the labor organizations.

Section 4. Policy Definitions and Terms. A policy or certificate shall not be advertised, solicited, or issued for delivery in ***Kentucky~~[this state]~~*** as a Medicare supplement policy or certificate unless the policy or certificate contains definitions or terms that conform to this section.

(1) "Accident", "accidental injury", or "accidental means" shall be defined to employ "result" language and shall not include words that establish an accidental means test or use words including "external, violent, visible wounds", or similar words of description or characterization.

(a) The definition shall not be more restrictive than the following: "Injury or injuries for which benefits are provided means accidental bodily injury sustained by the insured person, which is the direct result of an accident, independent of disease or bodily infirmity or any other cause, and occurs while insurance coverage is in force."

(b) The definition may provide that injuries shall not include injuries for which benefits are provided or available under any workers' compensation, employer's liability or similar law, or motor vehicle no-fault plan, unless the definition is prohibited by law.

(2) "Activities of daily living" shall include bathing, dressing, personal hygiene, transferring, eating, ambulating, assistance with drugs that are normally self-administered, and changing bandages or other dressings.

(3) "At-home recovery visit" shall mean the period of a visit required to provide at home recovery care, without limit on the duration of the visit, except each consecutive four (4) hours in a twenty-four (24) hour period of services provided by a care provider shall be one (1) visit.

(4) "Benefit period" or "Medicare benefit period" shall not be defined more restrictively than as defined in the Medicare program.

(5) "Care provider" shall mean a duly qualified or licensed home health aide or homemaker, personal care aide, or nurse provided through a licensed home health care agency or referred by a licensed referral agency or licensed nurses registry.

(6) "Convalescent nursing home", "extended care facility", or "skilled nursing facility" shall not be defined more restrictively than as defined in the Medicare Program.

(7) "Emergency care" shall mean care needed immediately because of an injury or an illness of sudden and unexpected onset.

(8) "Home" shall mean any place used by the insured as a place of residence, if the place would qualify as a residence for home health care services covered by Medicare. A hospital or skilled nursing facility shall not be considered the insured's place of residence.

(9) "Hospital" may be defined in relation to its status, facilities, and available services or to reflect its accreditation by the Joint Commission on Accreditation of Hospitals, but shall not be defined more restrictively than as defined in the Medicare Program.

(10) "Medicare" shall be defined in the policy and certificate. Medicare may be substantially defined as "The Health Insurance for the Aged Act, Title XVIII of the Social Security Amendments of 1965 as Then

Constituted or Later Amended", or "Title I, Part I of Public Law 89-97, as Enacted by the Eighty-Ninth Congress of the United States of America and popularly known as the Health Insurance for the Aged Act, as then constituted and any later amendments or substitutes thereof", or words of similar import.

(11) "Medicare eligible expenses" shall mean expenses of the kinds covered by Medicare Parts A and B, to the extent recognized as reasonable and medically necessary by Medicare.

(12) "Physician" shall not be defined more restrictively than as defined in the Medicare program.

(13) "Preexisting condition" shall not be defined more restrictively than a condition for which medical advice was given or treatment was recommended by or received from a physician within six (6) months before the effective date of coverage.

(14) ***Except as established in this subsection,*** "sickness" shall not be defined to be more restrictive than the following: "Sickness means illness or disease of an insured person ***that~~[which]~~*** first manifests itself after the effective date of insurance and while the insurance is in force." The definition may be further modified to exclude sicknesses or diseases for which benefits are provided under any workers' compensation, occupational disease, employer's liability, or similar law.

Section 5. Policy Provisions.

(1) Except for ***allowed~~[permitted]~~*** preexisting condition clauses as described in Sections 6(2)(a), 7(1)(a), and 8(1) of this administrative regulation, a policy or certificate shall not be advertised, solicited, or issued for delivery in ***Kentucky~~[this state]~~*** as a Medicare supplement policy if the policy or certificate contains limitations or exclusions on coverage that are more restrictive than those of Medicare.

(2) A Medicare supplement policy or certificate shall not:

(a) Contain a probationary or elimination period; or

(b) Use waivers to exclude, limit, or reduce coverage or benefits for specifically named or described preexisting diseases or physical conditions.

(3) A Medicare supplement policy or certificate in force in ***Kentucky~~[the state]~~*** shall not contain benefits that duplicate benefits provided by Medicare.

(4)

(a) ***In accordance with~~[Subject to]~~*** Sections 6(2)(d), (e), and (g), and 7(1)(d) and (e) of this administrative regulation, a Medicare supplement policy with benefits for outpatient prescription drugs in existence prior to January 1, 2006, shall be renewed for current policyholders who do not enroll in Part D at the option of the policyholder.

(b) A Medicare supplement policy with benefits for outpatient prescription drugs shall not be issued after December 31, 2005.

(c) After December 31, 2005, a Medicare supplement policy with benefits for outpatient prescription drugs shall not be renewed after the policyholder enrolls in Medicare Part D unless:

1. The policy is modified to eliminate outpatient prescription coverage for expenses of outpatient prescription drugs incurred after the effective date of the individual's coverage under a Part D plan; and

2. Premiums are adjusted to reflect the elimination of outpatient prescription drug coverage at Medicare Part D enrollment, accounting for any claims paid, if applicable.

Section 6. Minimum Benefit Standards for Pre-Standardized Medicare Supplement Benefit Plan Policies or Certificates Issued for Delivery Prior to January 1, 1992.

(1) A policy or certificate shall not be advertised, solicited, or issued for delivery in Kentucky as a Medicare supplement policy or certificate unless ***the policy or certificate~~[it]~~*** meets or exceeds the ***~~[following]~~***minimum standards ***established in subsections (2) and (3) of this section***, which shall not preclude the inclusion of other provisions or benefits that are not inconsistent with these standards.

(2) General standards. The ***[~~following~~]***standards ***established in paragraphs (a) through (g) of this subsection*** shall apply to Medicare supplement policies and certificates and are in addition to all other requirements of this administrative regulation.

(a) A Medicare supplement policy or certificate shall not exclude or limit benefits for losses incurred more than six (6) months from the effective date of coverage because it involved a preexisting condition, and the policy or certificate shall not define a preexisting condition more restrictively than Section 4(13) of this administrative regulation.

(b) A Medicare supplement policy or certificate shall not indemnify against losses resulting from sickness on a different basis than losses resulting from accidents.

(c) A Medicare supplement policy or certificate shall provide that benefits designed to cover cost sharing amounts under Medicare ***shall[~~will~~]*** be changed automatically to coincide with any changes in the applicable Medicare deductible, copayment, or coinsurance amounts. Premiums may be modified to correspond with the changes.

(d) A "noncancellable[,]", "guaranteed renewable[,]", or "noncancellable and guaranteed renewable" Medicare supplement policy shall not:

1. Provide for termination of coverage of a spouse solely because of the occurrence of an event specified for termination of coverage of the insured, other than the nonpayment of premium; or
2. Be cancelled or nonrenewed by the insurer solely on the grounds of deterioration of health.

(e)

1. An insurer shall not cancel or nonrenew a Medicare supplement policy or certificate for any reason other than nonpayment of premium or material misrepresentation.
2. If a group Medicare supplement insurance policy is terminated by the group policyholder and not replaced as provided in subparagraph 4. of this paragraph[~~paragraph (e)4 of this subsection~~], the insurer shall offer certificate holders an individual Medicare supplement policy with at least the following choices:
   a. An individual Medicare supplement policy currently offered by the insurer having comparable benefits to those contained in the terminated group Medicare supplement policy; and
   b. An individual Medicare supplement policy that provides the benefits as are required to meet the minimum standards as ***established[~~defined~~]*** in Section 8(2) of this administrative regulation.
3. If membership in a group is terminated, the insurer shall:
   a. Offer the certificate holder the conversion opportunities described in subparagraph 2. of this paragraph; or
   b. At the option of the group policyholder, offer the certificate holder continuation of coverage under the group policy.
4. If a group Medicare supplement policy is replaced by another group Medicare supplement policy purchased by the same policyholder, the insurer of the replacement policy shall offer coverage to all persons covered under the old group policy on its date of termination, and coverage under the new group policy shall not result in any exclusion for preexisting conditions that would have been covered under the group policy being replaced.

(f) Termination of a Medicare supplement policy or certificate shall be without prejudice to any continuous loss ***that[~~which~~]*** commenced while the policy was in force, but the extension of benefits beyond the period during which the policy was in force may be predicated upon the continuous total disability of the insured, limited to the duration of the policy benefit period, if any, or to payment of the maximum benefits. Receipt of Medicare Part D benefits shall not be considered in determining a continuous loss.

(g) If a Medicare supplement policy eliminates an outpatient prescription drug benefit as a result of requirements imposed by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, the modified policy shall satisfy the guaranteed renewal requirements of this subsection.

(3) Minimum benefit standards. The following minimum benefit standards shall apply to Medicare supplement policies and certificates and are in addition to all other requirements of this administrative regulation:***[:]***

(a) Coverage of Part A Medicare eligible expenses for hospitalization, to the extent not covered by Medicare from the 61st day through the 90th day in any Medicare benefit period;

(b) Coverage for either all or none of the Medicare Part A inpatient hospital deductible amount;

(c) Coverage of Part A Medicare eligible expenses incurred as daily hospital charges during use of Medicare's lifetime hospital inpatient reserve days;

(d) Upon exhaustion of all Medicare hospital inpatient coverage including the lifetime reserve days, coverage of ninety (90) percent of all Medicare Part A eligible expenses for hospitalization not covered by Medicare ***limited~~[subject]~~*** to a lifetime maximum benefit of an additional 365 days;

(e) Coverage under Medicare Part A for the reasonable cost of the first three (3) pints of blood, or equivalent quantities of packed red blood cells, pursuant to 42 C.F.R. 409.87(a)(2), unless replaced in accordance with 42 C.F.R. 409.87(c)(2) or already paid for under Part B;

(f) Coverage for the coinsurance amount, or in the case of hospital outpatient department services paid under a prospective payment system, the copayment amount, of Medicare eligible expenses under Part B regardless of hospital confinement, ***limited~~[subject]~~*** to a maximum calendar year out-of-pocket amount equal to the Medicare Part B deductible; and

(g) Effective January 1, 1990, coverage under Medicare Part B for the reasonable cost of the first three (3) pints of blood, or equivalent quantities of packed red blood cells, pursuant to 42 C.F.R. 409.87(a)(2), unless replaced in accordance with 42 C.F.R. 409.87(c)(2) or already paid for under Part A, ***limited~~[subject]~~*** to the Medicare deductible amount.

Section 7. Benefit Standards for 1990 Standardized Medicare Supplement Benefit Plan and Policies or Certificates Issued or Delivered on or After January 1, 1992, and With an Effective Date for Coverage Prior to June 1, 2010. The following standards shall apply to all Medicare supplement policies or certificates delivered or issued for delivery in Kentucky on or after January 1, 1992, and with an effective date for coverage prior to June 1, 2010. A policy or certificate shall not be advertised, solicited, delivered, or issued for delivery in ***Kentucky~~[this state]~~*** as a Medicare supplement policy or certificate unless it complies with ***subsections (1) through (4) of this section~~[these benefit standards]~~***.

(1) General Standards. The following standards shall apply to Medicare supplement policies and certificates and ***shall be~~[are]~~*** in addition to all other requirements of this administrative regulation.

(a) A Medicare supplement policy or certificate shall not exclude or limit benefits for losses incurred more than six (6) months from the effective date of coverage because it involved a preexisting condition, and the policy or certificate shall not define a preexisting condition more restrictively than Section 4(13) of this administrative regulation.

(b) A Medicare supplement policy or certificate shall not indemnify against losses resulting from sickness on a different basis than losses resulting from accidents.

(c) A Medicare supplement policy or certificate shall provide that benefits designed to cover cost sharing amounts under Medicare shall be changed automatically to coincide with any changes in the applicable Medicare deductible, copayment, or coinsurance amounts. Premiums may be modified to correspond with the changes.

(d) A Medicare supplement policy or certificate shall not provide for termination of coverage of a spouse solely because of the occurrence of an event specified for termination of coverage of the insured, other than the nonpayment of premium.

(e) Each Medicare supplement policy shall be guaranteed renewable.

1. The insurer shall not cancel or nonrenew the policy solely on health status of the individual.

2. The insurer shall not cancel or nonrenew the policy for any reason other than nonpayment of premium or material misrepresentation.

3. If the Medicare supplement policy is terminated by the group policyholder and is not replaced as provided under subparagraph 5. of this paragraph, the insurer shall offer certificate holders an option to choose an individual Medicare supplement policy which, at the option of the certificate holder ***provides for***:

a. ***[~~Provides for~~]***Continuation of the benefits contained in the group policy; or

b. ***[~~Provides for~~]***Benefits that meet the requirements of this subsection.

4. If an individual is a certificate holder in a group Medicare supplement policy and the individual terminates membership in the group, the insurer shall:

a. Offer the certificate holder the conversion opportunity described in subparagraph 3. of this paragraph; or

b. At the option of the group policyholder, offer the certificate holder continuation of coverage under the group policy.

5. If a group Medicare supplement policy is replaced by another group Medicare supplement policy purchased by the same policyholder, the insurer of the replacement policy shall offer coverage to all persons covered under the old group policy on its date of termination. Coverage under the new policy shall not result in any exclusion for preexisting conditions that would have been covered under the group policy being replaced.

6. If a Medicare supplement policy eliminates an outpatient prescription drug benefit as a result of requirements imposed by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173, the modified policy shall satisfy the guaranteed renewal requirements of this paragraph.

(f) Termination of a Medicare supplement policy or certificate shall be without prejudice to any continuous loss that commenced while the policy was in force, but the extension of benefits beyond the period during which the policy was in force may be conditioned upon the continuous total disability of the insured, limited to the duration of the policy benefit period, if any, or payment of the maximum benefits. Receipt of Medicare Part D benefits shall not be considered in determining a continuous loss.

(g)

1. A Medicare supplement policy or certificate shall provide that benefits and premiums under the policy or certificate shall be suspended at the request of the policyholder or certificate holder for the period, not to exceed twenty-four (24) months, in which the policyholder or certificate holder has applied for and is determined to be entitled to medical assistance under Title XIX of the Social Security Act, 42 U.S.C. 1396 et seq., but only if the policyholder or certificate holder notifies the insurer of the policy or certificate within ninety (90) days after the date the individual becomes entitled to assistance.

2. If suspension occurs and if the policyholder or certificate holder loses entitlement to medical assistance, the policy or certificate shall be automatically reinstituted, effective as of the date of termination of entitlement, as of the termination of entitlement if the policyholder or certificate

holder provides notice of loss of entitlement within ninety (90) days after the date of loss and pays the premium attributable to the period, effective as of the date of termination of entitlement.

3. Each Medicare supplement policy shall provide that benefits and premiums under the policy shall be suspended, for any period ***[~~that may be~~]***provided by 42 U.S.C. 1395ss(q)(5), at the request of the policyholder if the policyholder is entitled to benefits under Section 226[](b) of the Social Security Act, 42 U.S.C. 426(b), and is covered under a "group health plan", as defined ***by[~~in~~]*** Section 1862[](b)(1)(A)(v) of the Social Security Act, 42 U.S.C. 1395y(b)(1)(A)(v). If suspension occurs and if the policyholder or certificate holder loses coverage under the group health plan, the policy shall be automatically reinstituted, effective as of the date of loss of coverage, if the policyholder provides notice of loss of coverage within ninety (90) days after the date of the loss and pays the premium attributable to the period, effective as of the date of termination of enrollment in the group health plan.

4. Reinstitution of coverages as described in subparagraphs 2. and 3. of this paragraph:

a. Shall not provide for any waiting period with respect to treatment of preexisting conditions;

b. Shall provide for resumption of coverage that is substantially equivalent to coverage in effect before the date of suspension. If the suspended Medicare supplement policy provided coverage for outpatient prescription drugs, reinstitution of the policy for Medicare Part D enrollees shall be without coverage for outpatient prescription drugs and shall provide substantially equivalent coverage to the coverage in effect before the date of suspension; and

c. Shall provide for classification of premiums on terms at least as favorable to the policyholder or certificate holder as the premium classification terms that would have applied to the policyholder or certificate holder had the coverage not been suspended.

(h) If an insurer makes a written offer to the Medicare Supplement policyholders or certificate holders of one ***(1)*** or more of its plans, to exchange during a specified period from his or her 1990 Standardized plan, as described in Section 9 of this administrative regulation, to a 2010 Standardized plan, as described in Section 10 of this administrative regulation, the offer and subsequent exchange shall comply with ***subparagraphs 1. through 5. of this paragraph.[~~the following requirements:~~]***

1. An insurer shall not be required to provide justification to the commissioner if the insured replaces a 1990 Standardized policy or certificate with an issue age rated 2010 Standardized policy or certificate at the insured's original issue age. If an insured's policy or certificate to be replaced is priced on an issue age rate schedule at offer, the rate charged to the insured for the new exchanged policy shall recognize the policy reserve buildup, due to the pre-funding inherent in the use of an issue age rate basis, for the benefit of the insured. The method proposed to be used by an insurer shall be filed with the commissioner in accordance with KRS 304.14-120 and 806 KAR 14:007.

2. The rating class of the new policy or certificate shall be the class closest to the insured's class of the replaced coverage.

3. An insurer:

a. Shall not apply new pre-existing condition limitations or a new incontestability period to the new policy for those benefits contained in the exchanged 1990 Standardized policy or certificate of the insured***; and***

b.[~~, but~~] May apply pre-existing condition limitations of no more than six (6) months to any added benefits contained in the new 2010 Standardized policy or certificate not contained in the exchanged policy.

4. The new policy or certificate shall be offered to all policyholders or certificate holders within a given plan, except if the offer or issue would be in violation of state or federal law.

5. An insurer may offer its policyholders or certificate holders the following exchange options:

a. Selected existing plans; or

b. Certain new plans for a particular existing plan.

(2) Standards for basic (core) benefits common to benefit plans A ***through*** ~~***to***~~ J. Every insurer shall make available a policy or certificate including at a minimum the ~~***following***~~ basic "core" package of benefits ***established in paragraphs (a) through (e) of this subsection*** to each prospective insured. An insurer may make available to prospective insureds any of the other Medicare Supplement Insurance Benefit Plans in addition to the basic core package, but not in lieu of it, ***including:***

(a) Coverage of Part A Medicare eligible expenses for hospitalization to the extent not covered by Medicare from the 61st day through the 90th day in any Medicare benefit period;

(b) Coverage of Part A Medicare eligible expenses incurred for hospitalization to the extent not covered by Medicare for each Medicare lifetime inpatient reserve day used;

(c) Upon exhaustion of the Medicare hospital inpatient coverage, including the lifetime reserve days, coverage of 100 percent of the Medicare Part A eligible expenses for hospitalization paid at the applicable prospective payment system (PPS) rate, or other appropriate Medicare standard of payment, ***limited*** ~~***subject***~~ to a lifetime maximum benefit of an additional 365 days;

(d) Coverage under Medicare Parts A and B for the reasonable cost of the first three (3) pints of blood, or equivalent quantities of packed red blood cells, pursuant to 42 C.F.R. 409.87(a)(2), unless replaced in accordance with 42 C.F.R. 409.87(c)(2); and

(e) Coverage for the coinsurance amount or for hospital outpatient department services paid under a prospective payment system, the copayment amount, of Medicare eligible expenses under Part B regardless of hospital confinement, ***limited*** ~~***subject***~~ to the Medicare Part B deductible.

(3) Standards for Additional Benefits. The following additional benefits shall be included in Medicare Supplement Benefit Plans "B" through "J" only as provided by Section 9 of this administrative regulation:

(a) Medicare Part A Deductible, which is coverage for all of the Medicare Part A inpatient hospital deductible amount per benefit period;

(b) Skilled Nursing Facility Care, which is coverage for the actual billed charges up to the coinsurance amount from the 21st day through the 100th day in a Medicare benefit period for posthospital skilled nursing facility care eligible under Medicare Part A;

(c) Medicare Part B Deductible, which is coverage for all of the Medicare Part B deductible amount per calendar year regardless of hospital confinement;

(d) Eighty (80) Percent of the Medicare Part B Excess Charges, which is coverage for eighty (80) percent of the difference between the actual Medicare Part B charge as billed, not to exceed any charge limitation established by the Medicare program, and the Medicare-approved Part B charge;

(e) 100 Percent of the Medicare Part B Excess Charges, which is coverage for all of the difference between the actual Medicare Part B charges as billed, not to exceed any charge limitation established by the Medicare Program or state law, and the Medicare-approved Part B charge;

(f) Basic Outpatient Prescription Drug Benefit which is coverage for fifty (50) percent of outpatient prescription drug charges, after a $250 calendar year deductible, to a maximum of $1,250 in benefits received by the insured per calendar year, to the extent not covered by Medicare. The outpatient prescription drug benefit may be included for sale or issuance in a Medicare supplement policy until January 1, 2006;

(g) Extended Outpatient Prescription Drug Benefit, which is coverage for fifty (50) percent of outpatient prescription drug charges, after a $250 calendar year deductible to a maximum of $3,000 in benefits received by the insured per calendar year, to the extent not covered by Medicare. The outpatient prescription drug benefit may be included for sale or issuance in a Medicare supplement policy until January 1, 2006;

(h) Medically Necessary Emergency Care in a Foreign Country, which is coverage to the extent not covered by Medicare for eighty (80) percent of the billed charges for Medicare eligible expenses for medically necessary emergency hospital, physician, and medical care received in a foreign country, which care would have been covered by Medicare if provided in the United States and which care began during the first sixty (60) consecutive days of each trip outside the United States, ***limited[~~subject~~]*** to a calendar year deductible of $250, and a lifetime maximum benefit of $50,000***;[.]***

(i)

1. Preventive Medical Care Benefit, which is coverage for the following preventive health services not covered by Medicare:

a. An annual clinical preventive medical history and physical examination that may include tests and services from subparagraph 2. of this paragraph and patient education to address preventive health care measures; and

b. Preventive screening tests or preventive services, the selection and frequency of which are determined to be medically appropriate by the attending physician.

2. Reimbursement shall be for the actual charges up to 100 percent of the Medicare approved amount for each service, as if Medicare were to cover the service as identified in American Medical Association Current Procedural Terminology (AMA CPT) codes, to a maximum of $120 annually under this benefit. This benefit shall not include payment for any procedure covered by Medicare***; and[.]***

(j) At-Home Recovery Benefit, which is coverage for services to provide short term, at-home assistance with activities of daily living for those recovering from an illness, injury or surgery.

1. Coverage requirements and limitations.

a. At-home recovery services provided shall be primarily services that assist in activities of daily living.

b. The insured's attending physician shall certify that the specific type and frequency of at-home recovery services are necessary because of a condition for which a home care plan of treatment was approved by Medicare.

c. Coverage shall be limited to:

(i) No more than the number and type of at-home recovery visits certified as necessary by the insured's attending physician. The total number of at-home recovery visits shall not exceed the number of Medicare-approved home health care visits under a Medicare-approved home care plan of treatment;

(ii) The actual charges for each visit up to a maximum reimbursement of forty (40) dollars per visit;

(iii) $1,600 per calendar year;

(iv) Seven (7) visits in any one (1) week;

(v) Care furnished on a visiting basis in the insured's home;

(vi) Services provided by a "care provider***", as defined by[~~ as described in~~]*** Section 4(5) of this administrative regulation;

(vii) At-home recovery visits while the insured is covered under the policy or certificate and not excluded; and

(viii) At-home recovery visits received during the period the insured is receiving Medicare-approved home care services or no more than eight (8) weeks after the service date of the last Medicare-approved home health care visit.

2. Coverage shall be excluded for:

a. Home care visits paid for by Medicare or other government programs; and

b. Care provided by family members, unpaid volunteers, or providers who are not care providers.

(4) Standards for Plans K and L.

(a) Standardized Medicare supplement benefit plan "K" shall consist of***[~~the following~~]***:

1. Coverage of 100 percent of the Part A hospital coinsurance amount for each day used from the 61st through the 90th day in any Medicare benefit period;

2. Coverage of 100 percent of the Part A hospital coinsurance amount for each Medicare lifetime inpatient reserve day used from the 91st through the 150th day in any Medicare benefit period;

3. Upon exhaustion of the Medicare hospital inpatient coverage, including the lifetime reserve days, coverage of 100 percent of the Medicare Part A eligible expenses for hospitalization paid at the applicable prospective payment system (PPS) rate, or other appropriate Medicare standard of payment, subject to a lifetime maximum benefit of an additional 365 days;

4. Medicare Part A Deductible, which is coverage for fifty (50) percent of the Medicare Part A inpatient hospital deductible amount per benefit period until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

5. Skilled Nursing Facility Care, which is coverage for fifty (50) percent of the coinsurance amount for each day used from the 21st day through the 100th day in a Medicare benefit period for posthospital skilled nursing facility care eligible under Medicare Part A until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

6. Hospice Care, which is coverage for fifty (50) percent of cost sharing for all Part A Medicare eligible expenses and respite care until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

7. Coverage for fifty (50) percent, under Medicare Part A or B, of the reasonable cost of the first three (3) pints of blood (or equivalent quantities of packed red blood cells, pursuant to 42 C.F.R. 409.87(a)(2)), unless replaced in accordance with 42 C.F.R. 409.87(c)(2), until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

8. Except for coverage provided in subparagraph 9. of this paragraph, coverage for fifty (50) percent of the cost sharing applicable under Medicare Part B after the policyholder pays the Part B deductible until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

9. Coverage of 100 percent of the cost sharing for Medicare Part B preventive services after the policyholder pays the Part B deductible; and

10. Coverage of 100 percent of all cost sharing under Medicare Parts A and B for the balance of the calendar year after the individual has reached the out-of-pocket limitation on annual expenditures under Medicare Parts A and B of $4,000 in 2006, indexed each year by the appropriate inflation adjustment specified by the secretary.

(b) Standardized Medicare supplement benefit plan "L" shall consist of the ***benefits established in[~~following~~]***:

1. ***[~~The benefits described in~~]***Paragraph (a)1., 2., 3., and 9. of this subsection[~~section~~];

2. ***[~~The benefit described in~~]***Paragraph (a)4. ***through[~~, 5., 6., 7., and~~]*** 8. of this subsection[~~section~~], but substituting seventy-five (75) percent for fifty (50) percent; and

3. ***[~~The benefit described in~~]***Paragraph (a)10. of this section, but substituting $2,000 for $4,000.

Section 8. Benefit Standards for 2010 Standardized Medicare Supplement Benefit Plan Policies or Certificates Issued for Delivery with an Effective Date for Coverage on or After June 1, 2010. The ***[~~following~~]***standards ***established in subsections (1) through (3) of this section*** shall apply to all Medicare supplement policies or certificates delivered or issued for delivery in Kentucky with an effective date for coverage on or after June 1, 2010. A policy or certificate shall not be advertised, solicited, delivered, or issued for delivery in Kentucky as a Medicare supplement policy or certificate unless ***the policy or certificate[it]*** complies with these benefit standards. An insurer shall not offer any 1990

Standardized Medicare supplement benefit plan for sale on or after June 1, 2010. Benefit standards applicable to Medicare supplement policies and certificates issued before June 1, 2010, ***shall*** remain ***in compliance with[~~subject to~~]*** the requirements of Sections 7 and 9 of this administrative regulation.

(1) General Standards. The general standards of Section 7(1)(a) through (g), except 7(1)(e)6., shall apply to all policies ***in this section[~~under Section 8 of this administrative regulation~~]***.

(2) Standards for Basic (Core) Benefits Common to Medicare Supplement Insurance Benefit Plans A, B, C, D, F, High Deductible F, G, M and N. Every insurer of Medicare supplement insurance benefit plans shall make available a policy or certificate including, at a minimum, the ***[~~following~~]***basic "core" package of benefits ***established in paragraphs (a) and (b) of this subsection*** to each prospective insured. An insurer may make available to prospective insureds any of the other Medicare Supplement Insurance Benefit Plans in addition to the basic core package, but not in lieu of it***, including:[:]***

(a) ***[~~The basic core benefits included within~~]***Section 7(2)(a) through (e) of this administrative regulation shall be applied to plans under this section; and

(b) Hospice Care, which is coverage of cost sharing for all Part A Medicare eligible hospice care and respite care expenses.

(3) Standards for Additional Benefits. The following additional benefits shall be included in Medicare supplement benefit Plans B, C, D, F, High Deductible F, G, M, and N as provided by Section 10 of this administrative regulation***:[:]***

(a) Medicare Part A Deductible, which is coverage for 100 percent of the Medicare Part A inpatient hospital deductible amount per benefit period***;[:]***

(b) Medicare Part A Deductible, which is coverage for fifty (50) percent of the Medicare Part A inpatient hospital deductible amount per benefit period***;[:]***

(c) Skilled Nursing Facility Care, which is coverage for the actual billed charges up to the coinsurance amount from the 21st day through the 100th day in a Medicare benefit period for posthospital skilled nursing facility care eligible under Medicare Part A***;[:]***

(d) Medicare Part B Deductible, which is coverage for 100 percent of the Medicare Part B deductible amount per calendar year regardless of hospital confinement***;[:]***

(e) 100 percent of the Medicare Part B Excess Charges, which is coverage for the difference between the actual Medicare Part B charges as billed, not to exceed any charge limitation established by the Medicare program, and the Medicare-approved Part B charge***; and[:]***

(f) Medically Necessary Emergency Care in a Foreign Country, which is coverage to the extent not covered by Medicare for eighty (80) percent of the billed charges for Medicare-eligible expenses for medically necessary emergency hospital, physician, and medical care received in a foreign country, which care would have been covered by Medicare if provided in the United States and which care began during the first sixty (60) consecutive days of each trip outside the United States ***limited[~~subject~~]*** to a calendar year deductible of $250, and a lifetime maximum benefit of $50,000.

Section 9. Standard Medicare Supplement Benefit Plans for 1990 Standardized Medicare Supplement Benefit Plan Policies or Certificates Issued for Delivery on or After January 1, 1992, and with an Effective Date for Coverage Prior to June 1, 2010.

(1) An insurer shall make available to each prospective policyholder and certificate holder, a policy form or certificate form containing only the basic core benefits, as ***established[~~defined~~]*** in Section 7(2) of this administrative regulation.

(2) Groups, packages, or combinations of Medicare supplement benefits other than those listed in this section shall not be offered for sale in Kentucky, except as may be permitted in subsection (7) of this section and Section 11 of this administrative regulation.

(3) Benefit plans shall be uniform in structure, language, designation, and format to the standard benefit plans "A" through "L" listed in this section and conform to the definitions in Section 1 of this administrative regulation. Each benefit shall be structured in accordance with the format provided in Section[~~Sections~~] 7(2) and [~~7~~](3) or 7(4) of this administrative regulation and shall list the benefits in the order shown in this section.

(4) An insurer may use, in addition to the benefit plan designations required in subsection (3) of this section, other designations to the extent ***allowed[~~permitted~~]*** by law.

(5) Make-up of benefit plans.***[:]***

(a) Standardized Medicare supplement benefit Plan "A" shall be limited to the basic (core) benefits common to all benefit plans, as described in Section 7(2) of this administrative regulation.

(b) Standardized Medicare supplement benefit Plan "B" shall include only the***[~~following: The~~]*** core benefit as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible as described in Section 7(3)(a).

(c) Standardized Medicare supplement benefit Plan "C" shall include only the***[~~following: The~~]*** core benefit as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, skilled nursing facility care, Medicare Part B deductible and medically necessary emergency care in a foreign country as described in Section[~~Sections~~] 7(3)(a), (b), (c), and (h), respectively.

(d) Standardized Medicare supplement benefit Plan "D" shall include only the***[~~following: The~~]*** core benefit, as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, skilled nursing facility care, medically necessary emergency care in a[~~an~~] foreign country and the at-home recovery benefit as described in Section[~~Sections~~] 7(3)(a), (b), (h), and (j), respectively.

(e) Standardized Medicare supplement benefit Plan "E" shall include only the***[~~following: The~~]*** core benefit as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, skilled nursing facility care, medically necessary emergency care in a foreign country and preventive medical care as described in Section[~~Sections~~] 7(3)(a), (b), (h), and (i), respectively.

(f) Standardized Medicare supplement benefit Plan "F" shall include only the***[~~following: The~~]*** core benefit as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, the skilled nursing facility care, the Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as described in Section 7(3)(a), (b), (c), (e), and (h), respectively.

(g) Standardized Medicare supplement benefit high deductible Plan "F" shall include only the following: 100 percent of covered expenses following the payment of the annual high deductible Plan "F" deductible. The covered expenses shall include the core benefits as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, skilled nursing facility care, the Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as described in Section 7(3)(a), (b), (c), (e), and (h), respectively. The annual high deductible Plan "F" deductible shall consist of out-of-pocket expenses, other than premiums, for services covered by the Medicare supplement Plan "F" policy, and shall be in addition to any other specific benefit deductibles. The annual high deductible Plan "F" deductible shall be $1,500 for 1998 and 1999, and shall be based on the calendar year. It shall be adjusted annually thereafter by the secretary to reflect the change in the Consumer Price Index for all urban consumers for the twelve-month period ending with August of the preceding year, and rounded to the nearest multiple of ten (10) dollars.

(h) Standardized Medicare supplement benefit Plan "G" shall include only the***[~~following: The~~]*** core benefit as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, skilled nursing facility care, eighty (80) percent of the Medicare Part B excess charges,

medically necessary emergency care in a foreign country, and the at-home recovery benefit as described in Section 7(3)(a), (b), (d), (h), and (j), respectively.

(i) Standardized Medicare supplement benefit Plan "H" shall consist of only the ***[~~following: The~~]*** core benefit as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, skilled nursing facility care, basic prescription drug benefit, and medically necessary emergency care in a foreign country as described in Section 7(3)(a), (b), (f), and (h), respectively. The outpatient prescription drug benefit shall not be included in a Medicare supplement policy sold after December 31, 2005.

(j) Standardized Medicare supplement benefit Plan "I" shall consist of only the ***[~~following: The~~]*** core benefit as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, skilled nursing facility care, 100 percent of the Medicare Part B excess charges, basic prescription drug benefit, medically necessary emergency care in a foreign country, and at-home recovery benefit as described in Section 7(3)(a), (b), (e), (f), (h), and (j), respectively. The outpatient prescription drug benefit shall not be included in a Medicare supplement policy sold after December 31, 2005.

(k) Standardized Medicare supplement benefit Plan "J" shall consist of only the ***[~~following: The~~]*** core benefit as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, skilled nursing facility care, Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, extended prescription drug benefit, medically necessary emergency care in a foreign country, preventive medical care, and at-home recovery benefit as described in Section 7(3)(a), (b), (c), (e), (g), (h), (i), and (j), respectively. The outpatient prescription drug benefit shall not be included in a Medicare supplement policy sold after December 31, 2005.

(l) Standardized Medicare supplement benefit high deductible Plan "J" shall consist of only the following: 100 percent of covered expenses following the payment of the annual high deductible Plan "J" deductible. The covered expenses shall include the core benefits as described in Section 7(2) of this administrative regulation, plus the Medicare Part A deductible, skilled nursing facility care, Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, extended outpatient prescription drug benefit, medically necessary emergency care in a foreign country, preventive medical care benefit, and at-home recovery benefit as described in Section 7(3)(a), (b), (c), (e), (g), (h), (i) and (j), respectively. The annual high deductible Plan "J" deductible shall consist of out-of-pocket expenses, other than premiums, for services covered by the Medicare supplement Plan "J" policy, and shall be in addition to any other specific benefit deductibles. The annual deductible shall be $1,500 for 1998 and 1999, and shall be based on a calendar year. It shall be adjusted annually thereafter by the secretary to reflect the change in the Consumer Price Index for all urban consumers for the twelve (12) [-]month period ending with August of the preceding year, and rounded to the nearest multiple of ten (10) dollars. The outpatient prescription drug benefit shall not be included in a Medicare supplement policy sold after December 31, 2005.

(6) Design of two (2) Medicare supplement plans mandated by The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), Pub. L. 108-173.

(a) Standardized Medicare supplement benefit plan "K" shall consist of only those benefits described in Section 7(4)(a) of this administrative regulation.

(b) Standardized Medicare supplement benefit plan "L" shall consist of only those benefits described in Section 7(4)(b) of this administrative regulation.

(7)***(a)*** New or Innovative Benefits: An insurer may, with the prior approval of the commissioner ***as established in KRS 304.14-120, 304.14-130, and 304.14-510***, offer policies or certificates with new

or innovative benefits in addition to the benefits provided in a policy or certificate that complies with the applicable standards. The new or innovative benefits may include benefits that are:

1. Appropriate to Medicare supplement insurance;

2.[,] New, ***[~~or~~]***innovative, ***or not available;***

3.[, ~~Not available~~] Cost-effective;***[,]*** and

4. Offered in a manner that is consistent with the goal of simplification of Medicare supplement policies.

(b) After December 31, 2005, the innovative benefit shall not include an outpatient prescription drug benefit.

Section 10. Standard Medicare Supplement Benefit Plans for 2010 Standardized Medicare Supplement Benefit Plan Policies or Certificates with an Effective Date for Coverage on or After June 1, 2010. The following standards shall apply to all Medicare supplement policies or certificates with an effective date for coverage in this state on or after June 1, 2010. A policy or certificate shall not be advertised, solicited, delivered, or issued for delivery in Kentucky as a Medicare supplement policy or certificate unless ***the policy or certificate[it]*** complies with these benefit plan standards. Benefit plan standards applicable to Medicare supplement policies and certificates issued before June 1, 2010, shall remain ***in compliance with[~~subject to~~]*** the requirements of Sections[~~Section~~] 7 and 9 of this administrative regulation.

(1)

(a) An insurer shall make available to each prospective policyholder and certificate holder, a policy form or certificate form containing only the basic (core) benefits, as described in Section 8(2) of this administrative regulation.

(b) If an insurer makes available any of the additional benefits described in Section 8(3), or offers standardized benefit Plans K or L, as described in subsection (5)(h) and (i) of this section[~~Section 10(5)(h) and (i) of this administrative regulation~~], then the insurer shall make available to each prospective policyholder and certificate holder, in addition to a policy form or certificate form with only the basic (core) benefits as described in paragraph (a) of this subsection of this section, a policy form or certificate form containing either standardized benefit Plan C, as described in subsection (5)(c) of this section[~~Section 10(5)(c) of this administrative regulation~~], or standardized benefit Plan F, as described subsection (5)(e) of this section[~~Section 10(5)(c) of this administrative regulation~~].

(2) Groups, packages, or combinations of Medicare supplement benefits other than those listed in this section shall not be offered for sale in this state, except as ***established[~~may be permitted~~]*** in subsection (6) of this section[~~Section 10(6)~~] and in Section 12 of this administrative regulation.

(3) Benefit plans shall be uniform in structure, language, designation, and format to the standard benefit plans listed in this subsection and conform to the definitions in Section 1 of this administrative regulation. Each benefit shall be structured in accordance with the format provided in Section[~~Sections~~] 8(2) and [~~8~~](3) of this administrative regulation; or, in the case of plans K or L, in subsection(5)(h) or (i) of this section and list the benefits in the order shown.

(4) In addition to the benefit plan designations required in subsection (3) of this section, an insurer may use other designations if approved by the commissioner in accordance with subsection (6) of this section.

(5) 2010 Standardized Benefit Plans.***[:]***

(a) Standardized Medicare supplement benefit Plan A shall include only the ***[~~following: The~~]***basic (core) benefits as described in Section 8(2) of this administrative regulation.

(b) Standardized Medicare supplement benefit Plan B shall include only the ***[following: The]***basic (core) benefit as described in Section 8(2) of this administrative regulation, plus 100 percent of the Medicare Part A deductible as described in Section 8(3)(a) of this administrative regulation.

(c) Standardized Medicare supplement benefit Plan C shall include only the ***[following: The]***basic (core) benefit as described in Section 8(2) of this administrative regulation, plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, 100 percent of the Medicare Part B deductible, and medically necessary emergency care in a foreign country as described in Section 8(3)(a), (c), (d), and (f) of this administrative regulation, respectively.

(d) Standardized Medicare supplement benefit Plan D shall include only the ***[following: The]***basic (core) benefit, as described in Section 8(2) of this administrative regulation, plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, and medically necessary emergency care in a[an] foreign country as described in Section[Sections] 8(3)(a), (c), and (f) of this administrative regulation, respectively.

(e) Standardized Medicare supplement Plan F shall include only the ***[following: The]***basic (core) benefit as described in Section 8(2) of this administrative regulation, plus 100 percent of the Medicare Part A deductible, the skilled nursing facility care, 100 percent of the Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as described in Section[Sections] 8(3)(a), (c), (d), (e), and (f), respectively.

(f) Standardized Medicare supplement Plan High Deductible F shall include only the following: 100 percent of covered expenses following the payment of the annual deductible set forth in subparagraph 2. of this paragraph[of this subsection].

1. The basic (core) benefit as described in Section 8(2) of this administrative regulation, plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, 100 percent of the Medicare Part B deductible, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as described in Section[Sections] 8(3)(a), (c), (d), (e), and (f) of this administrative regulation, respectively.

2. The annual deductible in High Deductible Plan F shall consist of out-of-pocket expenses, other than premiums, for services covered by Plan F, and shall be in addition to any other specific benefit deductibles. The basis for the deductible shall be $1,500 and shall be adjusted annually from 1999 by the Secretary of the U.S. Department of Health and Human Services to reflect the change in the Consumer Price Index for all urban consumers for the twelve (12) month period ending with August of the preceding year, and rounded to the nearest multiple of ten (10) dollars.

(g)

1. Standardized Medicare supplement benefit Plan G shall include only the ***[following: The]***basic (core) benefit as described in Section 8(2) of this administrative regulation, plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, 100 percent of the Medicare Part B excess charges, and medically necessary emergency care in a foreign country as described in Section[Sections] 8(3)(a), (c), (e), and (f), respectively.

2. Beginning January 1, 2020, the standardized benefit plans described in Section 11[(11)](1)(d) of this administrative regulation (Redesignated Plan G High Deductible) may be offered to any individual who was eligible for Medicare prior to January 1, 2020.

(h) Standardized Medicare supplement Plan K is mandated by The Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173, and shall include only the***[following]***:

1. Part A Hospital Coinsurance 61st through 90th days: Coverage of 100 percent of the Part A hospital coinsurance amount for each day used from the 61st through the 90th day in any Medicare benefit period;

2. Part A Hospital Coinsurance, 91st through 150th days: Coverage of 100 percent of the Part A hospital coinsurance amount for each Medicare lifetime inpatient reserve day used from the 91st through the 150th day in any Medicare benefit period;

3. Part A Hospitalization After 150 Days: Upon exhaustion of the Medicare hospital inpatient coverage, including the lifetime reserve days, coverage of 100 percent of the Medicare Part A eligible expenses for hospitalization paid at the applicable prospective payment system (PPS) rate, or other appropriate Medicare standard of payment, ***with*** ~~***[subject to]***~~ a lifetime maximum benefit of an additional 365 days;

4. Medicare Part A Deductible: Coverage for fifty (50) percent of the Medicare Part A inpatient hospital deductible amount per benefit period until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

5. Skilled Nursing Facility Care: Coverage for fifty (50) percent of the coinsurance amount for each day used from the twenty-first (21) day through the 100th day in a Medicare benefit period for posthospital skilled nursing facility care eligible under Medicare Part A until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

6. Hospice Care: Coverage for fifty (50) percent of cost sharing for all Part A Medicare eligible expenses and respite care until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

7. Blood: Coverage for fifty (50) percent, under Medicare Part A or B, of the reasonable cost of the first three (3) pints of blood, or equivalent quantities of packed red blood cells, as described under 42 C.F.R. 409.87(a)(2) unless replaced in accordance with 42 C.F.R. 409.87(c)(2) until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

8. Part B Cost Sharing: Except for coverage provided in subparagraph 9. of this paragraph, coverage for fifty (50) percent of the cost sharing applicable under Medicare Part B after the policyholder pays the Part B deductible until the out-of-pocket limitation is met as described in subparagraph 10. of this paragraph;

9. Part B Preventive Services: Coverage of 100 percent of the cost sharing for Medicare Part B preventive services after the policyholder pays the Part B deductible; and

10. Cost Sharing After Out-of-Pocket Limits: Coverage of 100 percent of all cost sharing under Medicare Parts A and B for the balance of the calendar year after the individual has reached the out-of-pocket limitation on annual expenditures under Medicare Parts A and B of $4,000 in 2006, indexed each year by the appropriate inflation adjustment specified by the Secretary of the U.S. Department of Health and Human Services.

(i) Standardized Medicare supplement Plan L is mandated by The Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173, and shall include only the ***benefits established in*** ~~***[following]***~~:

1. ~~***[The benefits described in]***~~Paragraph(h)1., 2., 3., and 9. of this subsection;

2. ~~***[The benefit described in]***~~Paragraph(h)4. ***through*** ~~***[, 5., 6., 7., and]***~~ 8. of this subsection, but substituting seventy-five (75) percent for fifty (50) percent; and

3. ~~***[The benefit described in]***~~Paragraph(h)10. of this subsection, but substituting $2,000 for $4,000.

(j) Standardized Medicare supplement Plan M shall include only the ~~***[following: The]***~~basic core benefit as described in Section 8(2) of this administrative regulation, plus fifty (50) percent of the Medicare Part A deductible, skilled nursing facility care, and medically necessary emergency care in a foreign country as described in Section[~~Sections~~] 8(3)(a), (c) and (f) of this administrative regulation, respectively.

(k) Standardized Medicare supplement Plan N shall include only the ***[~~following: The~~]***basic core benefit as described in Section 8(2) of this administrative regulation, plus 100 percent of the Medicare Part A deductible, skilled nursing facility care, and medically necessary emergency care in a foreign country as described in Section[~~Sections~~] 8(3)(a), (c) and (f) of this administrative regulation, respectively, with copayments in the following amounts:

1. The lesser of twenty (20) dollars or the Medicare Part B coinsurance or copayment for each covered health care provider office visit, including visits to medical specialists; and
2. The lesser of fifty (50) dollars or the Medicare Part B coinsurance or copayment for each covered emergency room visit***[; however,]*** This copayment shall be waived if the insured is admitted to any hospital and the emergency visit is subsequently covered as a Medicare Part A expense.

(6)***(a)*** New or Innovative Benefits: An insurer may, with the prior approval of the commissioner ***as established in KRS 304.14-120, 304.14-130, and 304.14-510***, offer policies or certificates with new or innovative benefits, in addition to the standardized benefits provided in a policy or certificate that complies with the applicable standards of this section. The new or innovative benefits shall include only benefits that are:

1. Appropriate to Medicare supplement insurance;

2.[~~, are~~] New, ***[~~or~~]***innovative, ***or[~~are~~]*** not available;***[~~,~~]*** and

3.[~~are~~] Cost-effective.

(b) Approval of new or innovative benefits shall not adversely impact the goal of Medicare supplement simplification.

(c) New or innovative benefits shall not include an outpatient prescription drug benefit.

(d) New or innovative benefits shall not be used to change or reduce benefits, including a change of any cost-sharing provision, in any standardized plan.

Section 11. Standard Medicare Supplement Benefit Plans for 2020 Standardized Medicare Supplement Benefit Plan Policies or Certificates Issued for Delivery to individuals Newly Eligible for Medicare on or After January 1, 2020. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. 114-10, requires the ***[~~following~~]***standards ***established in subsections (1) through (4) of this section*** to be applicable to all Medicare supplement policies or certificates delivered or issued for delivery in this state to individuals newly eligible for Medicare on or after January 1, 2020. A policy or certificate providing coverage of the Medicare Part B deductible shall not be advertised, solicited, delivered, or issued for delivery in this state as a Medicare supplement policy or certificate to individuals newly eligible for Medicare on or after January 1, 2020. All policies shall comply with the ***[~~following~~]***benefit standards ***established in this section***. Benefit plan standards applicable to Medicare supplement policies and certificates issued to individuals eligible for Medicare before January 1, 2020, shall remain ***limited[~~subject~~]*** to the requirements of Sections 9 and 10 of this administrative regulation.

(1) Benefit Requirements. The standards and requirements of Section 10 ***of this administrative regulation*** shall apply to all Medicare supplement policies and certificates delivered or issued for delivery to individuals newly eligible for Medicare on or after January 1, 2020, with the ***[~~following~~]***exceptions ***established in paragraphs (a) through (d) of this subsection.[:]***

(a) Standardized Medicare supplement benefit Plan C ***shall be[is]*** redesignated as Plan D and shall provide the benefits contained in Section 10[~~(10)~~](5)(c) of this administrative regulation but shall not provide coverage for any portion of the Medicare Part B deductible.

(b) Standardized Medicare supplement benefit Plan F ***shall be[is]*** redesignated as Plan G and shall provide the benefits contained in Section 10[~~(10)~~](5)(e) of this administrative regulation but shall not provide coverage for 100 percent or any portion of the Medicare Part B deductible.

(c) Standardized Medicare supplement benefit plans C, F, and F with High Deductible shall not be offered to individuals newly eligible for Medicare on or after January 1, 2020.

(d)

1. Standardized Medicare supplement benefit Plan F with High Deductible ***shall be[is]*** redesignated as Plan G with High Deductible and shall provide the benefits contained in Section 10[~~(10)~~](5)(f) of this administrative regulation but shall not provide coverage for any portion of the Medicare Part B deductible.

2. The Medicare Part B deductible paid by the beneficiary shall be considered an ***out-of-pocket[~~out-of-pocket~~]***[~~out of pocket~~] expense in meeting the annual high deductible.

(2) Applicability to Certain Individuals. This section shall apply only to individuals ***who[that]*** are newly eligible for Medicare on or after January 1, 2020:

(a) By reason of attaining age sixty-five (65) on or after January 1, 2020; or

(b) By reason of entitlement to benefits under Part A pursuant to section 226(b) or 226A of the Social Security Act, 42 U.S.C. 426(b) or 426-1, or who is deemed eligible for benefits under section 226(a) of the Social Security Act, 42 U.S.C. 426(a), on or after January 1, 2020.

(3) Guaranteed Issue for Eligible Persons. For purposes of Section 14(5) of this administrative regulation, in the case of any individual newly eligible for Medicare on or after January 1, 2020, any reference to a Medicare supplement policy C or F (including F with High Deductible) shall be deemed to be a reference to Medicare supplement policy D or G (including G with High Deductible) respectively that meet the requirements of this section.

(4) Offer of Redesignated Plans to Individuals Other than Newly Eligible. On or after January 1, 2020, the standardized benefit plans described in subsection (1)(d) of this section may be offered to any individual who was eligible for Medicare prior to January 1, 2020 in addition to the standardized plans described in Section 10(5) of this administrative regulation.

Section 12. Medicare Select Policies and Certificates.

(1)

(a) This section shall apply to Medicare Select policies and certificates, as described in this section.

(b) A policy or certificate shall not be advertised as a Medicare Select policy or certificate unless it meets the requirements of this section.

(2) The commissioner may authorize an insurer to offer a Medicare Select policy or certificate, pursuant to this section and Section 4358 of the Omnibus Budget Reconciliation Act (OBRA) of 1990, 42 U.S.C. 1395ss and 42 U.S.C. 1320c-3, if the commissioner finds that the insurer has satisfied all of the requirements of this administrative regulation.

(3) A Medicare Select insurer shall not issue a Medicare Select policy or certificate in ***Kentucky[~~this state~~]*** until ***the insurer's[its]*** plan of operation has been approved by the commissioner pursuant to this section and KRS 304.14-120.

(4) A Medicare Select insurer shall file a proposed plan of operation with the commissioner. The plan of operation shall contain at least the following information:

(a) Evidence that all covered services that are ***with[~~subject to~~]*** restricted network provisions are available and accessible through network providers, including a demonstration that:

1. Covered services ***can[~~may~~]*** be provided by network providers with reasonable promptness with respect to geographic location, hours of operation, and after-hour care. The hours of operation and availability of after-hour care shall reflect usual practice in the local area. Geographic availability shall not be more than sixty (60) miles from the insured's place of residence;***[.]***

2. The number of network providers in the service area is sufficient, with respect to current and expected policyholders, either:

a. To deliver adequately all services that are ***with*** ~~***[subject to]***~~ a restricted network provision; or

b. To make appropriate referrals***;*** ~~***[.]***~~

3. There are written agreements with network providers describing specific responsibilities***;*** ~~***[.]***~~

4. Emergency care is available twenty-four (24) hours per day and seven (7) days per week***; and*** ~~***[.]***~~

5. If covered services are ***with*** ~~***[subject to]***~~ a restricted network provision and are provided on a prepaid basis, there are written agreements with network providers prohibiting the providers from billing or seeking reimbursement from or recourse against any individual insured under a Medicare Select policy or certificate. This subparagraph shall not apply to supplemental charges or coinsurance amounts as stated in the Medicare Select policy or certificate***;*** ~~***[.]***~~

(b) A statement or map providing a clear description of the service area***;*** ~~***[.]***~~

(c) A description of the grievance procedure to be utilized***;*** ~~***[.]***~~

(d) A description of the quality assurance program, including:

1. The formal organizational structure;

2. The written criteria for selection, retention, and removal of network providers; and

3. The procedures for evaluating quality of care provided by network providers, and the process to initiate corrective action if warranted***;*** ~~***[.]***~~

(e) A list and description, by specialty, of the network providers***;*** ~~***[.]***~~

(f) Copies of the written information proposed to be used by the insurer to comply with subsection (8) of this section***; and*** ~~***[.]***~~

(g) Any other information requested by the commissioner in accordance with this section, KRS 304.14-120, and KRS 304.14-130.

(5)

(a) A Medicare Select insurer shall file any proposed changes to the plan of operation, except for changes to the list of network providers, with the commissioner prior to implementing the changes. Changes shall be considered approved by the commissioner after sixty (60) days unless specifically disapproved ***as established in KRS 304.14-130***.

(b) An updated list of network providers shall be filed with the commissioner at least quarterly.

(6) A Medicare Select policy or certificate shall not restrict payment for covered services provided by nonnetwork providers if:

(a) The services are for symptoms requiring emergency care or are immediately required for an unforeseen illness, injury, or a condition;

(b) It is not reasonable to obtain services through a network provider; or

(c) There are no network providers available within sixty (60) miles of the insured's place of residence.

(7) A Medicare Select policy or certificate shall provide payment for full coverage under the policy for covered services that are not available through network providers.

(8) A Medicare Select insurer shall make full and fair disclosure in writing of the provisions, restrictions and limitations of the Medicare Select policy or certificate to each applicant. This disclosure shall include at least ~~***[the following]***~~:

(a) An outline of coverage sufficient to permit the applicant to compare the coverage and premiums of the Medicare Select policy or certificate with:

1. Other Medicare supplement policies or certificates offered by the insurer; and

2. Other Medicare Select policies or certificates***;*** ~~***[.]***~~

(b) A description, which shall include address, phone number, and hours of operation of the network providers, including primary care physicians, specialty physicians, hospitals, and other providers***;*** ~~***[.]***~~

(c) A description of the restricted network provisions, including payments for coinsurance and deductibles ***if[~~when~~]*** providers other than network providers are utilized. Except to the extent specified in the policy or certificate, expenses incurred ***if[~~when~~]*** using out-of-network providers shall not count toward the out-of-pocket annual limit contained in plans K and L;***[.]***

(d) A description of coverage for emergency and urgently needed care and other out-of-service area coverage;***[.]***

(e) A description of limitations on referrals to restricted network providers and to other providers;***[.]***

(f) A description of the policyholder's rights to purchase any other Medicare supplement policy or certificate offered by the insurer***; and[.]***

(g) A description of the Medicare Select insurer's quality assurance program and grievance procedure.

(9) Prior to the sale of a Medicare Select policy or certificate, a Medicare Select insurer shall obtain from the applicant a signed and dated form stating that the applicant has received the information provided pursuant to subsection (8) of this section and that the applicant understands the restrictions of the Medicare Select policy or certificate.

(10) A Medicare Select insurer shall have and use procedures for hearing complaints and resolving written grievances from the subscribers. The procedures shall be aimed at mutual agreement for settlement and may include arbitration procedures.

(a) The grievance procedure shall be described in the policy and certificates and in the outline of coverage.

(b) Upon issuance of the policy or certificate, the insurer shall provide detailed information to the policyholder describing how a grievance may be registered with the insurer.

(c) A grievance shall be considered in a ***within a reasonable time[~~timely manner~~]*** and shall be transmitted to appropriate decision makers who have authority to fully investigate the issue and take corrective action.

(d) If a grievance is found to be valid, ***then appropriate*** corrective action shall be taken***[~~promptly~~]***.

(e) All concerned parties shall be notified about the results of a grievance.

(f) The insurer shall report no later than each March 31st to the commissioner regarding its grievance procedure, including the number of grievances filed in the past year and a summary of the subject, nature, and resolution of grievances.

(11) Upon initial purchase, a Medicare Select insurer shall make available to each applicant for a Medicare Select policy or certificate, the opportunity to purchase any Medicare supplement policy or certificate offered by the insurer.

(12)

(a) At the request of an individual insured under a Medicare Select policy or certificate, a Medicare Select insurer shall make available to the individual insured the opportunity to purchase a Medicare supplement policy or certificate offered by the insurer that has comparable or lesser benefits and that does not contain a restricted network provision. The insurer shall make the policies or certificates available without requiring evidence of insurability after the Medicare Select policy or certificate has been in force for six (6) months.

(b) For the purposes of this subsection, a Medicare supplement policy or certificate shall be considered to have comparable or lesser benefits unless ***the policy or certificate[~~it~~]*** contains one (1) or more of the following significant benefits not included in the Medicare Select policy or certificate being replaced, coverage for:

1. The Medicare Part A deductible;
2. At-home recovery services; or
3. Part B excess charges.

(13) Medicare Select policies and certificates shall provide for continuation of coverage if the secretary determines that Medicare Select policies and certificates issued pursuant to this section shall be discontinued due to either the failure of the Medicare Select Program to be reauthorized under law or its substantial amendment.

(a) Each Medicare Select insurer shall make available to each individual insured under a Medicare Select policy or certificate, the opportunity to purchase any Medicare supplement policy or certificate offered by the insurer that has comparable or lesser benefits and that does not contain a restricted network provision. The insurer shall make these policies and certificates available without requiring evidence of insurability.

(b) For the purposes of this subsection, a Medicare supplement policy or certificate shall be considered to have comparable or lesser benefits unless ***the policy or certificate[~~it~~]*** contains one (1) or more of the following significant benefits not included in the Medicare Select policy or certificate being replaced, coverage for:

1. The Medicare Part A deductible;
2. At-home recovery services; or
3. Part B excess charges.

(14) A Medicare Select insurer shall comply with reasonable requests for data made by state or federal agencies, including the United States Department of Health and Human Services, for the purpose of evaluating the Medicare Select Program.

Section 13. Initial Open Enrollment.

(1)

(a) ***Except as established in KRS 304.14-525(3)(b)1.,*** an insurer shall not deny or condition the issuance or effectiveness of any Medicare supplement policy or certificate available for sale in Kentucky, nor discriminate in the pricing of a policy or certificate because of the health status, claims experience, receipt of health care, or medical condition of an applicant if ***the applicant***:

1.***a. [~~The applicant~~]*** Is enrolled for benefits under Medicare Part B; and

b. Submits[~~2.~~] an initial application for a policy or certificate ***[~~is submitted~~]*** prior to or during the six (6) month period beginning with the first day of the first month in which an individual is***[~~:a.~~]*** sixty-five (65) years of age or older; or[~~and~~]

2.[~~b. A non-age eligible person, who~~] Meets the requirements of KRS ***304.14-525(2)(a) or (b)[~~304.14-525(2)(b)2~~]***.

[~~2.~~] [~~The applicant is enrolled for benefits under Medicare Part B.~~]

(b) Each Medicare supplement policy and certificate currently available from an insurer shall be made available to all applicants who qualify under this subsection without regard to age.

(2) ***Except as established in KRS 304.14-525(3):***

(a) If an applicant qualifies under subsection (1) of this section and submits an application during the time period referenced in subsection (1) of this section and, as of the date of application, has had a continuous period of creditable coverage of at least six (6) months, the insurer shall not exclude benefits based on a preexisting condition***; and[~~.~~]***

(b) If the applicant qualifies under subsection (1) of this section and submits an application during the time period referenced in subsection (1) of this section and, as of the date of application, has had a continuous period of creditable coverage that is less than six (6) months, the insurer shall reduce the period of any preexisting condition exclusion by the aggregate of the period of creditable coverage applicable to the applicant as of the enrollment date. The secretary shall specify the manner of the reduction under this subsection.

(3) Except as provided in ***KRS 304.14-525(3),*** subsection (2) of this section, and Sections 14 and 25 of this administrative regulation, subsection (1) of this section shall not be construed as preventing the exclusion of benefits under a policy, during the first six (6) months, based on a preexisting condition for which the policyholder or certificate holder received treatment or was diagnosed during the six (6) months before the coverage became effective.

Section 14. Guaranteed Issue for Eligible Persons.

(1) Guaranteed Issue:

(a) Eligible persons ***shall be[~~are~~]*** those individuals described in subsection (2) of this section who seek to enroll under the policy during the period specified in subsection (3) of this section, and who submit evidence of the date of termination, disenrollment, or Medicare Part D enrollment with the application for a Medicare supplement policy.

(b) With respect to eligible persons, an insurer shall not:

1. Deny or condition the issuance or effectiveness of a Medicare supplement policy described in subsection (5) of this section that is offered and is available for issuance to new enrollees by the insurer;

2. Discriminate in the pricing of a Medicare supplement policy because of health status, claims experience, receipt of health care, or medical condition; and

3. Impose an exclusion of benefits based on a preexisting condition under a Medicare supplement policy.

(2) An eligible person shall include ***an individual who[~~the following~~]***:

(a) ***[~~An individual that~~]***Is enrolled under an employee welfare benefit plan that provides health benefits that supplement the benefits under Medicare; and the plan terminates, or the plan ceases to provide all the supplemental health benefits to the individual;

(b) ***[~~An individual~~]***Is enrolled]with a Medicare Advantage organization under a Medicare Advantage plan under part C of Medicare, and:

1. The individual is sixty-five (65) years of age or older and is enrolled with a Program of All-Inclusive Care for the Elderly (PACE) provider under Section 1894 of the Social Security Act, 42 U.S.C. 1395eee, and there are circumstances similar to those described in subparagraph 2. of this paragraph that would permit discontinuance of the individual's enrollment with the provider if the individual were enrolled in a Medicare Advantage plan; or

2. Any of the following circumstances apply:

a. The certification of the organization or plan has been terminated;

b. The organization has terminated or discontinued providing the plan in the area in which the individual resides;

c. The individual is no longer eligible to elect the plan because of a change in the individual's place of residence or other change in circumstances specified by the secretary, but not including termination of the individual's enrollment on the basis described in Section 1851(g)(3)(B) of the federal Social Security Act, 42 U.S.C 1395w-21(g)(3)(B), if the individual has not paid premiums on a timely basis or has engaged in disruptive behavior as specified in standards under Section 1856, 42 U.S.C. 1395w-26, or the plan is terminated for all individuals within a residence area; or

d. The individual demonstrates, in accordance with guidelines established by the secretary, that:

(i) The organization offering the plan substantially violated a material provision of the organization's contract under this part in relation to the individual, including the failure to provide an enrollee on a timely basis medically necessary care for which benefits are available under the plan or the failure to provide the covered care in accordance with applicable quality standards;

(ii) The organization, or agent or other entity acting on the organization's behalf, materially misrepresented the plan's provisions in marketing the plan to the individual; or

(iii) The individual meets the other exceptional conditions as the secretary may provide;

(c)

1. ***[~~An individual~~]***Is enrolled with:

a. An eligible organization under a contract under Section 1876 of the Social Security Act, 42 U.S.C. 1395mm regarding Medicare cost;

b. A similar organization operating under demonstration project authority, effective for periods before April 1, 1999;

c. An organization under an agreement under Section 1833(a)(1)(A) of the Social Security Act, 42 U.S.C. 1395l(a)(1)(A), regarding health care prepayment plan; or

d. An organization under a Medicare Select policy; and

2. ***[~~The enrollment~~]***Ceases ***to be enrolled*** under the same circumstances that would ***allow[~~permit~~]*** discontinuance of an individual's election of coverage under paragraph (b) of this subsection;

(d) ***[~~The individual~~]***Is enrolled Under a Medicare supplement policy and the enrollment ceases due to***[~~any of the following reasons~~]***:

1.

a. The insolvency of the insurer or bankruptcy of the non-insurer organization; or

b. The involuntary termination of coverage or enrollment under the policy;

2. The insurer of the policy substantially ***violating[~~violated~~]*** a material provision of the policy; or

3. The insurer, or an agent or other entity acting on the insurer's behalf, materially ***misrepresenting[~~misrepresented~~]*** the policy's provisions in marketing the policy to the individual;

(e)

1. ***[~~An individual that~~]***Was enrolled under a Medicare supplement policy and terminates enrollment and subsequently enrolls, for the first time, with***[~~any of the following~~]***:

a. A Medicare Advantage organization under a Medicare Advantage plan under part C of Medicare;

b. An eligible organization under a contract under Section 1876 of the Social Security Act, 42 U.S.C. 1395mm regarding Medicare cost;

c. A similar organization operating under demonstration project authority;

d. A PACE provider under Section 1894 of the Social Security Act, 42 U.S.C. 1395eee; or

e. A Medicare Select policy; and

2. ***Subsequently enrolls[~~The subsequent enrollment~~]*** Under subparagraph 1. of this paragraph ***and whose enrollment*** is terminated by the enrollee during any period within the first twelve (12) months of subsequent enrollment during which the enrollee is ***allowed[~~permitted~~]*** to terminate the subsequent enrollment under Section 1851(e) of the federal Social Security Act, 42 U.S.C. 1395w-21(e);

(f) ***[~~An individual who,~~]***Upon first becoming eligible for benefits under part A of Medicare at age sixty-five (65), enrolls in:

1. A Medicare Advantage plan under part C of Medicare, or with a PACE provider under Section 1894 of the Social Security Act, 42 U.S.C. 1395eee; and

2. Disenrolls from the plan or program by not later than twelve (12) months after the effective date of enrollment;[~~or~~]

(g)***[~~An individual that:~~]***

1. Enrolls in a Medicare Part D plan during the initial enrollment period;

2. Upon enrollment in Part D, was enrolled under a Medicare supplement policy that covers outpatient prescription drugs; and

3. Terminates enrollment in the Medicare supplement policy and submits evidence of enrollment in Medicare Part D along with the application for a policy described in subsection (5)(d) of this section; or

(h) ***[~~An individual that~~]***Is currently enrolled in a Medicare supplement policy ***and*** who satisfies the requirements of KRS 304.14-525(2)(c).

(3) Guaranteed issue time periods.

(a) For an individual described in subsection (2)(a) of this section, the guaranteed issue period shall:

1. Begin on the later of the date:

a. The individual receives a notice of termination or cessation of all supplemental health benefits, or, if a notice is not received, notice that a claim has been denied because of a termination or cessation; or

b. That the applicable coverage terminates or ceases; and

2. End sixty-three (63) days thereafter.***[;]***

(b) For an individual described in subsection (2)(b), (c), (e), [~~or~~](f), or (h) of this section whose enrollment is terminated involuntarily, the guaranteed issue period shall begin on the date that the individual receives a notice of termination and ends sixty-three (63) days after the date the applicable coverage is terminated.***[;]***

(c) For an individual described in subsection (2)(d)1. of this section, the guaranteed issue period shall end on the date that is sixty-three (63) days after the date the coverage is terminated and shall begin on the earlier of the date that:

1. The individual receives a notice of termination, a notice of the insurer's bankruptcy or insolvency, or other the similar notice if any; or

2. The applicable coverage is terminated.***[;]***

(d) For an individual described in subsection (2)(b), (d)2., (d)3., (e), or (f) of this section who disenrolls voluntarily, the guaranteed issue period shall begin on the date that is sixty (60) days before the effective date of the disenrollment and shall end on the date that is sixty-three (63) days after the effective date.***[;]***

(e) For an individual described in subsection (2)(g) of this section, the guaranteed issue period shall begin on the date the individual receives notice pursuant to Section 1882(v)(2)(B) of the Social Security Act, 42 U.S.C. 1395ss(v)(2)(B), from the Medicare supplement insurer during the sixty (60) day period immediately preceding the initial Part D enrollment period and shall end on the date that is sixty-three (63) days after the effective date of the individual's coverage under Medicare Part D.***[;]***[~~and~~]

(f) For an individual ***described in subsection (2)(a), (b), (c), (d), (e), (f), or (g) of this section but not as described in paragraphs (a), (b), (c), (d), or (e) of this subsection[~~described in subsection (2) of this section but not described in the preceding provisions of this subsection~~]***, the guaranteed issue period shall begin on the effective date of disenrollment and shall end on the date that is sixty-three (63) days after the effective date.***[; and]***[.]

(g) For an individual ***established[~~described~~]*** in subsection (2)(h) of this section, the guaranteed issue period shall begin annually on the insured's birthday and shall end sixty (60) days after their birth date.

(4) Extended Medigap Access for Interrupted Trial Periods.

(a) For an individual described in subsection (2)(e) of this section whose enrollment with an organization or provider described in Subsection (2)(e)1. of this section is involuntarily terminated within the first twelve (12) months of enrollment, and who, without an intervening enrollment, enrolls with another organization or provider, the subsequent enrollment shall be deemed to be an initial enrollment described in subsection(2)(e)of this section.***[;]***

(b) For an individual described in subsection (2)(f) of this section whose enrollment with a plan or in a program described in subsection (2)(f) of this section is involuntarily terminated within the first twelve (12) months of enrollment, and who, without an intervening enrollment, enrolls in another plan or program, the subsequent enrollment shall be deemed to be an initial enrollment described in subsection (2)(f) of this section.***[; and]***

(c) For purposes of subsection (2)(e) and (f) of this section, enrollment of an individual with an organization or provider described in subsection (2)(e)1. of this section, or with a plan or in a program described in subsection (2)(f) of this section, shall not be deemed to be an initial enrollment under this paragraph after the two (2) year period beginning on the date on which the individual first enrolled with an organization, provider, plan, or program.

(5) Products to which eligible persons ***shall be[are]*** entitled. The Medicare supplement policy to which eligible persons shall be entitled under:

(a) ***Subsection (2)(a) through (d) of this section shall consist of[Section 14(2)(a), (b), (c) and (d) of this administrative regulation is]*** a Medicare supplement policy that has a benefit package classified as Plan A, B, C, F, high deductible F, K, or L offered by any insurer;

(b) ***On or before December 31, 2005,[1. Subject to subparagraph 2. of this paragraph, a person eligible pursuant to]*** subsection (2)(e) of this section ***shall be[is]*** the same Medicare supplement policy in which the individual was most recently previously enrolled, if available from the same insurer, or, if not so available, a policy described in paragraph (a) of this subsection.***[;][2.]*** After December 31, 2005, if the individual was most recently enrolled in a Medicare supplement policy with an outpatient prescription drug benefit, a Medicare supplement policy described in this ***paragraph shall be[subparagraph is]***:

1.[a.] The policy available from the same insurer but modified to remove outpatient prescription drug coverage; or

2.[b.] At the election of the policyholder, an A, B, C, F, high deductible F, K, or L policy that is offered by any insurer;

(c) Subsection (2)(f) of this section shall include any Medicare supplement policy offered by any insurer;

(d) Subsection (2)(g) of this section ***shall be[is]*** a Medicare supplement policy that:

1. Has a benefit package classified as Plan A, B, C, F, high deductible F, K, or L; and
2. Is offered and available for issuance to new enrollees by the same insurer that issued the individual's Medicare supplement policy with outpatient prescription drug coverage***; or[.]***

(e) Subsection (2)(h) of this section ***shall be[is]*** a Medicare supplement policy that is the same Medicare supplement plan as the individual is currently enrolled but is issued by a different insurer.

(6) Notification provisions.

(a) Upon an event described in subsection (2) of this section resulting in a loss of coverage or benefits due to the termination of a contract or agreement, policy, or plan, the organization that terminates the contract or agreement, the insurer terminating the policy, or the administrator of the plan being terminated, respectively, shall notify the individual of the individual's rights under this section, and of the obligations of insurers of Medicare supplement policies under subsection (1) of this section. This notice shall be communicated simultaneously with the notification of termination.

(b) Upon an event described in subsection (2) of this section resulting in an individual ceasing enrollment under a contract or agreement, policy, or plan, the organization that offers the contract or agreement, regardless of the basis for the cessation of enrollment, the insurer offering the policy, or the administrator of the plan, respectively, shall notify the individual of the individual's rights under this section, and of the obligations of insurer of Medicare supplement policies under subsection (1) of

this section. The notice shall be communicated within ten (10) working days of the insurer receiving notification of disenrollment.

Section 15. Standards for Claims Payment.

(1) An insurer shall comply with 42 U.S.C. 1395ss, section 1882(c)(3) of the Social Security Act, by:

(a) Accepting a notice from a Medicare carrier on dually assigned claims submitted by participating physicians and suppliers as a claim for benefits in place of any other claim form required and making a payment determination on the basis of the information contained in that notice;

(b) Notifying the participating physician or supplier and the beneficiary of the payment determination;

(c) Paying the participating physician or supplier;

(d) Upon enrollment, furnishing each enrollee with a card listing the policy name, number, and a central mailing address to which notices from a Medicare carrier may be sent;

(e) Paying user fees for claim notices that are transmitted electronically or in another manner; and

(f) Providing to the secretary of, at least annually, a central mailing address to which all claims may be sent by Medicare carriers.

(2) Compliance with the requirements established in subsection (1) of this section shall be certified to the commissioner as part of the insurer's annual filing pursuant to KRS 304.3-240.

Section 16. Loss Ratio Standards and Refund or Credit of Premium.

(1) Loss Ratio Standards.

(a)

1. Pursuant to KRS 304.14-530, a Medicare Supplement policy form or certificate form shall not be delivered or issued for delivery in Kentucky unless it is expected to return to policyholders and certificate holders in the form of aggregate benefits, not including anticipated refunds or credits, provided under the policy form or certificate form which total:

a. At least seventy-five (75) percent of the aggregate amount of premiums earned in the case of group policies; or

b. At least sixty-five (65) percent of the aggregate amount of premiums earned in the case of individual policies.

2. The calculation shall be in accordance with accepted actuarial principles and practices; and

a. Based on:

(i) Incurred claims experience or incurred health care expenses if coverage is provided by a health maintenance organization on a service rather than reimbursement basis; and

(ii) Earned premiums for the period; and

b. Incurred health care expenses if coverage is provided by a health maintenance organization shall not include:

(i) Home office and overhead costs;

(ii) Advertising costs;

(iii) Commissions and other acquisition costs;

(iv) Taxes;

(v) Capital costs;

(vi) Administrative costs; and

(vii) Claims processing costs.

(b) A filing of rates and rating schedules shall demonstrate that expected claims in relation to premiums comply with the requirements of this section ***if[~~when~~]*** combined with actual experience to date. Filings of rate revisions shall also demonstrate that the anticipated loss ratio over the entire future

period for which the revised rates are computed to provide coverage can be expected to meet the appropriate loss ratio standards.

(c) For policies issued prior to October 14, 1990, expected claims in relation to premiums shall meet:

1. The originally filed anticipated loss ratio ***if[~~when~~]*** combined with the actual experience since inception;

2. The appropriate loss ratio requirement from paragraph (a)1.a. and b. of this subsection ***if[~~when~~]*** combined with actual experience beginning with July 5, 1996, to date; and

3. The appropriate loss ratio requirement from paragraph (a)1.a. and b. of this subsection over the entire future period for which the rates are computed to provide coverage.

(2) Refund or Credit Calculation.

(a) An insurer shall collect and file with the commissioner by May 31 of each year, the data contained in the applicable reporting form contained in HL-MS-1 for each type in a standard Medicare supplement benefit plan.

(b) If, on the basis of the experience as reported the benchmark ratio since inception (ratio 1) exceeds the adjusted experience ratio since inception (ratio 3), then a refund or credit calculation shall be required. The refund calculation shall be done on a statewide basis for each type in a standard Medicare supplement benefit plan. For purposes of the refund or credit calculation, experience on policies issued within the reporting year shall be excluded.

(c) For policies or certificates issued prior to October 14, 1990, the insurer shall make the refund or credit calculation separately for all individual policies, including all group policies ***with[~~subject to~~]*** an individual loss ratio standard ***at issuance[~~when issued~~]***, combined and all other group policies combined for experience after July 5, 1996.

(d) A refund or credit shall be made only ***if[~~when~~]*** the benchmark loss ratio exceeds the adjusted experience loss ratio and the amount to be refunded or credited exceeds the level as identified on the annual refund calculation form HL-MS-1. The refund shall include interest from the end of the calendar year to the date of the refund or credit at a rate specified by the Secretary of Health and Human Services, but it shall not be less than the average rate of interest for thirteen (13) week Treasury notes. A refund or credit against premiums due shall be made by September 30 following the experience year upon which the refund or credit is based.

(3) Annual filing of Premium Rates.

(a) An insurer of Medicare supplement policies and certificates issued before or after January 14, 1992, in ***Kentucky[~~this state~~]*** shall file annually for approval by the commissioner in accordance with the filing requirements and procedures prescribed by the commissioner in KRS 304.14-120[~~304-14-120~~]:

1. Rates;

2. Rating schedule; and

3. Supporting documentation, including ratios of incurred losses to earned premiums by policy duration.

(b) The supporting documentation shall also demonstrate in accordance with actuarial standards of practice using reasonable assumptions that the appropriate loss ratio standards can be expected to be met over the entire period for which rates are computed. The demonstration shall exclude active life reserves.

(c) An expected third-year loss ratio that is greater than or equal to the applicable percentage shall be demonstrated for policies or certificates in force less than three (3) years.

(d) As soon as practicable, but prior to the effective date of enhancements in Medicare benefits, every insurer of Medicare supplement policies or certificates in ***Kentucky[~~this state~~]*** shall file with the commissioner, in accordance with KRS 304.14-120[~~304-14.120~~]:

1.

a. Appropriate premium adjustments necessary to produce loss ratios as anticipated for the current premium for the applicable policies or certificates. The supporting documents necessary to justify the adjustment shall accompany the filing***;[.]***

b. Appropriate premium adjustments necessary to produce an expected loss ratio under the policy or certificate to conform to minimum loss ratio standards for Medicare supplement policies and that are expected to result in a loss ratio at least as great as that originally anticipated in the rates used to produce current premiums by the insurer for the Medicare supplement policies or certificates. A premium adjustment that would modify the loss ratio experience under the policy other than the adjustments described in this subsection shall not be made with respect to a policy at any time other than upon its renewal date or anniversary date***; and[.]***

c. If an insurer fails to make premium adjustments acceptable to the commissioner in accordance with this section, the commissioner may order premium adjustments, refunds, or premium credits necessary to achieve the loss ratio required by this section***; and[.]***

2. Any appropriate riders, endorsements, or policy forms needed to accomplish the Medicare supplement policy or certificate modifications necessary to eliminate benefit duplications with Medicare. The riders, endorsements, or policy forms shall provide a clear description of the Medicare supplement benefits provided by the policy or certificate.

(4) Public Hearings. The commissioner may conduct a public hearing***, which shall be conducted*** pursuant to KRS 304.2-310, to gather information concerning a request by an insurer for an increase in a rate for a policy form or certificate form issued before or after January 1, 1992, if the experience of the form for the previous reporting period is not in compliance with the applicable loss ratio standard. The determination of compliance shall be made without consideration of any refund or credit for the reporting period. Public notice of the hearing shall be ***submitted[~~furnished~~]*** in accordance with KRS 304.2-320.

Section 17. Filing and Approval of Policies and Certificates and Premium Rates.

(1) An insurer shall not deliver or issue for delivery a policy or certificate to a resident of Kentucky unless the policy form or certificate form has been filed with and approved by the commissioner in accordance with filing requirements and procedures in KRS 304.14-120.

(2) An insurer shall file, with the commissioner, any riders or amendments to policy or certificate forms, issued in Kentucky, to delete outpatient prescription drug benefits as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173.

(3) An insurer shall not use or change premium rates for a Medicare supplement policy or certificate unless the rates, rating schedule, and supporting documentation have been filed with and approved by the commissioner in accordance with KRS 304.14-120.

(4)

(a) Except as provided in paragraph (b) of this subsection, an insurer shall not file for approval more than one (1) form of a policy or certificate of each type for each standard Medicare supplement benefit plan.

(b) An insurer may offer, with the approval of the commissioner ***as established in KRS 304.14-120, 304.14-130, and 304.14-510***, up to four (4) additional policy forms or certificate forms of the same type for the same standard Medicare supplement benefit plan, one (1) for each of the following cases:

1. The inclusion of new or innovative benefits;
2. The addition of either direct response or agent marketing methods;
3. The addition of either guaranteed issue or underwritten coverage; and

4. The offering of coverage to individuals eligible for Medicare by reason of disability.

(c) A type of a policy or certificate form shall include:

1. An individual policy;
2. A group policy;
3. An individual Medicare Select policy; or
4. A group Medicare Select policy.

(5)

(a) Except as provided in subparagraph 1. of this paragraph, an insurer shall continue to make available for purchase any policy form or certificate form issued after January 1, 1992, that has been approved by the commissioner. A policy form or certificate form shall not be considered to be available for purchase unless the insurer has actively offered it for sale in the previous twelve (12) months.

1. An insurer may discontinue the availability of a policy form or certificate form if the insurer provides to the commissioner in writing its decision at least thirty (30) days prior to discontinuing the availability of the form of the policy or certificate. After receipt of the notice by the commissioner, the insurer shall not offer for sale the policy form or certificate form in Kentucky.

2. An insurer that discontinues the availability of a policy form or certificate form pursuant to subparagraph 1. of this paragraph shall not file for approval a new policy form or certificate form of the same type for the same standard Medicare supplement benefit plan as the discontinued form for a period of five (5) years after the insurer provides notice to the commissioner of the discontinuance. The period of discontinuance may be reduced if the commissioner determines***, upon good cause shown,*** that a shorter period is appropriate.

(b) The sale or other transfer of Medicare supplement business to another insurer shall be considered a discontinuance for the purposes of this subsection.

(c) A change in the rating structure or methodology shall be considered a discontinuance under paragraph (a) of this subsection unless the insurer***[~~complies with the following requirements~~]***:

1. ***[~~The insurer~~]***Provides an actuarial memorandum, describing the manner in which the revised rating methodology and resultant rates differ from the existing rating methodology and existing rates; and

2. ***[~~The insurer~~]***Does not subsequently put into effect a change of rates or rating factors that would cause the percentage differential between the discontinued and subsequent rates as ***established[~~described~~]*** in the actuarial memorandum to change. The commissioner***, as established in KRS 304.17-380 and 304.17-383,*** may approve a change to the differential that is in the public interest.

(6)

(a) Except as provided in paragraph (b) of this subsection, the experience of all policy forms or certificate forms of the same type in a standard Medicare supplement benefit plan shall be combined for purposes of the refund or credit calculation prescribed in Section 16 of this administrative regulation.

(b) Forms assumed under an assumption reinsurance agreement shall not be combined with the experience of other forms for purposes of the refund or credit calculation.

(7) An insurer shall not present for filing or approval a rate structure for its Medicare supplement policies or certificates issued after October 4, 2005, based upon a structure or methodology with any groupings of attained ages greater than one (1) year. The ratio between rates for successive ages shall increase smoothly as age increases.

(8) Any policy issued or delivered on or after January 1, 2024 to a non-age eligible individual shall not be charged more than the weighted average aged premium rate for the policy.

Section 18. Permitted Compensation Arrangements.

(1) An insurer or other entity may provide commission or other compensation to an agent or other representative for the sale of a Medicare supplement policy or certificate only if the first year commission or other first year compensation is no more than 200 percent of the commission or other compensation paid for selling or servicing the policy or certificate in the second year or period.

(2) The commission or other compensation provided in subsequent (renewal) years shall be the same as that provided in the second year or period and shall be provided for no fewer than five (5) renewal years.

(3) An insurer or other entity shall not provide compensation to its agents or other producers and an agent or producer shall not receive compensation greater than the renewal compensation payable by the replacing insurer on renewal policies or certificates if an existing policy or certificate is replaced.

Section 19. Required Disclosure Provisions.

(1) General Rules.

(a)

1. Medicare supplement policies and certificates shall include a renewal or continuation provision.
2. The language or specifications of a renewal or continuation provision shall be consistent with the type of contract issued.
3. The renewal or continuation provision shall:
   a. Be appropriately captioned;
   b. Appear on the first page of the policy; and
   c. Include any reservation by the insurer of the right to change premiums and any automatic renewal premium increases based on the policyholder's age.

(b)

1. A rider or endorsement added to a Medicare supplement policy after date of issue or at reinstatement or renewal that reduces or eliminates benefits or coverage in the policy shall require a signed acceptance by the insured, except for a rider or endorsement by which an insurer:
   a. Effectuates a request made in writing by the insured;
   b. Exercises a specifically reserved right under a Medicare supplement policy; or
   c. Is required to reduce or eliminate benefits to avoid duplication of Medicare benefits.
2. After the date of policy or certificate issue, any rider or endorsement that increases benefits or coverage with a concomitant increase in premium during the policy term shall be agreed to in writing signed by the insured, unless:
   a. The benefits are required by the minimum standards for Medicare supplement policies; or
   b. ***[If]***The increased benefits or coverage is required by law.
3. If a separate additional premium is charged for benefits provided in connection with riders or endorsements, the premium charge shall be set forth in the policy.

(c) Medicare supplement policies or certificates shall not provide for the payment of benefits based on standards described as "usual and customary," "reasonable and customary," or words of similar import.

(d) If a Medicare supplement policy or certificate contains any limitations with respect to preexisting conditions, these limitations shall appear as a separate paragraph of the policy and be labeled as "Preexisting Condition Limitations."

(e) Medicare supplement policies and certificates shall have a notice prominently printed on the first page of the policy or certificate, or attached thereto, stating in substance that the policyholder or certificate holder shall have the right to return the policy or certificate within thirty (30) days of its

delivery and to have the premium refunded if, after examination of the policy or certificate, the insured person is not satisfied for any reason.

(f)

1. Insurers of accident and sickness policies or certificates ***that~~[which]~~*** provide hospital or medical expense coverage on an expense incurred or indemnity basis to persons eligible for Medicare shall provide to those applicants a Guide to Health Insurance for People with Medicare in the language, format, type size, type proportional spacing, bold character, and line spacing developed jointly by the National Association of Insurance Commissioners and Centers for Medicare and Medicaid Services and in a type size no smaller than twelve (12) point type.

2. Delivery of the guide described in subparagraph 1. of this paragraph shall be made:

a. Whether or not the policies or certificates are advertised, solicited, or issued as Medicare supplement policies or certificates as described in this administrative regulation***; and~~[.]~~***.

b. To the applicant upon application and acknowledgement of receipt of the guide***, which*** shall be obtained by the insurer, except that direct response insurer shall deliver the guide to the applicant upon request but not later than at policy delivery.

(2) Notice requirements.

(a) As soon as practicable, but no later than thirty (30) days prior to the annual effective date of any Medicare benefit changes, an insurer shall notify ***the insurer's~~[its]~~*** policyholders and certificate holders of modifications ***the insurer~~[it]~~*** has made to Medicare supplement insurance policies or certificates. The notice shall:

1. Include a description of revisions to the Medicare Program and a description of each modification made to the coverage provided under the Medicare supplement policy or certificate; and

2. Inform each policyholder or certificate holder as to if any premium adjustment is to be made due to changes in Medicare.

(b) The notice of benefit modifications and any premium adjustments shall be in outline form and in clear and simple terms so as to facilitate comprehension.

(c) The notices shall not contain or be accompanied by any solicitation.

(3) Insurers shall comply with any notice requirements of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub.L. 108-173.

(4) Outline of Coverage Requirements for Medicare Supplement Policies.

(a) An insurer shall provide an outline of coverage to all applicants ***with~~[when]~~*** an application ***~~[is~~]***presented to the prospective applicant and, except for direct response policies, shall obtain an acknowledgement of receipt of the outline from the applicant.

(b) If an outline of coverage is provided at application and the Medicare supplement policy or certificate is issued on a basis that would require revision of the outline, a substitute outline of coverage properly describing the policy or certificate shall accompany the policy or certificate when it is delivered and contain the following statement, in no less than twelve (12) point type, immediately above the company name: "NOTICE: READ THIS OUTLINE OF COVERAGE CAREFULLY. IT IS NOT IDENTICAL TO THE OUTLINE OF COVERAGE PROVIDED UPON APPLICATION AND THE COVERAGE ORIGINALLY APPLIED FOR HAS NOT BEEN ISSUED."

(c)***1.*** The outline of coverage provided to applicants pursuant to this section shall consist of four (4) parts:

a. A cover page***;***

b.~~[.]~~ Premium information***;***

c.~~[.]~~ Disclosure pages***;~~[.]~~*** and

d. Charts displaying the features of each benefit plan offered by the insurer.

2. The outline of coverage shall be in the language and format prescribed in the HL-MS-09[~~HL-MS-4 or the Plan Benefit Chart~~] in no less than twelve (12) point type.

3. All plans shall be shown on the cover page, and the plans that are offered by the insurer shall be prominently identified.

4. Premium information for plans that are offered shall be shown on the cover page or immediately following the cover page and shall be prominently displayed.

5. The premium and mode shall be stated for all plans that are offered to the prospective applicant.

6. All possible premiums for the prospective applicant shall be illustrated.

(5) Notice Regarding Policies or Certificates That Are Not Medicare Supplement Policies.

(a)

1. Any accident and sickness insurance policy or certificate, other than a Medicare supplement policy, a policy issued pursuant to a contract under Section 1876 of the Federal Social Security Act, 42 U.S.C. 1395 et seq., disability income policy, or other policy identified in Section 3(2) of this administrative regulation, issued for delivery in Kentucky to persons eligible for Medicare shall notify insureds under the policy that the policy is not a Medicare supplement policy or certificate.
2. The notice shall either be printed or attached to the first page of the outline of coverage delivered to insureds under the policy, or if no outline of coverage is delivered, to the first page of the policy, or certificate delivered to insureds.
3. The notice shall be in no less than twelve (12) point type and shall contain the following language: "THIS (POLICY OR CERTIFICATE) IS NOT A MEDICARE SUPPLEMENT (POLICY OR CONTRACT). If you are eligible for Medicare, review the Guide to Health Insurance for People with Medicare available from the company."

(b) Applications provided to persons eligible for Medicare for the health insurance policies or certificates described in paragraph (a) of this subsection shall disclose, using the applicable statement in HL-MS-3 the extent to which the policy duplicates Medicare. The disclosure statement shall be provided as a part of, or together with, the application for the policy or certificate.

Section 20. Requirements for Application Forms and Replacement Coverage.

(1) Comparison statement.

(a) If a Medicare Advantage or Medicare supplement policy or certificate is to replace another Medicare supplement or Medicare Advantage policy or certificate, ***HL-MS-5[~~there~~]*** shall be presented to the applicant, no later than the application date***[~~, HL-MS-5~~]***.

(b) Direct response insurers shall present the comparison statement to the applicant not later than when the policy is delivered.

(c) Agents shall:

1. Obtain the signature of the applicant on the comparison statement;
2. Sign the comparison statement; and
3. Send the comparison statement to the insurer and attach a copy of the comparison statement to the replacement policy.

(2)

(a) Application forms shall include the questions on HL-MS-6 designed to elicit information as to whether, as of the date of the application:

1. The applicant currently has Medicare supplement, Medicare Advantage, Medicaid coverage, or another health insurance policy or certificate in force; or

2. A Medicare supplement policy or certificate is intended to replace any other accident and sickness policy or certificate presently in force.

(b) An agent shall provide the HL-MS-07 to the applicant.

(c) A supplementary application or other form to be signed by the applicant and agent containing the questions as found on the HL-MS-06 and statements on HL-MS-07 may be used.

(3) Agents shall list, on HL-MS-06 or on the supplementary form as identified in subsection (2)(c) of this section, any other health insurance policies ***the agent has[~~they have~~]*** sold to the applicant including:

(a) Policies sold that are still in force; and

(b) Policies sold in the past five (5) years that are no longer in force.

(4) For an insurer that uses direct response, a copy of the application or supplemental form, signed by the applicant, and acknowledged by the insurer, shall be returned to the applicant by the insurer upon delivery of the policy.

(5) Upon determining that a sale will involve replacement of Medicare supplement coverage, any insurer, other than an insurer that uses direct response, or its agent, shall ***provide[~~furnish~~]*** the applicant, prior to issuance or delivery of the Medicare supplement policy or certificate, a notice regarding replacement of Medicare supplement coverage. One (1) copy of the notice signed by the applicant and the agent, except if the coverage is sold without an agent, shall be provided to the applicant and an additional signed copy shall be retained by the insurer. An insurer that uses direct response shall deliver to the applicant at issuance of the policy, the notice regarding replacement of Medicare supplement coverage. Upon receipt of the notice, the applicant or the applicant's designee shall notify the insurer who previously provided Medicare supplement coverage of the replacement coverage.

(6) The notice required by subsection (5) of this section for an insurer shall be provided as specified in HL-MS-08, in no less than twelve (12) point type or in a form developed by the insurer, which shall:

(a) Meet the requirements of this section; and

(b) Be filed with and approved by the commissioner***, as established in KRS 304.14-130,*** prior to use.

Section 21. Filing Requirements for Advertising and Policy Delivery.

(1) An insurer shall provide a copy of any Medicare supplement advertisement intended for use in Kentucky whether through written, electronic, radio, ***[~~or~~]***television, or any other medium to the commissioner for review prior to use. Advertisements shall not require approval prior to use, but an advertisement shall not be used if it has been disapproved by the commissioner***, as established in KRS 304.14-130,*** and notice of the disapproval has been given to the insurer.

(2) Insurers and agents shall not use the names and addresses of persons purchased as "leads" unless the solicitation material used to obtain the names and addresses of the "leads" are filed as advertisement as required by this section. Insurers and agents shall not use "leads" if the solicitation materials have been disapproved by the commissioner ***as established in KRS 304.14-130***.

(3) If a Medicare supplement policy is not delivered by mail, the agent or insurer shall obtain a signed and dated delivery receipt from the insured. If the delivery receipt is obtained by an agent, the agent shall forward the delivery receipts to the insurer.

Section 22. Standards for Marketing.

(1) An insurer, directly or through its agents or other representatives, shall:

(a) Establish marketing procedures to assure that any comparison of policies by its agents or other representatives ***shall[~~will~~]*** be fair and accurate***;[.]***

(b) Establish marketing procedures to assure excessive insurance is not sold or issued***;[.]***

(c) Display prominently by type, stamp, or other appropriate means, on the first page of the policy the following disclosure: "Notice to buyer: This policy may not cover all of your medical expenses***[.]***"***;***

(d) Inquire and make every reasonable effort to identify if a prospective applicant or enrollee for Medicare supplement insurance already has accident and sickness insurance and the types and amounts of any insurance***; and[.]***

(e) Establish auditable procedures for verifying compliance with this subsection.

(2) In addition to the practices prohibited in KRS Chapter 304.12 and 806 KAR 12:092, the following acts and practices shall be prohibited:

(a) Twisting. Making any unfair or deceptive representation or incomplete or fraudulent comparison of any insurance policies or insurers for the purpose of inducing, or tending to induce, any person to lapse, forfeit, surrender, terminate, retain, pledge, assign, borrow on, or convert an insurance policy or to take out a policy of insurance with another insurer***;[.]***

(b) High pressure tactics. Employing any method of marketing having the effect of or tending to induce the purchase of insurance through force, fright, threat, whether explicit or implied, or undue pressure to purchase or recommend the purchase of insurance***; and[.]***

(c) Cold lead advertising. Making use of any method of marketing ***that[which]*** fails to disclose in a conspicuous manner that a purpose of the method of marketing is solicitation of insurance and that contact will be made by an insurance agent or insurance company.

(3) The terms "Medicare Supplement," "Medigap," "Medicare Wrap-Around", and similar words shall not be used unless the policy is issued in compliance with this administrative regulation.

Section 23. Appropriateness of Recommended Purchase and Excessive Insurance.

(1) In recommending the purchase or replacement of any Medicare supplement policy or certificate, an agent shall make reasonable efforts to determine the appropriateness of a recommended purchase or replacement.

(2) Any sale of a Medicare supplement policy or certificate that will provide an individual more than one (1) Medicare supplement policy or certificate shall be prohibited.

(3) An insurer shall not issue a Medicare supplement policy or certificate to an individual enrolled in Medicare Part C unless the effective date of the coverage is after the termination date of the individual's Part C coverage.

Section 24. Reporting of Multiple Policies.

(1) On or before March 1 of each year, an insurer shall report to the commissioner the following information, using HL-MS-2, for every individual resident of Kentucky for which the insurer has in force more than one (1) Medicare supplement policy or certificate:

(a) Policy and certificate number; and

(b) Date of issuance.

(2) The items set forth in subsection (1) of this section shall be grouped by individual policyholder.

Section 25. Prohibition Against Preexisting Conditions, Waiting Periods, Elimination Periods, and Probationary Periods in Replacement Policies or Certificates.

(1) If a Medicare supplement policy or certificate replaces another Medicare supplement policy or certificate, the replacing insurer shall waive any time periods applicable to preexisting conditions, waiting periods, elimination periods, and probationary periods in the new Medicare supplement policy or certificate to the extent time was spent under the original policy.

(2) If a Medicare supplement policy or certificate replaces another Medicare supplement policy or certificate which has been in effect for at least six (6) months, the replacing policy shall not provide any time period applicable to preexisting conditions, waiting periods, elimination periods, and probationary periods.

Section 26. Prohibition Against Use of Genetic Information and Requests for Genetic Testing.*[~~This section shall apply to all policies with policy years beginning on or after the effective date of this administrative regulation.~~]*

(1) An insurer of a Medicare supplement policy or certificate shall not:

(a) Deny or condition the issuance or effectiveness of the policy or certificate, including the imposition of any exclusion of benefits under the policy based on a pre-existing condition, on the basis of the genetic information with respect to any individual; and

(b) Discriminate in the pricing of the policy or certificate, including the adjustment of premium rates, of an individual on the basis of the genetic information with respect to any individual.

(2) Subsection (1) of this section shall not be construed to limit the ability of an insurer, to the extent permitted by law, from:

(a) Denying or conditioning the issuance or effectiveness of the policy or certificate or increasing the premium for a group based on the manifestation of a disease or disorder of an insured or applicant; or

(b) Increasing the premium for any policy issued to an individual based on the manifestation of a disease or disorder of an individual who is covered under the policy, and the manifestation of a disease or disorder in one individual ***shall not****[~~cannot~~]* also be used as genetic information about other group members and to further increase the premium for the group.

(3) Except as provided by subsection (6) of this section, an insurer of a Medicare supplement policy or certificate shall not request or require an individual or a family member of an individual to undergo a genetic test.

(4) Subsection (3) of this section shall not be construed to prohibit an insurer of a Medicare supplement policy or certificate from obtaining and using the results of a genetic test in making a determination regarding payment, as described for the purposes of applying the regulations promulgated under part C of title XI of the Social Security Act, 42 U.S.C. 1320d et seq., and section 264 of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d-2, and consistent with subsection (1) of this section.

(5) For purposes of carrying out subsection (4) of this section, an insurer of a Medicare supplement policy or certificate may request only the minimum amount of information necessary to accomplish the intended purpose.

(6) *[~~Notwithstanding subsection (3) of this section,~~]*An insurer of a Medicare supplement policy may request, but shall not require, that an individual or a family member of the individual undergo a genetic test if*[~~each of the following conditions is met~~]*:

(a) The request ***is****[~~shall be~~]* made pursuant to research that complies with 45 C.F.R. part 46, or equivalent federal regulations, and any applicable state or local law, or administrative regulations, for the protection of human subjects in research*;[.]*

(b) The insurer clearly indicates to each individual, or if a minor child, to the legal guardian of the child, to whom the request is made that:

1. Compliance with the request shall be voluntary; and

2. Noncompliance shall have no effect on enrollment status or premium or contribution amounts*;[.]*

(c) Genetic information collected or acquired under this subsection shall not be used for underwriting, determination of eligibility to enroll or maintain enrollment status, premium rates, or the issuance, renewal, or replacement of a policy or certificate*;[.]*

(d) The insurer notifies the secretary in writing that the insurer is conducting activities pursuant to the exception provided for under this subsection, including a description of the activities conducted*; and[.]*

(e) The insurer complies with other conditions as the secretary may by federal regulation require for activities conducted under this subsection.

(7) An insurer of a Medicare supplement policy or certificate shall not request, require, or purchase genetic information for underwriting purposes.

(8) An insurer of a Medicare supplement policy or certificate shall not request, require, or purchase genetic information with respect to any individual prior to an individual's enrollment under the policy in connection with enrollment.

(9) If an insurer of a Medicare supplement policy or certificate obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, the request, requirement, or purchase shall not be considered a violation of subsection (8) of this section if the request, requirement, or purchase is not in violation of subsection (7) of this section.

Section 27. Incorporated by Reference.

(1) The following material is ***incorporated*** ~~***[corporate]***~~ by reference:

(a) "HL-MS-1", July 2009 edition;

(b) "HL-MS-2", July 2009 edition;

(c) "HL-MS-3", July 2009 edition;

(d) "HL-MS-4", October 2009 edition;

(e) "HL-MS-5", May 2018 edition;

(f) "HL-MS-06", July 2009 edition;

(g) "HL-MS-07", July 2009 edition;

(h) "HL-MS-08", October 2009 edition; and

(i) "***HLMS-9*** ~~***[HL-MS-09]***~~", ***[October]*** ~~***[October]***~~2023 edition[~~"Plan Benefit Chart", April 2018 edition~~].

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Insurance, 500 Mero Street,[~~215 West Main Street,~~] Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

(3) This material may also be obtained at the department's Web site at https://insurance.ky.gov/ppc/CHAPTER.aspx[~~insurance.ky.gov/ppc/new_laws.aspx~~].

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CABINET FOR HEALTH AND FAMILY SERVICES

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SECRETARY

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October 7, 2024

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
083, Capitol Annex
702 Capitol Ave.
Frankfort KY 40601

Re: 902 KAR 45:001. Definitions for hemp-derived cannabinoid products.

Dear Co-Chairs West and Lewis,

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 45:001, the Department for Public Health proposes the enclosed suggested substitute to 902 KAR 45:001.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at (502) 229-3377.

Sincerely,

Krista Quarles

Krista Quarles
Policy Specialist
Office of Legislative and Regulatory Affairs

Subcommittee Substitute
Final version 9/30/2024

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amended After Comments)

902 KAR 45:001. Definitions for hemp-derived cannabinoid products.

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, 260.850, 438.305(4), 2023 Ky Acts ch. 78**, 7 C.F.R. 990.1**

STATUTORY AUTHORITY: KRS 217.125, 217.135

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215. KRS 217.135 authorizes the secretary to establish food standards by administrative regulation including a reasonable definition, standard of identity, and designation of optional ingredients that shall be named on the label. This administrative regulation establishes the definitions applicable to hemp-derived cannabinoid products.

Section 1. Definitions. (1) "Adult-use cannabinoid" means a product with intoxicating properties that changes the function of the nervous system and results in alterations of perception, cognition, or behavior.

(2) "Approved source" means:

(a) A Kentucky hemp grower or handler licensed by the Kentucky Department of Agriculture, or an out-of-state hemp grower or handler who is duly authorized to produce hemp under the laws of the applicable jurisdiction;

(b) A hemp product manufacturer or processor permitted by the Kentucky Department for Public Health; or

(c) A manufacturer or processor permitted by another state regulatory authority for hemp-derived cannabinoid products if that state has been approved by the department as having equivalent state standards for processing, laboratory testing, and labeling requirements.

(3) "Cabinet" is defined by KRS 217.015(3).

(4) "Cannabidiol" or "CBD" is defined by KRS 217.039(1)(a).

(5) "Cannabinoid" means a compound found in the hemp plant Cannabis sativa L from a United States Department of Agriculture sanctioned domestic hemp production program and does not include cannabinoids derived from any other substance.

(6) "Cannabinoid product class" means a group of cannabinoid products that:

(a) Have all ingredients in common; and

(b) Are produced by or for the same company.

(7) "Cartoon" means any drawing or other depiction of an object, person, animal, creature, or any similar caricature that satisfies any of the following criteria:

(a) The use of comically exaggerated features;

(b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or

(c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds, or transformation.

(8) "Child-resistant" means packaging that is:

(a) Designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for adults to use properly; and

(b) Resealable to maintain this effectiveness for children through multiple openings for any product intended for more than a single use or containing multiple servings.

(9) "Cosmetic" is defined by KRS 217.015(7).

(10) "Direct supervision" means the continuous, on-site observation of an employee with the supervisor physically present.

(11) "Food service establishment" is defined by KRS 217.015(21).

(12) "Hemp" is defined by KRS 260.850(5).

(13) "Hemp-derived cannabinoid" means an ingestible, inhalable, or cosmetic product that is processed or derived from hemp.

(14) "Home-based processor" is defined by KRS 217.015(56).

(15) "Hydrogenation" means the chemical reaction between molecular hydrogen (H_2) and another compound or element.

(16) "Imminent health hazard" is defined by KRS 217.015(24).

(17) "Infused" means adding a cannabinoid ingredient to an ingestible cannabinoid product.

(18) "Non-intoxicating cannabinoid" means a product with non-psychoactive properties that does not change the function of the nervous system and does not result in alteration of perception, cognition, or behavior.

(19) "Person" is defined by KRS 217.015(32).

(20) "Proof of age" is defined by KRS 438.305(4).

(21) "Revocation" means the permit to operate is cancelled by the department.

(22) "Serious adverse event" means a medical occurrence associated with the use of a cannabinoid product that results in ***[~~one (1) or more of the following~~]***:

(a) Death;

(b) A life-threatening event;

(c) Inpatient hospitalization, or prolongation of an existing hospitalization;

(d) A persistent or significant incapacity, or substantial disruption in the ability to conduct normal life functions; or

(e) A congenital anomaly or birth defect.

(23) "Tentatively identified compounds" or "TIC" means compounds detected in a sample that are not among the target analytes.

(24) "Total THC" is defined by 7 C.F.R. 990.1.

CONTACT PERSON: Julie Brooks, Policy Specialist, Dept. for Public Health, 275 East Main St., HS1GW-A, Frankfort, KY 40621; Phone: (502) 564-3970; Email: julied.brooks@ky.gov.

Andy Beshear
GOVERNOR

CABINET FOR HEALTH AND FAMILY SERVICES

Eric Friedlander
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October 7, 2024

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
083, Capitol Annex
702 Capitol Ave.
Frankfort KY 40601

Re: 902 KAR 45:012. Hemp-derived cannabinoid product retail and food service establishment requirements.

Dear Co-Chairs West and Lewis,

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 45:012, the Department for Public Health proposes the enclosed suggested substitute to 902 KAR 45:012.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at (502) 229-3377.

Sincerely,

Krista Quarles

Krista Quarles
Policy Specialist
Office of Legislative and Regulatory Affairs

Subcommittee Substitute
Final Version
9/30/2024

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amended After Comments)

902 KAR 45:012. Hemp-derived cannabinoid product retail and food service establishment requirements.

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, 217.992, 2023 Ky Acts ch. 78

STATUTORY AUTHORITY: KRS 217.125, 217.127, 217.135, 217.155

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215. KRS 217.125(2) requires the secretary to provide by administrative regulation a schedule of fees for permits to operate and for inspection activities carried out by the cabinet pursuant to KRS 217.025 through 217.390. KRS 217.135 authorizes the secretary to establish food standards by administrative regulation including a reasonable definition, standard of identity, and designation of optional ingredients that shall be named on the label. KRS 217.155 ***authorizes*** ~~***[allows]***~~ the cabinet or its duly authorized agent free access at reasonable times for the purpose of inspection ***of*** any factory, warehouse, or establishment where foods, drugs, devices, or cosmetics are manufactured or held for sale. This administrative regulation establishes the requirements for retail sale of hemp-derived cannabinoid products, including the permit fee, and methods for use of hemp-derived cannabinoid as an additive to food products. Retail establishments registered with the department prior to **December 31, 2024** ~~**[the effective date of this administrative regulation]**~~ shall be exempted from the permit fee requirement until the annual renewal date. In accordance with 2023 Ky. Act ch 78, in order to limit the ability of minor children accessing adult-use hemp-derived cannabinoid use products, this administrative regulation prohibits the sale of adult-use products within 1,000 feet of an elementary, middle, or high school. Retail establishments registered with the department prior to **December 31, 2024 online at https://redcap.chfs.ky.gov/surveys/?s=C8AHC9AYMP74REEM** ~~**[the effective date of this administrative regulation]**~~ shall be exempted from this location requirement.

Section 1. Retail Establishment and Food Service Establishment Registration.

(1)(a) Only approved cannabinoid products or class of products in accordance with 902 KAR 45:021 may be sold in retail and food service establishments. All other cannabinoid products or class of products shall be prohibited.

(b) **All** ~~**[Adult-use]**~~ cannabinoid products or class of products shall be registered in accordance with 902 KAR 45:021, Section 1(4).

(c) A retailer **or distributor** shall ensure that all cannabinoid products sold are properly registered with the department.

(d) A retailer may register a product in ***place*** ***[lieu]*** of the processor or manufacturer.

(2) Retail establishments and food service establishments offering adult-use cannabinoid products shall be permitted by the cabinet in accordance with this administrative regulation.

(3) The permit shall be:

(a) **[Completed online at https://redcap.chfs.ky.gov/surveys/?s=C8AHC9AYMP74REEM; (b)]** Nontransferable in regard to person or address;

(b)[(c)] Renewed annually; and

(c)[(d)] Include a $2,000 annual permit fee.

(4) All retail establishments registered with the department prior to **December 31, 2024** **[April 27, 2024]**, shall have the fee required by subsection (3)***(c)[(d)]*** of this section waived until the date of the next annual renewal.

(5) A retailer shall ensure all locations are permitted by the cabinet.

(6) Retail establishments and food service establishments**, not permitted by the cabinet,** offering adult-use cannabinoid products at a temporary event or festival shall:

(a) Register with the cabinet at https://redcap.chfs.ky.gov/surveys/?s=C8AHC9AYMP74REEM; and

(b) Include a $250 temporary event registration fee.

(7) Retail establishments offering adult-use cannabinoid products shall not be located within 1,000 feet of an elementary, middle, or high school. Retail establishments registered with the department prior to **December 31, 2024** **[April 27, 2024]**, shall be exempted from the location requirements.

(8) **An in-state** **[A]** business that distributes, sells, or serves adult-use hemp-derived cannabinoid products shall not employ any person who is under twenty-one (21) years of age, unless the person employed is at least eighteen (18) years of age and under the direct supervision of a person twenty-one (21) years of age or older.

Section 2. Retail Sale of Cannabinoid Products.

(1) All cannabinoid products sold in a retail establishment shall:

(a) Be from an approved source;

(b) Be packaged and labeled in accordance with 902 KAR 45:021, Section ***(4)*** ***[3]***; and

(c) Have a valid certificate of analysis available upon request.

(2) Cannabinoid retailers shall maintain records of wholesale cannabinoid product ***purchases*** ***[purchase]***, including the name and address of the cannabinoid processor or manufacturer***[,]*** and the wholesaler or distributor.

(3) The following hemp-derived products shall not be marketed, sold, or distributed **direct to the consumer in a retail setting** **[to any person in the commonwealth]**:

(a) Whole hemp buds;

(b) Ground hemp floral material;

(c) Ground hemp leaf material; and

(d) Any hemp product with a **total** **[delta-9-]**THC concentration in excess of zero and three-tenths (0.3) percent.

(4) All adult-use cannabinoid products shall:

(a) Be secured in the retail setting to prevent theft or other access to persons under the age of twenty-one (21); and

(b) Not be sold, gifted, or otherwise transferred to any person under the age of twenty-one (21).

(5)(a) Any person who sells adult-use cannabinoid products at retail shall require proof of age of the buyer to verify the buyer is age twenty-one (21) years or older; and

(b) May deliver or ship adult-use cannabinoid products to consumers over twenty-one (21) years of age in packages clearly marked "Adult-use only".

(6) All persons located in another state or country who deliver, ship, or cause to be delivered or shipped cannabinoid products directly to any Kentucky consumer shall **be registered in accordance with 902 KAR 45:021** **[~~hold a valid hemp cannabinoid wholesaler or distributor permit issued by the Commonwealth~~]**.

Section 3. Ingestible Cannabinoid Products at Food Service Establishments.

(1) Only registered, pre-packaged adult-use ingestible cannabinoid products may be offered as ready-to-consume or for direct consumption at food service establishments.

(2) Adult-use cannabinoids shall not be added to an ingestible food product at a food service establishment.

(3) Non-intoxicating cannabinoids may be added to an ingestible product prior to retail sale at a food service establishment.

(4) The non-intoxicating cannabinoid shall be obtained from an approved source.

(5) The food service establishment shall obtain a valid certificate of analysis from the approved source and provide a copy upon inspection.

(6) A food service establishment offering non-intoxicating cannabinoid products in a finished food product shall provide to consumers upon request:

(a) The common name of the product; and

(b) The manufacturer or distributor of the product.

(7) A food service establishment shall notify the cabinet within twenty-four (24) hours of becoming aware or within twenty-four (24 hours) of when the food service establishment should have been aware of any serious adverse event to a hemp-derived cannabinoid product sold by the establishment.

Section 4. Inspection and Enforcement.

(1)(a) Retail establishments offering adult-use cannabinoid products shall be inspected by the cabinet or its duly authorized agent; and

(b) Retail establishments offering only non-intoxicating cannabinoid products may be inspected by the cabinet or its duly authorized agent upon complaint, receipt of a report of a serious adverse event, or at the discretion of the cabinet.

(2) The location of the permitted establishment, all general business records, including employee records, and vehicles utilized to transport products are subject to reasonable inspection.

(3) All cannabinoid establishments, whether permitted or not, shall cooperate with the cabinet or its duly authorized agent during any inspections, complaint investigation, requests for information or data, in order to verify compliance with this administrative regulation.

(4)**(a)** Products not in compliance with this administrative regulation shall be seized **[~~and~~**

~~destroyed~~] by the cabinet or its duly authorized agent.

(b) The permit holder shall be given notice that *it has [~~they have~~]* ten (10) days to file an appeal pursuant to subsection (12) of this section.

(c) If *a [~~no~~]* request for an appeal is *not* filed, seized products shall be destroyed.

(5) The permit holder shall take immediate steps to correct conditions that have caused an imminent health hazard.

(6)(a) The permit holder shall notify the cabinet within twenty-four (24) hours of the knowledge of an imminent health hazard that cannot be controlled by immediate corrective action or if product, product packaging, cosmetic, or cosmetic packaging has become contaminated because of an imminent health hazard.

(b) Notification to the cabinet shall be made by:

1. Email to food.safety@ky.gov; or

2. Phone to (502) 564-7181.

(7) If the cabinet has evidence that a permit holder has failed to act to correct an imminent health hazard:

(a) The permit shall be suspended immediately; and

(b) The permit holder may request an administrative hearing in accordance with KRS Chapter 13B.

(8) A permit holder shall notify the cabinet within **twenty-four (24) hours** [~~one (1) business day~~] of becoming aware of any serious adverse event to a cannabinoid product sold or transferred by the permit holder.

(9) In all other instances of violation of this administrative regulation, the cabinet shall serve the permit holder with a written notice specifying the violation and afford the holder an opportunity to correct.

(10) If a permit holder has failed to comply with the written notice within the timeframe granted, the cabinet shall issue a notice of intent to suspend the permit.

(11)(a) The notice in subsection **(9)[~~(11)~~]** of this section shall include notification that the permit shall be suspended at the end of ten (10) days following service of the notice, unless a written request for an administrative hearing is filed with the cabinet by the permit holder within the ten (10) day period; and

(b) The administrative hearing shall be conducted in accordance with KRS 13B.080.

(12) For a permitted establishment that has had a suspended permit two (2) or more times within a five (5) year period, the cabinet shall initiate permit revocation proceedings. Prior to this action, the cabinet shall notify the permit holder in writing, stating the reasons for which the permit revocation is being sought and advising that the permit shall be permanently revoked at the end of ten (10) days following service of the notice, unless a request for an administrative hearing is filed with the cabinet pursuant to KRS Chapter 13B by the permit holder within the ten (10) day period.

(13) Any person who knowingly violates any provision of this administrative regulation may be fined, found guilty **of** [~~or~~]a criminal offense, or both pursuant to KRS 217.992.

(14) State and local law enforcement officers shall have concurrent jurisdiction to enforce violations of this ***administrative regulation*** *[~~section~~]*.

CONTACT PERSON: Julie Brooks, Policy Specialist, Dept. for Public Health, 275 East Main St., HS1GW-A, Frankfort, KY 40621; Phone: (502) 564-3970; Email: julied.brooks@ky.gov.

Andy Beshear
GOVERNOR

CABINET FOR HEALTH AND FAMILY SERVICES

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SECRETARY

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October 7, 2024

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
083, Capitol Annex
702 Capitol Ave.
Frankfort KY 40601

Re: 902 KAR 45:021. Hemp-derived cannabinoid products registration, processing, manufacturing, storage and distribution requirements.

Dear Co-Chairs West and Lewis,

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 45:021, the Department for Public Health proposes the enclosed suggested substitute to 902 KAR 45:021.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at (502) 229-3377.

Sincerely,

Lucie Estill

Lucie Estill
Staff Assistant
Office of Legislative and Regulatory Affairs

Subcommittee Substitute
Final Version
9/30/2024

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amended After Comments)

902 KAR 45:021. Hemp-derived cannabinoid products registration, processing, manufacturing, storage and distribution requirements.

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, 217.992, 2023 Ky Acts ch. 78

STATUTORY AUTHORITY: KRS 217.125, 217.127, 217.135, 217.155

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215. KRS 217.125***(2), (4)[~~(12)~~]*** requires the secretary to provide by administrative regulation a schedule of fees for permits to operate and for inspection activities carried out by the cabinet pursuant to KRS 217.025 through 217.390. KRS 217.135 authorizes the secretary to establish food standards by administrative regulation including a reasonable definition, standard of identity, and designation of optional ingredients that shall be named on the label. KRS 217.155 ***authorizes[~~allows~~]*** the cabinet or its duly authorized agent free access at reasonable times for the purpose of inspecting any factory, warehouse, or establishment where foods, drugs, devices, or cosmetics are manufactured or held for sale. This administrative regulation establishes the product registration, the processing and manufacturing procedures for hemp-derived cannabinoid products, including the permit fee, and the labeling and packaging requirements for products containing hemp-derived cannabinoids. Establishments permitted with the department prior to **December 31, 2024, [~~the effective date of this administrative regulation~~]** shall be exempted from the permit fee requirement until the annual renewal date.

Section 1. Permit and Product Registration.

(1) In-state permit.

(a) A person located in Kentucky seeking to process, manufacture, store, or distribute hemp-derived cannabinoid products shall be permitted by the cabinet.

(b) The permit shall ***[~~be~~]***:

1. ***Be*** nontransferable in regard to person or address;
2. ***Be*** posted in a conspicuous place in the facility;
3. ***Be*** renewed annually; ***[~~and~~]***
4. Include the fee paid in accordance with ***the following***:

a. For a hemp processing permit, the fee is $3,000***;[.]***

b. For a hemp manufacturing permit, the fee is $1,000***;[.]***

c. For a hemp cannabinoid wholesale warehouse and distributor permit, the fee is $1,000**; and[.]**

d. For a hemp cosmetic permit, the fee is $200**; and[.]**

5. Include the product registration fee required by subsection ***(5) [(4)]*** of this section.

(2) The permit fee established pursuant to subsection (1)(b)4. of this section shall be waived for all facilities permitted as of **December 31, 2024 [~~April 27, 2024~~]**, and ***those [~~such~~]***facilities shall pay the permit fee at next annual renewal date.

(3)(a) All out-of-state processors and manufacturers of hemp-derived cannabinoid products available for distribution in Kentucky shall **complete the business registration as required by [~~submit an annual registration to~~]** the department.

(b) The registration for an out-of-state processor or manufacturer shall:

1. Be renewed annually by December 31 each year; and

2. Include:

a. A copy of the current, valid permit to process or manufacture hemp-derived cannabinoids issued from the state regulatory authority;

b. A copy of the state regulation pertaining to the production of hemp-derived cannabinoid products; **[~~and~~]**

c. **The fee required by subparagraph (1)(b)4.c. of this section; and**

d. The product registration fee required by subsection (5) of this section.

(4) Cannabinoids requiring registration:

(a) Adult-use cannabinoids shall include:

Cannabinoid	CAS Number
Delta-10-tetrahydrocannabinol (Delta-10-THC)	95543-62-7
Delta-9-tetrahydrocannabinol (THC) with three tenths of one percent (0.3%) or less Total THC	1972-08-3
Delta-8-tetrahydrocannabinol (Delta-8-THC)	5957-75-5
Delta-9-tetrahydrocannabinolic acid A (THCA-A) with three tenths of one percent (0.3%) or less Total THC	23978-85-0
Delta-9-tetrahydrocannabivarin (THCV)	31262-37-0
Delta-9-tetrahydrocannabivarinic acid (THCVA)	39986-26-0
Delta-6-tetrahydrocannabinol (Delta 6)	95720-02-8
Hexahydrocannabinol (HHC)(-)	6692-85-9
Tetrahydrocannabiphorol (THCp)	54763-99-4
Tetrahydrocannabinol methyl ether (THCM)	36403-68-6

(b) Non-intoxicating cannabinoids shall include:

Cannabinoid	CAS Number
Cannabidiol (CBD)	13956-29-1
Cannabidiolic acid (CBDA)	1244-58-2
Cannabidivarin (CBDV)	24274-48-4
Cannabidivarinic acid (CBDVA)	31992-13-5
Cannabichromene (CBC)	20675-51-8
Cannabichromenic acid (CBCA)	185505-15-1

Cannabigerolic acid (CBGA)	25555-57-1
Cannabigerol (CBG)	25654-31-3
Cannabinol (CBN)	521-35-7
Cannabitriol (CBT)	11003-36-4

(c) All other cannabinoids are prohibited for sale in Kentucky unless pre-approved by the cabinet.

(5) Product registration fee.

(a) A product registration fee of $200 shall be paid for each cannabinoid product or cannabinoid product class sold in Kentucky.

(b) The fee shall be paid to the cabinet by check or money order made payable to the Kentucky State Treasurer.

(6) A new product registration shall be required for changes:

(a) In the chemical composition or formula of the cannabinoid product; ***or***

(b) To the serving size or directions for use.

(7) All in-state processors and manufacturers permitted by the cabinet, and all out-of-state processors and manufacturers registering with the cabinet shall submit:

(a) The name and address of the applicant;

(b) The name and address of the brand or company whose name shall appear on the label, if other than the applicant's;

(c) The name of the product;

(d) The name and address of the origin of the adult-use cannabinoid product with which the final product was manufactured;

(e) A complete copy of the front and back of the label that will appear on the product; and

(f) A certificate of analysis from an accredited third-party laboratory for the lot for each product.

(8) A new **product** **[~~in-state processor or manufacturer permit, or out-of-state~~]** registration shall be required for any changes to the requirements of subsection (7) of this section.

Section 2. Processing, Manufacture, Storage, or Distribution of Hemp-derived Cannabinoid Products.

(1) All processors and manufacturers shall meet:

(a) The applicable requirements of 902 KAR 45:160 Section 2(1)(u); and

(b) The requirements of 902 KAR 45:160, Sections 4 ***through[~~, 5, 6, 7, 8, 9, 10,~~]*** 11, and 14.

(2) Cannabinoid products shall not be manufactured, marketed, sold, or distributed by a home-based processor.

(3) The following hemp-derived products shall not be manufactured **with the intent for retail sale**:

(a) Hemp cigarettes;

(b) Hemp cigars;

(c) Chew, dip, or other smokeless material consisting of hemp leaf material or hemp floral material; **[~~and~~]**

(d) Hemp leaf material or floral material teas**; and**

(e) Hemp bud or floral material.

(4) A business that processes, manufactures, warehouses, distributes, sells, or serves adult-use hemp-derived cannabinoid products shall not employ any person who is under twenty-one (21)

years of age, unless the person employed is at least eighteen (18) years of age and under the direct supervision of a person twenty-one (21) years of age or older.

(5) Non-intoxicating cannabinoid products shall:

(a) Have at least a fifteen (15) non-intoxicating cannabinoid to one (1) adult-use cannabinoid ratio; and

(b) Contain two and five-tenths (2.5) milligrams or less of adult-use cannabinoid per serving.

(6) **Products not meeting the requirements of subsection (5) of this section shall be considered adult-use products.**

(7) The serving size of an ingestible cannabinoid product shall be:

(a) As a whole unit where one (1) unit equals one (1) serving;

(b) Equal ***to*** the maximum amount recommended, as appropriate, on the label for consumption per occasion in whole units; and

(c) Based on the amount typically consumed.

(8)[~~(7)~~] A hemp-derived cannabinoid processing or manufacturing facility shall not treat or otherwise adulterate a cannabinoid product with:

(a) Any non-cannabinoid additive that increases toxicity or addictive potential, excluding caffeine;

(b) Alcohol;

(c) Nicotine; or

(d) Other chemicals that may increase carcinogenicity or cardiac effects.

(9)[~~(8)~~] All products shall be homogenized to ensure uniform distribution of cannabinoids throughout the product.

(10)[~~(9)~~] Only permitted hemp-derived cannabinoid processing facilities shall perform cannabinoid extraction, conversion, catalyzation, distillation, hydrogenation, or other refinement processes.

(11)[~~(10)~~] A hemp-derived cannabinoid processor or manufacturer shall only use the following solvents: water, glycerin, vegetable oils, animal fats, butane, propane, carbon dioxide, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent is expressly prohibited unless pre-approved by the cabinet.

(12)[~~(11)~~] A hemp-derived cannabinoid processor using hydrocarbon-based solvents shall use only ***those[~~such~~]*** solvents of ninety-nine (99) percent or better purity. Nonhydrocarbon-based solvents shall be food grade.

(13)[~~(12)~~] (a) A current copy of safety data sheets and a receipt of purchase for all solvents used or to be used in an extraction process shall be kept on file;

(b) The processor shall retain in its facility a certificate of analysis (COA) from the original manufacturer with purity and impurity limits and results for all solvents used; and

(c) Certificates shall be retained for two (2) years.

(14)[~~(13)~~] (a) Solvents shall be collected and stored in food-grade containers to maintain purity; and

(b) Solvent containers shall be replaced or safely purged, cleaned, and sanitized periodically.

(15)[~~(14)~~] Extraction processes shall take place in an environment properly ventilated to control all sources of ignition where a flammable atmosphere is, or could be, present.

(16)[~~(15)~~] Cannabinoid processing facilities shall not use pressurized canned flammable fuel, such as butane intended for use in outdoor activities, handheld torch ***devices*** ***[~~devises~~]***, and

refillable cigarette lighters.

(17)[~~(16)~~] Cannabinoid processing facilities using carbon dioxide shall have equipment and facilities approved by local fire code officials, if applicable.

(18)[~~(17)~~] Processes using flammable gas or flammable liquid shall have leak or gas detection measures, or both.

(19)[~~(18)~~] A permittee shall not use dimethylsulfoxide (DMSO) in the manufacture of hemp-derived cannabinoid products, and possession upon the permitted premises is prohibited.

(20)[~~(19)~~] (a) A hemp-derived cannabinoid manufacturer may use terpenes or other hemp essential oil but shall not use non-cannabinoid derived inactive ingredients not listed in the federal Food and Drug Administration inactive ingredient database at https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm in the manufacture of inhalable hemp-derived cannabinoid product and distillate intended for use through a vaporizer delivery device or pressurized metered dose inhaler; and

(b) Any non-cannabinoid derived inactive ingredients used shall be less than or equal to the concentration listed in the database.

(21)[~~(20)~~] The following substances shall be prohibited in hemp-derived cannabinoid extraction intended for inhalation:

(a) Acetates;

(b) Medium-chain triglycerides (MCT);

(c) Polyethylene glycol (PEG);

(d) Propylene glycol (PG or PPG);

(e) Diketones:

1. 2,3-butanedione (Diacetyl);
2. 2,3-pentanedione (acetylpropionyl); and
3. 3-hydroxybutanone (acetoin);

(f) Myclobutanil;

(g) Artificial food coloring; and

(h) Benzoic acid.

(22)[~~(21)~~] Hazard analysis and risk-based preventive controls.

(a) Processing facilities shall conduct a hazard analysis in accordance with 902 KAR 45:160 Section 2(1)(u) to identify and evaluate, based on experience, illness data, scientific report, and other information known, or reasonably foreseeable hazards associated with each type of cannabinoid product produced by extraction, conversion, catalyzation, or distillation, hydrogenation, or other refinement processes, and shall include:

1. Processing reagents or catalysis;
2. Processing by-products or compounds; and
3. Tentatively identified compounds.

(b) The hazard analysis shall include an evaluation of the hazards identified to assess the severity of illness or injury from the hazard and the probability that the hazard will occur in the absence of preventive controls.

(c) A processing facility shall identify and implement preventive controls to provide assurances that any hazards requiring a preventive control shall be significantly minimized or prevented, and the hemp-derived cannabinoid product not adulterated.

(d) The cabinet may initiate an investigation of a processing facility as a result of a by-product

or compound with no toxicity study or a TICs report from a testing facility and may require a processing or manufacturing facility to submit samples for additional testing, including testing for analytes that are not required by this administrative regulation, at the processing or manufacturing facility's expense.

Section 3. Record Keeping.

(1) A master formulation record shall be prepared and maintained for each unique hemp-derived cannabinoid product.

(2) The master formulation record shall include at least the following information:

(a) Name of the cannabinoid product;

(b) Ingredient identities and amounts;

(c) Specifications on the delivery device (if applicable);

(d) Complete instructions for preparing the cannabinoid product, including equipment, supplies, and description of the manufacturing steps;

(e) Process controls and procedures; and

(f) Any other information needed to describe the production and ensure its repeatability.

(3) A batch or process lot manufacturing record shall be created for each production batch of cannabinoid product.

(4) The batch manufacturing record shall include at the least the following information:

(a) Name of the cannabinoid product;

(b) Master formulation record reference for the cannabinoid product;

(c) Date and time of preparation of the cannabinoid product;

(d) Production batch number;

(e) Signature or initials of individuals involved in each manufacturing step;

(f) Name, vendor, or manufacturer, production batch number, and expiration date of each ingredient;

(g) Weight or measurement of each ingredient;

(h) Documentation of process controls;

(i) Any deviations from the master formulation record, and any problems or errors experienced during the manufacture, and corrective actions; and

(j) Total quantity of the cannabinoid product manufactured.

Section 4. Product Packaging and Labeling.

(1) Each cannabinoid product manufactured, marketed, sold, or distributed in the commonwealth shall be packaged and labeled in accordance with KRS 217.037, HB 544, 2023 Ky. Acts ch. 78, and this administrative regulation.

(2) Each container of adult-use cannabinoid product**, excluding cosmetics,** shall:

(a) Have a tamper-evident seal; and

(b) Be in child-resistant packaging.

(3) Each container of non-intoxicating cannabinoid product or cosmetic shall have a tamper-evident seal.

(4) Cannabinoid product packaging shall not include:

(a) Any cartoon images;

(b) Likeness to images, characters, or phrases that are popularly used to advertise to children;

(c) Likeness to or imitation of any commercially available candy, snack, baked good, or beverage packaging or labeling;

(d) The terms "candy" or "candies", or any variation in the spelling of these words; or

(e) The logo of the department or cabinet, or any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe the product has been endorsed, manufactured, or used by any state, county, or municipality or any agency thereof, excluding the use of seals associated with state or federal programs used in accordance with state or federal law and regulations.

(5) The total amount of hemp-derived cannabinoid per serving and the total amount per container shall accurately reflect testing results and shall not contain less than eighty (80) percent or more than 120% of the concentration of total cannabinoid content as listed on the product label:

(a) For hemp-derived cannabinoid ingestible and inhalable products, potency shall be labeled as milligrams per serving for total tetrahydrocannabinol and the primary cannabinoid marketed, as applicable; and milligrams per package for total tetrahydrocannabinol and the primary cannabinoids marketed; and

(b) Other hemp-derived cannabinoids labeled milligrams per gram (mg/g) per serving, excluding cosmetics, and milligrams per package, if listed on the label.

(6) Adult-use hemp-derived cannabinoid products shall include the following warning label statements:

(a) "Warning: Contains THC*";[.]*

(b) "This product is intended for use by adults 21 years and older. Keep out of reach of children*";[.]*

(c) "There may be health risks associated with the consumption of this product*";[.]*

(d) "There may be additional health risks associated with the consumption of this product for those who are pregnant, nursing, or plan to become pregnant*";[.]*

(e) "The intoxicating effects of this product may be delayed by two or more hours*";[.]*

(f) "May cause drowsiness or impairment. Do not drive a motor vehicle or operate machinery while using this product*"; and[.]*

(g) "Use of this product may result in a positive drug screen*".[.]*

(7) A quick response or QR code may be used as a link to the warning statements required by subsection (6) of this section. The QR code shall be labeled as "Warning Statements" directly above or below the code and shall be large enough to be smart-phone readable.

Section 5. Inspection and Enforcement. (1) The cabinet or its duly authorized agent shall conduct an onsite inspection of all permitted cannabinoid processing and manufacturing establishments, storage warehouses, and distribution centers.

(2) The location of the permitted establishment, all general business records, including employee records, and vehicles utilized to transport products are subject to reasonable inspection.

(3) All cannabinoid establishments, whether permitted or not, shall cooperate with the cabinet or its duly authorized agent during any inspections, complaint investigation, and requests for information or data, in order to verify compliance with this administrative regulation.

(4)**(a)** All products not in compliance with this administrative regulation may be seized **[~~and destroyed~~]** by the cabinet or its duly authorized agent.

(b) The permit holder shall be given notice that *it has [~~they have~~]* ten (10) days to file an appeal pursuant to subsection (12) of this section.

(c) If *a [~~no~~]* request for an appeal is *not* filed, seized products shall be destroyed.

(5) The permit holder shall take immediate steps to correct conditions that have caused an imminent health hazard.

(6)(a) The permit holder shall notify the cabinet within twenty-four (24) hours of the knowledge of an imminent health hazard that cannot be controlled by immediate corrective action or if product, product packaging, cosmetic, or cosmetic packaging has become contaminated because of an imminent health hazard.

(b) Notification to the cabinet shall be made by:

1. Email to food.safety@ky.gov; or

2. Phone to (502)564-7181.

(7) If the cabinet has evidence that a permit holder has failed to act to correct an imminent health hazard, the following enforcement provisions shall be initiated:

(a) Suspend the permit without an administrative hearing; or

(b) Suspend that portion of the operation affected by the imminent health hazard without an administrative hearing.

(8) If a permit suspension is due to an imminent health hazard, the permit holder may submit a request for an administrative hearing to the cabinet in accordance with KRS Chapter 13B.

(9) A permit holder shall notify the cabinet within twenty-four (24) hours of becoming aware of any serious adverse event to a hemp-derived cannabinoid product sold or transferred by the permit holder.

(10) In all other instances of violation of this administrative regulation, the cabinet shall serve the permit holder with a written notice specifying the violation and afford the holder an opportunity to correct.

(11) If a permit holder has failed to comply with the written notice within the timeframe granted, the cabinet shall issue a notice of intent to suspend the permit.

(12)(a) The notice in subsection (11) of this section shall include notification that the permit shall be suspended at the end of ten (10) days following service of the notice, unless a written request for an administrative hearing is filed with the cabinet by the permit holder within the ten (10) day period; and

(b) The administrative hearing shall be conducted in accordance with KRS 13B.080.

(13) For a permitted facility that has had a suspended permit two (2) or more times within a five (5) year period, the cabinet shall initiate permit revocation proceedings. Prior to this action, the cabinet shall notify the permit holder in writing, stating the reasons for which the permit revocation is being sought and advising that the permit shall be permanently revoked at the end of ten (10) days following service of the notice, unless a request for an administrative hearing is filed with the cabinet pursuant to KRS Chapter 13B by the permit holder within the ten (10) day period.

(14) Any person who violates any provision of this administrative regulation may be fined, found guilty **of** **[~~or~~]**a criminal offense, or both pursuant to KRS 217.992.

(15) State and local law enforcement officers shall have concurrent jurisdiction to enforce violations of this ***administrative regulation*** ***[~~section~~]***.

CONTACT PERSON: Julie Brooks, Policy Specialist, Dept. for Public Health, 275 East Main St., HS1GW-A, Frankfort, KY 40621; Phone: (502) 564-3970; Email: julied.brooks@ky.gov.

Andy Beshear
GOVERNOR

CABINET FOR HEALTH AND FAMILY SERVICES

Eric Friedlander
SECRETARY

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October 7, 2024

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
083, Capitol Annex
702 Capitol Ave.
Frankfort KY 40601

Re: 902 KAR 45:031. Hemp-derived cannabinoid product sampling and testing requirements.

Dear Co-Chairs West and Lewis,

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 45:031, the Department for Public Health proposes the enclosed suggested substitute to 902 KAR 45:031.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at (502) 229-3377.

Sincerely,

Stacy Carey

Stacy Carey
Executive Staff Advisor
Office of Legislative and Regulatory Affairs

Subcommittee Substitute
Final Version
9/30/2024

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amended After Comments)

902 KAR 45:031. Hemp-derived cannabinoid product sampling and testing requirements.

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, 260.850, 438.305(4), 2023 Ky Acts ch. 78

STATUTORY AUTHORITY: KRS 217.125, 217.155

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215. KRS 217.155 ***authorizes*** ***[~~allows~~]*** the cabinet or its duly authorized agent free access at reasonable times for the purpose of inspection any factory, warehouse, or establishment where foods, drugs, devices, or cosmetics are manufactured or held for sale. This administrative regulation establishes the hemp-derived cannabinoid product sampling and testing requirements.

Section 1. Product Sampling and Testing Requirements. (1) Sampling and testing for all cannabinoid products shall be:

(a) Done for each batch or process lot; and

(b) Conducted with representative samples to ensure:

1. All batches or process lots are adequately assessed for contaminants; and

2. The cannabinoid profile is consistent throughout.

(2) Testing shall only be performed on the final product equivalent to what will be consumed.

(3) Samples shall be collected using appropriate aseptic techniques.

(4) A cannabinoid processing or manufacturing facility shall assign each batch or process lot a unique batch or lot number that shall be:

(a) Documented and maintained in the processing and manufacturing facility for at least two (2) years and available to the department upon request;

(b) Provided to the individual responsible for taking samples; and

(c) Included on the product **package or** label.

(5) Sample size, handling, storage, and disposal.

(a) Cannabinoid products samples shall consist of enough material from the batch or process lot to ensure that the required attributes in the products are homogenous and consistent with the testing facility's accredited sampling policies and procedures.

(b) A cannabinoid processing or manufacturing permittee shall prepare sampling policies and procedures that contain the information necessary for collecting and transporting samples from

cannabinoid products in a manner that does not endanger the integrity of the sample for any analysis required by this administrative regulation.

(6) Reserve samples.

(a) Processors and manufacturers shall collect and hold reserve samples of each batch or process lot of packaged and labeled product.

(b) The reserve samples shall:

1. Be held using the same container-closure system that the packaged and labeled product is distributed, or if distributing to be packaged and labeled, using a container-closure system that provides the same characteristics to protect against contamination or deterioration;

2. Be identified with the batch or process number;

3. Be retained for the shelf-life date, as applicable, or for two (2) years from the date of distribution of the last batch or process lot of the product associated with the reserve sample; and

4. Consist of at least twice the quantity necessary for all tests or examinations to determine if the product meets specifications.

(7) Laboratory requirements.

(a) Testing facilities used by the cannabinoid processing or manufacturing facility shall be an independent third-party, fully accredited to the standard established by International Organization for Standardization (ISO) 17025 by an International Laboratory Accreditation Cooperation recognized accreditation body.

(b) The testing facility shall:

1. Maintain ISO 17025 accreditation; and

2. Comply with all required analytes standards for the relevant test methods of:

a. Cannabinoids;

b. Microbial impurities;

c. Mycotoxins;

d. Residual pesticides;

e. Heavy metals; and

f. Residual solvents, if applicable.

(c) Cannabinoid processing or manufacturing facilities shall maintain on file proof of a valid certificate of accreditation for the laboratory completing product testing that:

1. Is issued by an accreditation organization; and

2. Attests to the laboratory's competence to perform testing, including all the required analytes for the relevant test methods required.

(8) Testing requirements.

(a) A processing or manufacturing facility shall test every batch or process lot of cannabinoid product for sale or distribution prior to sell or transfer.

(b) ***Testing*** ***~~[Test]~~*** shall be performed using ***a*** cannabinoid quantification technique with a high enough specificity and sensitivity to differentiate between cannabinoids and isomers of cannabinoids.

(c) Cannabinoid products shall be tested for:

1. Cannabinoids, which shall include all cannabinoids specified in 902 KAR 45:021, Section 1***(4)~~[(3)]~~***(a);

2. Microbial impurities;

3. Mycotoxins;

4. Residual pesticides;

5. Heavy metals; and

6. Residual solvents, if applicable.

(d) Infused cannabinoid products may not require additional testing for microbial impurities, mycotoxins, residual pesticides, heavy metals, or residual solvents, as applicable, if the cannabinoid distillate used to make an infused product was:

1. Tested for microbial impurities, mycotoxins, residual pesticides, heavy metals, or residual solvents in compliance with this administrative regulation; and

2. Test results indicate the batch or process lot was within established limits.

(e) An infused cannabinoid product shall be tested if the addition of ingredients or processing practice create a reasonable or foreseeable microbial impurity, mycotoxin, residual pesticide, heavy metals, or residual solvents hazard.

(f) All vaporizer delivery device or pressurized metered dose inhaler cartridge batches or process lots shall be tested for acetates.

(g) In accordance with KRS 217.039, all applicable certificates of analysis shall accompany the final product.

Section 2. Standards for Cannabinoid Testing.

(1) A testing facility shall establish a limit of quantitation of one (1) milligram per gram (mg/g) or lower for all adult-use cannabinoids analyzed and reported.

(2) A testing facility shall report the result of the cannabinoid testing on the certificate of analysis, that includes at minimum:

(a) Total tetrahydrocannabinol concentration, calculated in accordance with subsection (3) of this section and reported in percentages;

(b) Tetrahydrocannabinol-A concentration;

(c) Milligrams per serving for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable;

(d) Milligrams per package for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable; and

(e) The results of all other hemp-derived cannabinoids analyzed on the COA both as a percentage and milligrams per gram (mg/g).

(3) The following calculation shall be used for calculating total tetrahydrocannabinol concentration expressed in weight: Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g) **on a dry weight basis**.

(4) For cannabinoid infused products, excluding cosmetics, potency shall be reported as milligrams of total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics per gram.

(5) Cannabinoid products shall not contain a delta-9 tetrahydrocannabinol concentration of more than three-tenths of one percent (0.3) on a dry ***weight*** ***~~[weigh]~~***basis.

(6) The serving size from a vaporizer delivery device or pressurized metered dose inhaler shall not exceed one (1) inhalation lasting two (2) seconds per serving.

Section 3. Standards for Microbial Impurities.

(1) Cannabinoid products shall be tested by a testing facility for the presence of microbial impurities.

(2) The sample of inhalable cannabinoid products shall be deemed to have passed the microbial impurities testing if the following conditions are met:

(a) Total Escherichia coli is not detected above 100 colony forming units/gram;

(b) Shiga toxin–producing Escherichia coli is not detected in one (1) gram;

(c) Salmonella spp. is not detected in one (1) gram;

(d) Pathogenic Aspergillus species A. fumigatus, A. flavus, A. niger, and A. terreus are not detected in one (1) gram; **and**

(e) **[~~Listeria Spp. is not detected in one (1) gram; and~~**

~~(f)~~] A total combined yeast and mold do not exceed 100,000 colony forming units per gram.

(3) The sample of ingestible or cosmetic cannabinoid products shall be deemed to have passed the microbial impurities testing if the following conditions are met:

(a) Total Escherichia coli is not detected above 100 colony forming units/gram;

(b) Shiga toxin–producing Escherichia coli is not detected in one (1) gram;

(c) Salmonella spp. is not detected in one (1) gram; **and**

(d) **[~~Listeria Spp. is not detected in one (1) gram; and~~**

~~(e)~~] A total combined yeast and mold do not exceed 100,000 colony forming units per gram.

(4) If the sample fails microbial impurities testing, the batch or process lot from which the sample was collected shall not be released for retail sale.

(5) If a sample from a batch or process lot of a cannabinoid product fails microbiological contaminant testing, the batch may be further processed if the processing method effectively sterilizes the batch.

(6) A batch or process lot that is sterilized in accordance with subsection (5) of this section shall be sampled and tested in accordance with this administrative regulation, if not otherwise required for that product, for microbiological contaminants, and residual solvents.

(7) A batch or process lot that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (5) of this section shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 4. Standards for Mycotoxin Testing. (1) Cannabinoid products shall be tested by a testing facility for the following mycotoxins: aflatoxin B1, B2, G1, and G2 ochratoxin A.

(2) A batch or process lot shall be deemed to have passed mycotoxin testing if the following conditions are met:

(a) Total of aflatoxin B1, B2, G1, and G2 does not exceed twenty (20) microgram per kilogram (µg/kg) of substance; and

(b) Ochratoxin A does not exceed twenty (20) µg/kg of substance.

(3) A batch or process lot that fails mycotoxin testing in accordance with this subsection shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 5. Standards for Testing Residual Pesticides. (1) Cannabinoid products shall be tested by a testing facility for the following residual pesticides and shall not exceed the maximum allowable concentration for each:

Residual pesticide	Chemical Abstract Service (CAS) assigned number	Maximum allowable concentration stated in parts per million (ppm)
Abamectin	71751-41-2	0.5 ppm
Acephate	30560-19-1	0.4 ppm
Acequinocyl	57960-19-7	2.0 ppm
Acetamiprid	135410-20-7	0.2 ppm
Aldicarb	116-06-3	0.4 ppm
Azoxystrobin	131860-33-8	0.2 ppm
Bifenazate	149877-41-8	0.2 ppm
Bifenthrin	82657-04-3	0.2 ppm
Boscalid	188425-85-6	0.4 ppm
Carbaryl	63-25-2	0.2 ppm
Carbofuran	1563-66-2	0.2 ppm
Chlorantraniliprole	500008-45-7	0.2 ppm
Chlorfenapyr	122453-73-0	1.0 ppm
Chlormequat chloride	7003-89-6	0.2 ppm
Chlorpyrifos	2921-88-2	0.2 ppm
Clofentezine	74115-24-5	0.2 ppm
Cyfluthrin	68359-37-5	1.0 ppm
Cypermethrin	52315-07-8	1.0 ppm
Daminozide	1596-84-5	1.0 ppm
DDVP (Dichlorvos)	62-73-7	0.1 ppm
Diazinon	333-41-5	0.2 ppm
Dimethoate	60-51-5	0.2 ppm
Ethoprophos	13194-48-4	0.2 ppm
Etofenprox	80844-07-1	0.4 ppm
Etoxazole	153233-91-1	0.2 ppm
Fenoxycarb	72490-01-8	0.2 ppm
Fenpyroximate	134098-61-6	0.4 ppm
Fipronil	120068-37-3	0.4 ppm
Flonicamid	158062-67-0	1.0 ppm
Fludioxonil	131341-86-1	0.4 ppm
Hexythiazox	78587-05-0	1.0 ppm
Imazalil	35554-44-0	0.2 ppm
Imidacloprid	138261-41-3	0.4 ppm
Kresoxim-methy	143390-89-0	0.4 ppm
Malathion	121-75-5	0.2 ppm
Metalaxyl	57837-19-1	0.2 ppm
Methiocarb	2032-65-7	0.2 ppm
Methomyl	16752-77-5	0.4 ppm
Methyl parathion	298-00-0	0.2 ppm

Myclobutanil,	88671-89-0	0.2 ppm (prohibited at any concentration for inhalation)
Naled	300-76-5	0.5 ppm
Oxamyl	23135-22-0	1.0 ppm
Paclobutrazol	76738-62-0	0.4 ppm
Permethrins (measured as the cumulative residue of cis- and trans-isomers)	52645-531 (54774-45-7 and 51877-74-8)	0.2 ppm
Phosmet	732-11-6	0.2 ppm
Piperonyl_butoxide	51-03-6	2.0 ppm
Prallethrin	23031-36-9	0.2 ppm
Propiconazole	60207-90-1	0.4 ppm
Propoxur	114-26-1	0.2 ppm
Pyrethrins (measured as the cumulative residue of pyrethrin 1, cinerin 1 and jasmolin 1)	8003-34-7(121-21-1,25402-06-6 and 4466-14-2)	1.0 ppm
Pyridaben	96489-71-3	0.2 ppm
Spinosad	168316-95-8	0.2 ppm
Spiromesifen	283594-90-1	0.2 ppm
Spirotetramat	203313-25-1	0.2 ppm
Spiroxamine	118134-30-8	0.4 ppm
Tebuconazole	107534-96-3	0.4 ppm
Thiacloprid	111988-49-9	0.2 ppm
Thiamethoxam	153719-23-4	0.2 ppm
Trifloxystrobin	141517-21-7	0.2 ppm

(2) A batch or process lot that fails residual pesticide testing in accordance with this section shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 6. Standards for Testing for Heavy Metals.

(1) Cannabinoid products shall be tested by a testing facility for the following metals and shall not exceed the maximum allowable concentration for each:

(a) Arsenic, maximum allowable concentration: one and five-tenths (1.5) ppm;

(b) Cadmium, maximum allowable concentration: zero and four-tenths (0.4) ppm;

(c) Lead, maximum allowable concentration: one (1) ppm; and

(d) Mercury, maximum allowable concentration: one and two-tenths (1.2) ppm.

(2) Cannabinoid distillate intended for inhalable products shall be tested by a testing facility for the following metals and shall not exceed the maximum allowable concentration for each:

(a) Arsenic, maximum allowable concentration: zero and two-tenths (0.2) ppm;

(b) Cadmium, maximum allowable concentration: zero and two-tenths (0.2) ppm;

(c) Lead, maximum allowable concentration: zero and five-tenths (0.5) ppm; and

(d) Mercury, maximum allowable concentration: zero and one-tenths (0.1) ppm.

(3) A batch or process lot that fails heavy metals testing in accordance with this section shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 7. Standards for Testing Residual Solvents. (1) Cannabinoid products shall be tested by a testing facility for residual solvents, as appropriate, and shall not exceed the maximum allowable concentration for each solvent used according to the table below:

Solvent	CAS assigned number	Maximum allowable concentration stated in parts per million (ppm)
Acetone	67-64-1	1,000 ppm
Benzene	71-43-2	2 ppm
Butanes, (measured as the cumulative residue of n-butane and iso-butane),	106-97-8 and 75-28-5	1,000 ppm
Ethanol	64-17-5	5,000 ppm
Ethyl Acetate	141-78-6	1,000 ppm
Heptane	142-82-5	1,000 ppm
Hexanes (measured as the cumulative residue of n-hexane, 2-methylpentane, 3-methylpentane, 2,2-dimethylbutane, and 2,3-dimethylbutane)	110-54-3, 107-83-5 and 79-29-8	60 ppm
Methanol	67-56-1	600 ppm
Pentanes (measured as the cumulative residue of n-pentane, iso-pentane, and neo-pentane)	109-66-0, 78-78-4 and 463-82-1	1,000 ppm
2-Propanol (IPA)	67-63-0	1,000 ppm
Propane	74-98-6	1,000 ppm
Toluene*	108-88-3	180 ppm
Total Xylenes* (measured as the cumulative residue of 1,2-dimethylbenzene, 1,3-dimethylbenzene, and 1,4-dimethylbenzene, and the non-xylene, ethylbenzene),	1330-20-7 (95-47-6, 108-38-3 and 106-42-3 and 100-41-4)	430 ppm
*Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use, limits have been listed here accordingly.		

(2) A processing or manufacturing facility shall be exempt from testing for solvents if the facility:

(a) Did not use any solvent listed in subsection (1) of this section;

(b) Used a mechanical extraction process to separate cannabinoids; or

(c) Used only water, animal fat, or vegetable oil as a solvent to separate the cannabinoids.

(3) If a sample from a batch or process lot fails solvent testing, the batch or process lot may be remediated using procedures that would reduce the concentration of solvents to less than the action level.

(4) A batch or process lot that is remediated in accordance with subsection (3) of this section shall be:

(a) Sampled and tested in accordance with this administrative regulation; and

(b) Tested for solvents if not otherwise required for that product under this administrative regulation.

(5) A batch or process lot that fails solvent testing that is not remediated or that if remediated fails testing shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 8. Standards for Water Activity. (1) Plant material, such as flower, shake, and plant trim, used to process and manufacture hemp-derived cannabinoid products shall have a water activity (Aw) rate of less than 0.65.

(2) If the plant material sample fails testing for water activity, the batch from which the sample was taken may:

(a) Be used to make a cannabinoid distillate; or

(b) Continue to dry or cure.

(3) Plant material that undergoes additional drying or curing as described in subsection (2)(b) of this section shall be re-sampled and tested in accordance with this section.

Section 9. Failed Testing and Remediation. (1) A sample that fails any initial testing may be reanalyzed by the testing facility.

(2) If the reanalyzed sample passes, the processing or manufacturing facility shall resample the batch or process lot using another accredited testing facility to confirm the result in order for the batch or process lot to pass testing.

(3) A batch or process lot shall fail testing if the testing facility detects the presence of a contaminant in a sample above any limit of detection (LOD) established in this administrative regulation:

(a) During an initial test where no reanalysis is requested; or

(b) Upon reanalysis as described in this subsection.

(4) If a sample fails a test or a reanalysis, the batch or process lot:

(a) May be remediated or sterilized in accordance with this administrative regulation; or

(b) If it cannot be remediated or sterilized in accordance with this administrative regulation, it shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

(5) A hemp-derived cannabinoid product batch or process lot shall only be remediated twice. If the batch or process lot fails after a second remediation attempt and the second retesting, the entire batch or process lot shall be destroyed in a manner approved by the cabinet.

(6) A hemp-derived cannabinoid product from a batch or process lot that failed testing shall not be combined with another batch or process lot. Mixed products shall be considered adulterated, regardless of the LOD or defect level of the final product.

Section 10. Certificate of Analysis. (1) The testing facility shall:

(a) Generate a certificate of analysis (COA) for each representative sample that the testing facility analyzes; and

(b) Ensure the COA contains the results of all required analyses performed for the representative sample.

(2) The COA shall contain, at minimum:

(a) The testing facility's name, premises address, and license number, processor's or manufacturer's name, and premises address;

(b) Batch or lot number of the batch or process lot from which the sample was obtained. For products that are already packaged at the time of sampling, the labeled batch or lot number on the packaged hemp-derived cannabinoid products shall match the batch or lot number on the COA;

(c) Sample identifying information, including matrix type and unique sample identifiers;

(d) Sample history, including the date collected, the date received by the testing facility, and the date of all sample analyses and corresponding testing results;

(e) The analytical methods, analytical instrumentation used, and corresponding LOD and limits of quantitation (LOQ);

(f) Analytes detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed, if any; and

(g) A chromatograph of the cannabinoid test results.

(3) The testing facility shall report test results for each representative sample on the COA as an overall "pass" or "fail" for the entire batch:

(a) When reporting qualitative results for each analyte, the testing facility shall indicate "pass" or "fail";

(b) When reporting quantitative results for each analyte, the testing facility shall use the appropriate units of measurement as required in accordance with this administrative regulation;

(c) When reporting results for each test method, the testing facility shall indicate "pass" or "fail";

(d) When reporting results for any analytes that were detected below the analytical method LOQ, indicate "<LOQ", notwithstanding cannabinoid results;

(e) When reporting results for any analytes that were not detected or detected below the LOD, indicate "ND"; and

(f) Indicate "NT" for any test that the testing facility did not perform.

(4)(a) In accordance with 2023 Ky. Acts ch. 78, a cannabinoid manufacturer or processor that ships adult-use products out-of-state for use or sale outside the Commonwealth of Kentucky:

1. Shall abide by the testing and labeling requirements of this administrative regulation if the receiving state or jurisdiction does not have testing and labeling requirements; or

2. May defer to the receiving state's testing requirements if that state has equivalent testing requirements.

3. Products intended for out-of-state sale shall be stored separately from in-state products and shall have signage indicating the products are for out-of-state sale.

(b) Batch number of the batch from which the sample was obtained shall be on the COA for all products shipped out of state.

CONTACT PERSON: Julie Brooks, Policy Specialist, Dept. for Public Health, 275 East Main St., HS1GW-A, Frankfort, KY 40621; Phone: (502) 564-3970; Email: julied.brooks@ky.gov.

Andy Beshear
GOVERNOR

CABINET FOR HEALTH AND FAMILY SERVICES

Eric Friedlander
SECRETARY

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October 9, 2024

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
083, Capitol Annex
702 Capitol Ave.
Frankfort KY 40601

Re: 915 KAR 1:010. Initial and renewal applications for cannabis business licenses.

Dear Co-Chairs West and Lewis,

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 915 KAR 1:010, the Kentucky Medical Cannabis Program proposes the enclosed suggested substitute to 915 KAR 1:010.

If you have any questions regarding this matter, please contact Oran S McFarlan, III, Kentucky Medical Cannabis Program at (502) 564-5313 or oran.mcfarlan@ky.gov.

Sincerely,

Stacy Carey

Stacy Carey
Executive
Staff Advisor
Office of Legislative and Regulatory
Affairs

Subcommittee Substitute
Final version 9/30/2024

CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary
(Amended After Comments)

915 KAR 1:010. Initial and renewal applications for cannabis business licenses.

RELATES TO: KRS Chapter 13B, Chapter 218B, 523.100
STATUTORY AUTHORITY: KRS 218B.140
NECESSITY, FUNCTION, AND CONFORMITY: KRS 218B.140 requires the Cabinet for Health and Family Services to promulgate administrative regulations establishing initial application and renewal procedures for cannabis business licenses. This administrative regulation establishes those procedures.

Section 1. Types of Applications for Cannabis Business Licenses.
(1) The cabinet shall accept the following types of applications for cannabis business licenses:
(a) Initial application; and
(b) Renewal application.
(2) By submitting an initial or renewal application to the cabinet, an applicant consents to any investigation of the applicant's ability to meet the requirements of KRS Chapter 218B and 915 KAR Chapter 1.
(3) An application for an initial license or renewal license ***shall be incomplete*** ***[~~is not complete~~]*** and shall be rejected by the cabinet unless:
(a) The payment of the applicable fee ***established*** ***[~~provided~~]*** in Section 2 or Section 4 ***of this administrative regulation*** is submitted with the application; and
(b) All required information for each section of the application, including attachments and any supplemental information requested by the cabinet, is submitted to the cabinet within the allowable time period.
(4) An application submitted under this administrative regulation shall contain the following statement acknowledged by the applicant: "A false statement made in this application is punishable under the applicable provisions of KRS 523.100."

Section 2. Initial License Application Fees.
An applicant for an initial cannabis business license shall pay the applicable application fee by credit card or automated clearing house (ACH) transfer at the time of application submission to the cabinet. The initial application fee ***shall be*** ***[~~is~~]*** nonrefundable except as ***established*** ***[~~indicated below~~]*** in Section 3(6) of this administrative regulation. The initial license application fees shall be:
(1) Tier I cultivator: $3,000;
(2) Tier II cultivator: $10,000;
(3) Tier III cultivator: $20,000;
(4) Tier IV cultivator: $30,000;

(5) Processor: $5,000;
(6) Producer: $5,000 plus the applicable cultivator tier application fee;
(7) Dispensary: $5,000; and
(8) Safety Compliance Facility: $3,000.

Section 3. Initial Applications for Cannabis Business Licenses.
(1) An initial license ***shall be*** ***[is]*** valid for one (1) year from the date of issuance shown on the license. The cabinet shall publish notice of initial license application availability on the Web site for the Kentucky Medical Cannabis Program, https://kymedcan.ky.gov, including the time frame during which initial license applications shall be accepted. This notice shall also state the category and number of cannabis business licenses available for issuance at the close of the application period.
(2) An applicant shall only use the initial license application form prescribed by the cabinet and made available through the Web site for the Kentucky Medical Cannabis Program, https://kymedcan.ky.gov.
(3) An applicant shall submit an initial license application to the cabinet in the manner prescribed by the application instructions.
(4) An applicant shall apply for a separate license for each location where it intends to operate a cannabis business. During an initial license application availability period, an applicant shall only apply for a license in one (1) cannabis business license type (cultivator, processor, producer, dispensary, or safety compliance facility) being offered at that time. An applicant may submit multiple applications for a license within one (1) cannabis business license type ***if*** ***[so long as]*** the following criteria is met:
(a) Each application ***shall contain*** ***[contains]*** a separate and distinct physical address where the applicant proposes to conduct cannabis business activities;
(b) Each application ***shall contain*** ***[contains]*** documentation of sufficient capital in accordance with subsection (5)(q) of this section and the applicant shall not use the same capital for more than one (1) application;
(c) For the four (4) cannabis cultivator tiers, an applicant shall only submit one (1) application per cultivation tier; and
(d) For dispensaries, an applicant shall only submit one (1) application per medicinal cannabis region as identified in 915 KAR 1:020, Section 3 and shown on the map published on the Web site of the Kentucky Medical Cannabis Program, https://kymedcan.ky.gov.
(5) ***In the initial license application,*** the applicant shall submit ***[the following in the initial license application]***:
(a) The legal name, business type, any trade or doing business as (DBA) name, mailing address, federal tax identification number, Web site (if any), email address, and phone number of the proposed cannabis business and confirmation that the entity is registered with the Kentucky Secretary of State in good standing and authorized to do business in Kentucky;
(b) The type of cannabis business license requested;
(c) ***The*** business entity formation documents such as articles of incorporation, articles of organization, or bylaws;
(d) ***The*** proposed location of cannabis business activities, including the physical address of the proposed cannabis business and the global positioning system (GPS) coordinates for any

proposed cannabis business activities as well as:
1. Documentation such as a contingent agreement for property sale or lease or an existing deed or lease that shows the applicant has the authority to use the proposed location as a cannabis business for, at a minimum, the term of the license; and
2. A site plan for the proposed cannabis business.
(e) The name, address, date of birth, and curricula vitae or resume of each principal officer and board member of the proposed cannabis business as well as any additional information required by the cabinet;
(f) Disclosure of any individual or business entity with an ownership interest of at least ten (10) percent equity or similar interest in the proposed cannabis business and each identified individual or entity's ownership percentage as well as any additional information required by the cabinet;
(g) Disclosure of any parent company or parent individual that has an ownership interest in the proposed cannabis business and each identified individual or entity's ownership percentage as well as any additional information required by the cabinet;
(h) A document showing the ownership organizational structure of the proposed cannabis business;
(i) The name and address of any individual or entity providing financial support to the proposed cannabis business that are not involved in the day-to-day operations beyond providing financial resources as well as any additional information required by the cabinet;
(j) The name and address of any physician or advanced practice registered nurse that has an ownership or investment interest in or compensation agreement with the proposed cannabis business as well as any additional information required by the cabinet;
(k) Disclosure of whether any principal officer or board member of the applicant has been convicted of a felony criminal offense, and if so, a description of each felony offense;
(l) Disclosure of any instances in which a business or not-for-profit entity that any of the applicant's board members managed or served on the board of was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding;
(m) If applicable, documentation that the applicant is capable of successfully establishing and operating a cannabis business in the Commonwealth, including:
1. Demonstrated experience establishing and operating a for-profit or nonprofit organization or other business within Kentucky or any other jurisdiction, and the nature of the business conducted by the organization;
2. Any history relating to receipt of a similar license or other authorization in other jurisdictions, including provisional licenses, suspensions, revocations, or disciplinary actions to include civil monetary fines or warnings; and
3. Any history of response to suspensions, revocations, disciplinary actions, civil monetary fines, or warnings imposed relating to any similar license or other authorization in another jurisdiction, and the plans of correction or other responses made to those actions.
(n) A description of the duties, responsibilities, and roles of each principal officer, board member, employee, and any other individual or entity with a financial interest in the proposed cannabis business who are not involved in the day-to-day operations of the business;
(o) A timeline showing the steps and estimated amount of time the applicant shall take to begin cannabis business activities in the Commonwealth;
(p) ***A*** financial plan for the proposed cannabis business, including budget and cash flow planning

and debt management;
(q) Documentation of sufficient capital available to the applicant, either on deposit or through extension of credit from one (1) or more financial institutions, in the following amounts as applicable:
1. Tier I cultivator: $50,000;
2. Tier II cultivator: $200,000;
3. Tier III cultivator: $500,000;
4. Tier IV cultivator: $1,000,000;
5. Processor: $150,000;
6. Producer: $150,000 plus the applicable cultivator tier amount;
7. Dispensary: $150,000; or
8. Safety Compliance Facility: $150,000.
(r) A summary of the intended plan of operation that describes, at a minimum, how the applicant's proposed cannabis business operations shall address:
1. Security;
2. Employee qualifications, supervision, and training;
3. Transportation of medicinal cannabis;
4. Storage and labeling of medicinal cannabis;
5. Inventory management;
6. Recordkeeping;
7. Preventing unlawful diversion of medicinal cannabis; and
8. Workforce development and job creation.
(s) The name, mailing address, business title, phone number, and email address of the primary contact for the application as well as the name, address, and email address of any entity or individual who assisted the applicant with preparing the application;
(t) Documentation of any management service agreement in place for the proposed cannabis business;
(u) A notarized signature page signed by the applicant; and
(v) An attestation that:
1. The site of the proposed cannabis business is not within ***1,000*** ***[~~one thousand (1,000)~~]***[~~1,000~~] feet of an existing elementary or secondary school or a daycare center. For the purpose of this administrative regulation, ***1,000*** ***[~~one thousand (1,000)~~]***[~~1,000~~] feet shall be measured in a straight line from the nearest property line of an existing elementary school, secondary school, or daycare center to the nearest property line of the applicant's proposed place of business;
2. The applicant can continuously maintain sufficient capital for operations of its proposed cannabis business for, at a minimum, the term of the initial license;
3. The applicant can continuously maintain effective security, surveillance, and accounting control measures to prevent diversion, abuse, and other illegal conduct regarding medicinal cannabis;
4. The applicant shall comply with KRS Chapter 218B and 915 KAR Chapter 1;
5. The applicant consents to the cabinet verifying information provided in the application with any relevant governmental agency or third party;
6. If issued a license, the applicant shall pay the applicable license fee within fifteen (15) calendar days of notification in a manner prescribed by the cabinet;***[.]***
7. If issued a license, the applicant shall conduct a criminal background check into the criminal

history of each person seeking to be a principal officer, board member, agent, volunteer, or employee of the cannabis business before that person begins work and shall not employ, take on as a volunteer, or have as a board member, principal officer, or agent any person who was convicted of a disqualifying felony offense or is younger than twenty-one (21) years of age;
8. The applicant consents to reasonable inspections, examinations, searches, and seizures as contemplated by KRS Chapter 218B and 915 KAR Chapter 1;
9. The applicant shall obtain and maintain workers' compensation insurance for all employees in the Commonwealth and shall pay all required employer contributions to the Kentucky Office of Unemployment Insurance;
10. The applicant shall obtain and maintain commercial general liability insurance for $1,000,000 per occurrence and $2,000,000 per aggregate and commercial automobile insurance for any vehicle used to transport medicinal cannabis or medicinal cannabis products;
11. The applicant shall complete all trainings required by the cabinet for the proposed cannabis business's principals, agents, employees, and volunteers;
12. The applicant shall establish any standard operating procedures required by KRS Chapter 218B and 915 KAR Chapter 1 prior to the first date of cannabis business activities in the Commonwealth, including those specific to its cannabis business category. The standard operating procedures that apply to cannabis businesses include:
a. Security;
b. Recordkeeping;
c. Employee qualifications, supervision, and training;
d. Quality assurance;
e. Adverse event reporting and recall;
f. Waste disposal and sanitation;
g. Transportation of medicinal cannabis;
h. Inventory management, including storage and labeling of medicinal cannabis;
i. Cash management and anti-fraud procedures; and
j. Preventing unlawful diversion of medicinal cannabis.
13. For an applicant seeking a safety compliance facility license, one (1) or more of its prospective principal officers or board members shall not be a principal officer or board member of a cultivator, processor, producer, or dispensary applying to operate in the Commonwealth;
14. For an applicant seeking a cultivator, processor, producer, or dispensary license, one (1) or more of its prospective principal officers or board members shall not be a principal officer or board member of a safety compliance facility applying to operate in the Commonwealth;
15. The applicant consents to sharing medicinal cannabis sales data with law enforcement;
16. The applicant shall use the Commonwealth's designated electronic monitoring system and seed to sale tracking system required by KRS 218B.140 in the manner prescribed by the cabinet;
17. The applicant has disclosed all individuals and entities with an ownership interest of at least ***ten percent*** ***[~~10%~~]*** equity or similar interest in the proposed cannabis business as well as any parent companies and parent company individuals with an ownership interest in its proposed cannabis business; and
18. The applicant swears ***or*** ***[and]*** affirms that all information and documentation provided with the initial license application is true and correct.
(6) An initial license application received after the submission time frame stated in the published

notice of initial license application availability shall be rejected by the cabinet without further consideration along with the return of the initial application fee.
(7) The cabinet shall acknowledge receipt of an initial application for a cannabis business license within fifteen (15) calendar days of submission by the applicant. The cabinet shall review each application to determine whether the application is complete. The cabinet shall provide written notice to an applicant when it has determined the application is complete. If the cabinet determines an application is not complete, the cabinet shall provide written notice to the applicant of the identified deficiencies in the application. The applicant shall have ten (10) calendar days from the date of the deficiency notification to cure the identified deficiencies and provide any missing information or documentation to the cabinet in the manner prescribed by the cabinet. If the applicant fails to cure any deficiency within ten (10) calendar days from the date of the deficiency notification, the cabinet shall reject the application as incomplete.
(8) The cabinet shall provide notification to applicants as to whether an application for a license has been approved or denied within forty-five (45) calendar days of receiving an application and determining ***it is*** ***[~~its~~]*** complete. Any application denials shall be done in accordance with KRS 218B.090(2) and (4), including providing written notice to the applicant that he or she may file a written request for an administrative hearing on the application within thirty (30) calendar days after the mailing date of the notice. Any hearing resulting from the applicant's written request shall be conducted in accordance with KRS Chapter 13B.

Section 4. License Renewal Fees.
An applicant for renewal of a cannabis business license shall pay the applicable annual renewal fee by credit card or ACH transfer at the time of application submission to the cabinet. The annual renewal fee ***shall be*** ***[~~is~~]*** refundable if the renewal application is denied. The annual renewal fees ***shall be*** ***[~~are~~]***:
(1) Tier I cultivator: $12,000;
(2) Tier II cultivator: $25,000;
(3) Tier III cultivator: $50,000;
(4) Tier IV cultivator: $100,000;
(5) Processor: **$25,000[~~$15,000~~]**;
(6) Producer: **$25,000[~~$15,000~~]** plus the applicable cultivator tier annual renewal fee;
(7) Dispensary: **$30,000[~~$15,000~~]**; and
(8) Safety Compliance Facility: $12,000.

Section 5. Renewal Applications for Cannabis Business Licenses.
(1) A renewal license ***shall be*** ***[~~is~~]*** valid for one (1) year from the date of issuance shown on the license. The requirements that a licensed cannabis business shall meet to receive an initial license are continuing requirements to maintain the license. A cannabis business shall continuously comply with the licensing requirements of KRS Chapter 218B and 915 KAR Chapter 1 during the initial licensure period and any subsequent renewal period.
(2) The cabinet shall notify each licensee at least ninety (90) calendar days prior to the date the license expires to allow the licensee to begin the renewal process if the licensee so chooses.
(3) A licensee shall only use the license renewal application form prescribed by the cabinet and made available through the Web site of the Kentucky Medical Cannabis Program,

https://kymedcan.ky.gov.
(4) A license renewal application shall be submitted to the cabinet at least sixty (60) calendar days prior to the expiration of the license. The cabinet shall reject a license renewal application if it is not submitted at least sixty (60) calendar days prior to the expiration of the license and shall return the annual renewal fee to the licensee along with written notice of the rejection.
(5) A licensee shall submit a license renewal application to the cabinet in the manner prescribed by the application instructions.
(6) A licensee shall include the following information with a license renewal application:
(a) Information regarding any charge, or any initiated, pending, or concluded investigation or proceeding, during the period of the initial license or prior renewal period, by any governmental or administrative agency, including an investigation or proceeding involving theft, loss, or possible diversion of medicinal cannabis by the licensee or from the licensee's facility;
(b) Information regarding the licensee's ability to continue with licensed activities, including any staffing issues, delays, medicinal cannabis shortages, medicinal cannabis product recalls, location issues, and financial issues that occurred since the license was issued;
(c) The licensee's history of compliance with KRS Chapter 218B and 915 KAR Chapter 1, including a summary of any noncompliance and corrective action taken during the current and any previous licensing period or a statement indicating that the licensee has not violated KRS Chapter 218B or 915 KAR Chapter 1 as of the date the renewal application is submitted; and
(d) Any additional information required by the cabinet.
(7) The cabinet shall acknowledge receipt of a renewal license application within fifteen (15) calendar days of submission by the applicant. The cabinet shall review each application to determine whether the application is complete. If the cabinet determines an application is not complete, the cabinet shall provide written notice to the applicant of the identified deficiencies in the application. The applicant shall have ten (10) calendar days from the date of the deficiency notification to cure the identified deficiencies and provide any missing information or documentation to the cabinet in the manner prescribed by the cabinet. If the applicant fails to cure any deficiency within ten (10) calendar days from the date of the deficiency notification, the cabinet shall reject the application as incomplete.
(8) If the cabinet determines that a license renewal application is lacking sufficient information upon which to make a renewal determination, the cabinet shall notify the licensee in writing of the factors that require additional information and documentation. The licensee shall have ten (10) calendar days from the date of the notice to provide the requested information and documentation to the cabinet. A licensee's failure to provide the requested information to the cabinet by the deadline shall be grounds for denial of the license renewal application.
(9) The cabinet may conduct an onsite inspection of the licensee's facilities and records to assist with determining continuing compliance with KRS Chapter 218B and 915 KAR Chapter 1.
(10) An existing cannabis business license ***shall be*** ~~***[is]***~~ immediately invalid upon expiration if the licensee has not filed a license renewal application and paid the required renewal fee in accordance with Section 4 of this administrative regulation. If a licensee properly submits a timely renewal application with applicable renewal fee, the cabinet may extend its existing license from the date the existing license expires until the cabinet can complete its renewal application review and issue a determination.

Section 6. Minimum Performance Standards for License Renewal.
(1) Pursuant to KRS 218B.080(5)(b), the renewal of a cannabis business license shall be contingent upon successful achievement of minimal performance standards established by the cabinet. The minimum performance standards for licensees participating in the Kentucky Medical Cannabis Program ***shall be that*** ***[~~are~~]***:
(a) The licensee has, and is likely to continue to maintain, effective controls against diversion of medicinal cannabis at its facility;
(b) The licensee has not made false or misleading statements in:
1. A renewal application or any other application submitted to the cabinet;
2. Any document or written communication submitted to the cabinet; or
3. Any verbal communication to the cabinet.
(c) The licensee has a documented history of compliance with the licensee requirements in KRS Chapter 218B and 915 KAR Chapter 1;
(d) The licensee has effectively addressed any identified compliance issues through corrective action;
(e) The licensee has shown it has the ability to continue to comply with all state and local laws and administrative regulations applicable to the activities in which it may engage under the license, if renewed;
(f) The licensee has a documented history of successfully addressing and mitigating any quality or safety issues with its medicinal cannabis or medicinal cannabis products;
(g) The licensee timely completes all reporting required by KRS Chapter 218B and 915 KAR Chapter 1; and
(h) The licensee participates in surveys distributed by the cabinet and provides full, complete, and timely responses.
(2) The cabinet shall deny a renewal application for a cannabis business license if it determines the licensee has failed to:
(a) Meet one (1) or more of the minimum performance standards established in this section; or
(b) Any additional basis ***established*** ***[~~provided~~]*** in KRS 218B.090.
(3) The cabinet shall provide written notification to a licensee as to whether its renewal application has been approved or denied within forty-five (45) calendar days of receiving an application and determining ***it is*** ***[~~its~~]*** complete. Any renewal application denials shall be done in accordance with KRS 218B.090(4), including providing written notice to the applicant that he or she may file a written request for an administrative hearing on the application within thirty (30) calendar days after the mailing date of the notice. Any hearing resulting from the applicant's written request shall be conducted in accordance with KRS Chapter 13B.

Section 7. Duty to Report. During the application process, an applicant for an initial cannabis business license or renewal license shall, upon discovery of any change in facts or circumstances reflected in the initial application or renewal application submitted to the cabinet, notify the cabinet in writing of the change or any newly discovered fact or circumstance that would have been included in the application if known at the time the application was submitted. The notification required under this section shall be sent ***by*** ***[~~via~~]*** electronic mail to kymedcanreporting@ky.gov within twenty-four (24) hours of discovery. Failure to timely notify the cabinet of a change or newly discovered facts or circumstances may result in denial of the

application.

CONTACT PERSON: Oran S. McFarlan, III, Kentucky Medical Cannabis Program, Cabinet for Health and Family Services, 275 E. Main Street, 5th Floor, Frankfort, KY 40621; Phone Number: (502) 564-5313; Email: oran.mcfarlan@ky.gov.

Andy Beshear
GOVERNOR

CABINET FOR HEALTH AND FAMILY SERVICES

Eric Friedlander
SECRETARY

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October 7, 2024

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
083, Capitol Annex
702 Capitol Ave.
Frankfort KY 40601

Re: 915 KAR 1:020. Cannabis business licenses.

Dear Co-Chairs West and Lewis,

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 915 KAR 1:020, the Kentucky Medical Cannabis Program proposes the enclosed suggested substitute to 915 KAR 1:020.

If you have any questions regarding this matter, please contact Oran S McFarlan, III, Kentucky Medical Cannabis Program at (502) 564-5313 or oran.mcfarlan@ky.gov.

Sincerely,

Lucie Estill

Lucie Estill
Staff Assistant
Office of Legislative and Regulatory Affairs

Subcommittee Substitute
Final version 9/30/2024

CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary
(Amended After Comments)

915 KAR 1:020. Cannabis business licenses.

RELATES TO: KRS Chapter ***13B,*** 218B, ***[KRS]*** 304.39-110, ***[KRS]*** 523.100***[, KRS Chapter 13B]***
STATUTORY AUTHORITY: KRS 218B.140
NECESSITY, FUNCTION, AND CONFORMITY: KRS 218B.140 requires the Cabinet for Health and Family Services to promulgate administrative regulations establishing procedures for the issuance, renewal, suspension, and revocation of cannabis business licenses. This administrative regulation establishes those procedures.

Section 1. General Requirements for Cannabis Business Licenses.
(1) The cabinet shall issue a license, by name and address, to a cannabis business only for the specific location identified by the cannabis business during the application and issuance process. A license ***shall only be*** ***[is only]*** valid for the person or entity named in the license and only for the activity and location specified in the license.
(2) A licensed cannabis business shall conspicuously display its license within the premises of the cannabis business in a manner that is visible to visitors upon initial entry into its facility.
(3) A license shall not be issued to a cannabis business for operation within a personal residence or any other location where the cabinet or its authorized agents or law enforcement have limited access.
(4) A license shall not be issued to a cannabis business for a site or facility located on lands owned by the United States of America or the Commonwealth of Kentucky.
(5) A license ***shall be*** ***[is]*** valid for one (1) year from the date of issuance as shown on the license.

Section 2. License Fees for Cannabis Businesses.
(1) A cannabis business shall pay the applicable license fee by credit card or automated clearing house (ACH) transfer to the cabinet within fifteen (15) calendar days of receipt of the invoice from the cabinet. The cabinet shall not issue a license to a cannabis business that fails to timely pay the applicable license fee.
(2) The initial nonrefundable license fees shall be:
(a) Tier I cultivator: $12,000;
(b) Tier II cultivator: $25,000;
(c) Tier III cultivator: $50,000;
(d) Tier IV cultivator: $100,000;
(e) Processor: $25,000;
(f) Producer: $25,000 plus the applicable cultivator tier initial license fee;
(g) Dispensary: $30,000; and
(h) Safety compliance facility: $12,000.

(3) The annual renewal license fees, which ***shall be*** ***[~~are~~]*** refundable if the renewal application is denied, shall be:
(a) Tier I cultivator: $12,000;
(b) Tier II cultivator: $25,000;
(c) Tier III cultivator: $50,000;
(d) Tier IV cultivator: $100,000;
(e) Processor: **$25,000[~~$15,000~~]**;
(f) Producer: **$25,000[~~$15,000~~]** plus the applicable cultivator tier renewal license fee;
(g) Dispensary: **$30,000[~~$15,000~~]**; and
(h) Safety compliance facility: $12,000.

Section 3. Initial Licensure of Cannabis Businesses and Use of Lottery.
(1) The cabinet shall publish notice of the number and category of cannabis business licenses available for distribution at the close of an initial license application period and provide the time frame during which initial license applications shall be accepted by the cabinet. This notice shall be published on the website of the Kentucky Medical Cannabis Program, https://kymedcan.ky.gov.
(2) ***[~~In order~~]*** To promote patient access to medicinal cannabis across the Commonwealth, the cabinet shall issue dispensary licenses within designated regions. The cabinet shall publish a map clearly identifying the medicinal cannabis regions on the website of the Kentucky Medical Cannabis Program. The eleven (11) medicinal cannabis regions in the Commonwealth ***shall be*** ***[~~are~~]***:
(a) Region 1 (Bluegrass): The geographical region comprised of the counties of Anderson, Bourbon, Boyle, Clark, Fayette, Franklin, Garrard, Harrison, Jessamine, Madison, Mercer, Scott, and Woodford;
(b) Region 2 (Kentuckiana): The geographical region comprised of the counties of Bullitt, Henry, Jefferson, Oldham, Shelby, Spencer, and Trimble;
(c) Region 3 (Northeast): The geographical region comprised of the counties of Bath, Boyd, Carter, Elliott, Fleming, Greenup, Lewis, Mason, Menifee, Montgomery, Morgan, Nicholas, Robertson, and Rowan;
(d) Region 4 (South Central): The geographical region comprised of the counties of Allen, Barren, Butler, Edmonson, Logan, Metcalfe, Monroe, Simpson, and Warren;
(e) Region 5 (Cumberland): The geographical region comprised of the counties of Bell, Casey, Clinton, Cumberland, Harlan, Knox, Laurel, Lincoln, McCreary, Pulaski, Rockcastle, Russell, Wayne, and Whitley;
(f) Region 6 (Mountain): The geographical region comprised of the counties of Breathitt, Clay, Estill, Floyd, Jackson, Johnson, Knott, Lawrence, Lee, Leslie, Letcher, Magoffin, Martin, Owsley, Perry, Pike, Powell, and Wolfe;
(g) Region 7 (Pennyrile): The geographical region comprised of the counties of Caldwell, Christian, Hopkins, Lyon, Muhlenberg, Todd, and Trigg;
(h) Region 8 (West Kentucky): The geographical region comprised of the counties of Ballard, Calloway, Carlisle, Crittenden, Fulton, Graves, Hickman, Livingston, McCracken, and Marshall;
(i) Region 9 (Lincoln Trail): The geographical region comprised of the counties of Adair, Breckinridge, Grayson, Green, Hardin, Hart, Larue, Marion, Meade, Nelson, Taylor, and Washington;

(j) Region 10 (Northern Kentucky): The geographical region comprised of the counties of Boone, Bracken, Campbell, Carroll, Gallatin, Grant, Kenton, Owen, and Pendleton; and
(k) Region 11 (Green River): The geographical region comprised of the counties of Daviess, Hancock, Henderson, McLean, Ohio, Union, and Webster.
(3) The cabinet shall issue at least four (4) dispensary licenses per medicinal cannabis region. For regions containing an urban-county government or a consolidated local government, the cabinet shall issue at least six (6) dispensary licenses, two (2) of which shall be issued to eligible cannabis businesses that physically locate their dispensary in the counties with an urban-county government or a consolidated local government. For all counties without an urban-county government or a consolidated local government, there shall ***not*** be ***[no]*** more than one (1) dispensary per county.
(4) A dispensary licensee shall not change its retail location to another location within the same region without prior cabinet approval. A dispensary licensee shall not change its retail location to outside of the region where it was initially licensed.
(5) The licenses for cultivators, processors, producers, and safety compliance facilities are not subject to regional restrictions within the Commonwealth, and those licensees shall operate at the physical address identified on their respective licenses.
(6) Applicants for initial cannabis business licenses who comply with all application requirements contained in KRS Chapter 218B and 915 KAR 1:010, and whose applications are deemed complete by the cabinet, shall be eligible to receive the license requested. If the number of eligible applications does not exceed the maximum number of licenses available within a cannabis business category following the close of an initial license application period, the cabinet shall provide written notice to the eligible applicants that a license shall be issued to them upon timely payment of the applicable license fee. When an eligible applicant timely pays the applicable license fee, the cabinet shall issue a copy of the license to the applicant that contains the cannabis business's name, license number, physical location, issue date, and expiration date.
(7) If the number of eligible applications exceeds the maximum number of licenses available within a cannabis business category following the close of an initial license application period, the cabinet shall conduct a lottery to issue the licenses for that cannabis business category. The cabinet shall notify the eligible applicants of their entry into the lottery and publicly announce the date, time, and manner of randomly selecting eligible applicants for the requested license. A lottery to select the licensees in each cannabis business category, as needed, shall be held in a manner that can be observed by the public.
(8) The cabinet may consult or contract with a third-party lottery operator or other public agencies with relevant expertise in conducting lotteries. The entity selected to conduct the lottery shall conduct an independent lottery for each cannabis business category where the number of eligible applicants exceeds the number of available licenses. The cabinet shall assign a number to each eligible applicant in each license lottery and maintain the confidentiality of ***[~~the list(s)containing~~]*** the eligible applicants and their assigned numbers until after the random drawings have occurred.
(9) The cabinet shall provide written notice to the eligible applicants selected through the lottery process that a license shall be issued to them upon timely payment of the applicable license fee. When an eligible applicant timely pays the applicable license fee, the cabinet shall issue a copy of the license to the applicant that contains the cannabis business's name, license number, physical location, issue date, and expiration date.

(10) **Prior to license issuance, if an eligible applicant selected through the lottery process needs to change their location for cannabis business activities due to a local government prohibiting all cannabis business operations within its territory as authorized by KRS 218B.130 or other circumstances, a provisional license may be issued to the eligible applicant upon timely payment of the applicable license fee.**

(a) *Pursuant to KRS Chapter 218B and this administrative regulation,* if a provisional license is issued, the provisional licensee shall have a maximum of 120 calendar days from issuance to request a change of location to an allowable county or city *[~~under KRS Chapter 218B and this administrative regulation~~]*. If the new location is approved by the program, a new license shall be issued that contains the cannabis business's name, license number, physical location, issue date, and an expiration date which shall be one (1) year from the date of provisional license issuance.

(b) If the provisional licensee fails to request a location change within 120 calendar days from issuance or the request is denied, the cabinet shall revoke their provisional license and the license fee shall not be refunded.

(c) Provisional licenses shall not be sold or transferred to another individual or entity and shall not authorize a provisional licensee to begin any cannabis business activities.

(11) The cabinet shall provide written notice to eligible applicants that were not selected through the lottery process informing them of the same.

(12)[(~~11~~)] If at the conclusion of the lottery selection process an eligible applicant declines the license or fails to pay its license fee within the required timeframe, the cabinet may conduct supplemental license lotteries as needed until all available cannabis business licenses have been issued and initial license fees paid. For any supplemental lottery for a license within a cannabis business category, eligible applicants who were not previously issued a license through the lottery process for that cannabis business category shall be entered into the supplemental lottery **[~~if their selection would comply with any applicable geographic restrictions contained in this administrative regulation~~]**.

Section 4. Requirements for Licensees Prior to First Day of Cannabis Business Activities.

(1) Prior to its first day of cannabis business activities in the Commonwealth, a licensee shall provide written confirmation to the cabinet that:

(a) The licensee has complied and ***shall [~~will~~]*** continue to comply with all applicable requirements of KRS Chapter 218B, including KRS 218B.095 and 915 KAR Chapter 1, and shall make available all records and documentation verifying ***[~~such~~]*** compliance upon the request of the cabinet;

(b) The licensee has submitted its complete physical address and the global positioning system (GPS) coordinates for any cannabis business activities to the cabinet and confirmed its business is not located within ***1,000 [~~one thousand (1,000)~~]*** feet of an existing elementary or secondary school or a daycare center. For the purpose of this administrative regulation, ***1,000 [~~one thousand (1,000)~~]*** feet shall be measured in a straight line from the nearest property line of an existing elementary school, secondary school, or daycare center to the nearest property line of the licensee's place of business. The cabinet shall have an opportunity to inspect the location prior to the first day of cannabis business activities at that location ***[~~in order~~]*** to identify any deficiencies for correction;

(c) The licensee has conducted and shall continue to conduct criminal background checks of each person seeking to be a principal officer, board member, agent, volunteer, or employee of the cannabis business before that person begins work and shall not employ, take on as a volunteer, or have as a board member, principal officer, or agent any person who was convicted of a

disqualifying felony offense or is younger than twenty-one (21) years of age. The licensee shall maintain records of these background checks and provide ***the records*** ***[same]*** to the cabinet during subsequent inspections or upon request;

(d) The licensee has obtained and shall maintain workers compensation insurance for all employees in the Commonwealth and shall pay all required employer contributions to the Kentucky Office of Unemployment Insurance;

(e) The licensee has obtained and shall maintain, at a minimum, commercial general liability insurance for $1,000,000 per occurrence and $2,000,000 per aggregate and commercial automobile insurance as required by Kentucky law, specifically KRS 304.39-110, for any vehicle used to transport medicinal cannabis or medicinal cannabis products;

(f) The licensee has established written standard operating procedures required by KRS Chapter 218B and 915 KAR Chapter 1, including those specific to its cannabis business category, and shall provide written or electronic copies of the procedures to the cabinet during inspections or upon request. The standard operating procedures that apply to cannabis businesses ***shall*** include:

1. Security;
2. Recordkeeping;
3. Employee qualifications, supervision, and training;
4. Quality assurance;
5. Adverse event reporting and recall;
6. Waste disposal and sanitation;
7. Transportation of medicinal cannabis;
8. Inventory management, including storage and labeling of medicinal cannabis;
9. Cash management and anti-fraud procedures;
10. **Odor mitigation and control;**

11. Preventing unlawful diversion of medicinal cannabis; and

12.[11.] Incident reporting procedures to notify the cabinet.***[;]***

(g) The licensee continues to maintain sufficient capital for operations of its cannabis business for, at a minimum, the term of the license;

(h) The licensee has implemented appropriate security measures to deter and prevent theft of medicinal cannabis and unauthorized entrance into areas containing medicinal cannabis;

(i) The licensee has and shall continue to display its license at all times in a conspicuous location within the premises of the cannabis business in a manner that is visible to visitors upon initial entry into its facility;

(j) The licensee's principals, agents, employees, and volunteers have completed all trainings required by the cabinet to be completed prior to its first day of cannabis business activities in the Commonwealth;

(k) The licensee understands how to properly use the Commonwealth's designated electronic monitoring system and seed to sale tracking system for medicinal cannabis and shall use those systems as required throughout the entirety of its licensure period;

(l) **The licensee has implemented appropriate odor mitigation procedures or technics to ensure the capture of any potential fugitive odors emitted by the facility;**

(m) The licensee consents to reasonable inspections, examinations, searches, and seizures; and

(n)[(m)] The licensee swears ***or[and]*** affirms that all information and documentation provided to the cabinet is true and correct and that any false statement made to the cabinet by the licensee

is punishable under the applicable provisions of KRS 523.100.
(2) A licensee shall also provide the cabinet with thirty (30) calendar days advance notice of its intended first day of cannabis business activities in the Commonwealth and allow the cabinet an opportunity to inspect the licensee's site and facility prior to the first day of cannabis business activities. The licensee shall promptly correct any deficiencies identified by the cabinet during this inspection and shall not commence operations until deficiencies are corrected and approved by the cabinet. If the licensee fails to provide the notice required under this ***subsection*** ***[~~section~~]*** or fails to correct identified deficiencies, the cabinet may take one (1) or more of the actions described in Section 12 of this administrative regulation.
(3) Once a cultivator or producer has received approval from the cabinet to commence operations, the cultivator or producer shall:
(a) Bring a start-up inventory of medicinal cannabis seeds, seedlings, **tissue cultures, clones,** and plants into its facility;
(b) Submit a written request to the cabinet ***by[~~via~~]*** electronic mail to kymedcanreporting@ky.gov requesting that the cabinet open a window in the state's designated seed to sale tracking system for the cultivator or producer to enter its start-up inventory of medicinal cannabis seeds, seedlings, **tissue cultures, clones,** and plants into the system. ***The*** ***[~~This~~]*** written request shall include the number and strain of all medicinal cannabis seeds, seedlings, **tissue cultures, clones,** and plants brought into the facility;
(c) Have fourteen (14) calendar days from receipt of the cabinet's approval of the cultivator or producer's written request in which to enter its start-up inventory into the state's designated seed to sale tracking system. A cultivator or producer shall enter its start-up inventory into the state's designated seed to sale tracking system as follows:
1. Seeds shall be entered into the system as a package; ***and***
2. Seedlings**, tissue cultures, and clones**[**~~and plants~~**] shall be entered into the system as a batch; and
(d) Notify the cabinet in writing ***by[~~via~~]*** electronic mail to kymedcanreporting@ky.gov when all its start-up inventory has been fully and accurately entered into the state's designated seed to sale tracking system and confirm the number and strain of medicinal cannabis seeds, seedlings, **tissue cultures, clones,** and plants brought into the facility.
(4) Following acquisition of its start-up inventory, a cultivator or producer may submit a written request to the cabinet ***by[~~via~~]*** electronic mail to kymedcanreporting@ky.gov requesting that the cabinet open a window in the state's designated seed to sale tracking system for the cultivator or producer to enter new medicinal cannabis seeds, seedlings, **tissue cultures, clones,** or plants into the system. This written request shall:
(a) State the proposed date to bring new inventory into the facility; and
(b) Provide the number and strain of all new medicinal cannabis seeds, seedlings, **tissue cultures, clones,** and plants that the cultivator or producer requests to bring into the facility.
(5) Upon receipt of the cabinet's approval of a written request made pursuant to subsection (4) ***of this section***, the cultivator or producer shall have seven (7) calendar days to enter its new inventory into the state's designated seed to sale tracking system. A cultivator or producer shall enter its new inventory into the state's designated seed to sale tracking system as described in subsection 3(c) ***of this section***. A cultivator or producer shall notify the cabinet in writing ***by[~~via~~]*** electronic mail to kymedcanreporting@ky.gov when all new inventory has been fully and

accurately entered into the state's designated seed to sale tracking system and confirm the number and strain of medicinal cannabis seeds, seedlings, **tissue cultures, clones,** and plants brought into the facility.

Section 5. Requirements for Licensees During Licensure Period.

(1) ***Except as provided in Section 10(4) of this administrative regulation,*** a licensee shall only hold licenses in one (1) cannabis business category at any given time***[, except as provided in Section 10(4) of this administrative regulation]***. A licensee may hold multiple licenses in the same cannabis business category ***if [as long as]*** each license contains a separate and distinct physical address where the cannabis business conducts licensed cannabis activities and the licensee is otherwise in compliance with the requirements of KRS Chapter 218B and 915 KAR Chapter 1, including any geographic restrictions contained in this administrative regulation.

(2) Duty to Report.

(a) During the licensure period, a licensee shall notify the cabinet in writing of any change in facts or circumstances reflected in the initial license application, supplemental written confirmations, or any license renewal application submitted to the cabinet, or any newly discovered fact or circumstance which would have been included in the application or information provided to the cabinet if known at the time the information was submitted. ***The [This]*** duty to report ***shall include [includes]***:

1. Notifying the cabinet of any physical change, alteration, or modification to a licensed facility that materially or substantially alters the facility or its usage, including an increase or decrease in the total square footage of the facility;
2. Significant electrical modifications that require inspection by local authorities; and
3. Sealing off, creation of, or relocation of a common entryway, doorway, passage, or other means of ingress or egress when the common entryway, doorway, or passage alters or changes limited access areas.

(b) During the licensure period, a licensee shall notify the cabinet following knowledge or discovery of the following events:

1. Inventory discrepancies;
2. Diversion, theft, or loss of any medicinal cannabis or medicinal cannabis product;
3. Unauthorized destruction of medicinal cannabis;
4. Any criminal proceeding involving the licensee's owners, principal officers, board members, employees, volunteers, financial backers, or agents arising out of actions taken on the licensee's premises or while using licensee property;
5. Security alarm activation or other event that requires response by law enforcement or security personnel;
6. Any loss, unauthorized dissemination, or unauthorized alteration of records related to medicinal cannabis, cardholders, employees, volunteers, or agents;
7. Accidents involving transport vehicles that occur while the licensee is transporting or delivering medicinal cannabis;
8. Any act involving cultivating, processing, producing, testing, transporting, or dispensing medicinal cannabis by any person that may create a health or safety risk to cardholders or the general public;
9. A dispensary declines the sale of medicinal cannabis to a cardholder; ***or*** ***and***

10. A dispensary desires to prohibit a cardholder from entering its premises.
(c) The notifications required under this subsection shall be:
1. Provided on a form prescribed by the cabinet and available on the website of the Kentucky Medical Cannabis Program, https://kymedcan.ky.gov, that includes time and date of the event, individuals involved, and a detailed description of the event; and
2. Sent ***by[~~via~~]*** electronic mail to kymedcanreporting@ky.gov **or through the cannabis business licensing portal** within twenty-four (24) hours of discovery or knowledge of the event.
(d) If ***a [~~the~~]*** licensee fails to provide the notice required under this section, the cabinet may take one (1) or more of the actions described in Section 12 of this administrative regulation.
(e) ***If [~~In the event~~]*** a local government prohibits all cannabis business operations within its territory in accordance with KRS 218B.130, a licensee located within the affected territory shall notify the cabinet in writing ***by[~~via~~]*** electronic mail to kymedcanreporting@ky.gov within twenty-four (24) hours of notification or discovery of this prohibition, including all information known regarding the prohibition, and may make a written request to the cabinet to change its cannabis business location in accordance with Section 9 of this administrative regulation.
(3) Inspection and investigation.
(a) The cabinet may conduct announced or unannounced inspections or investigations to determine the licensee's compliance with KRS Chapter 218B and 915 KAR Chapter 1. ***The [~~These~~]*** investigations and inspections may occur during regular working hours and at other reasonable times ***[~~in order~~]*** to inspect the licensee's place of business, question privately any ***[~~such~~]*** principal officer, board member, agent, employee, or employee's representative, and investigate ***[~~such~~]*** facts, conditions, practices, or other matters deemed appropriate to determine whether the licensee is operating in compliance with KRS Chapter 218B and 915 KAR Chapter 1. If a licensee refuses ***[~~such~~]*** entry onto its premises, the cabinet may apply to the circuit court in the county in which the licensee is located for an order to enforce the right of entry.
(b) Following completion of an inspection or investigation, the cabinet shall have the authority to confiscate, possess, transport, and destroy any medicinal cannabis that has been deemed noncompliant with the standards established by KRS Chapter 218B and 915 KAR Chapter 1.
(c) The cabinet's authorized representatives shall also have the authority to:
1. Administer oaths;
2. Examine witnesses under oath;
3. Take depositions;
4. Certify to official acts;
5. Review records and accounts;
6. Take photographs;
7. Secure any other evidence deemed necessary to evaluate compliance with KRS Chapter 218B and 915 KAR Chapter 1; and
8. Issue subpoenas to compel the attendance of witnesses and parties and the production of books, accounts, correspondence, memoranda, and other records considered necessary and relevant to the matter under investigation by the cabinet.
(d) When a witness or party fails to comply with a subpoena issued by the cabinet, the circuit court in the county in which the witness or party is located may compel ***compliance [~~obedience~~]*** by proceedings for contempt ***[~~as in the case of disobedience~~]*** of a subpoena or order issued from ***the[~~such~~]*** court or a refusal to testify therein, and may adjudge ***a [~~such~~]*** person guilty of contempt

of court and punish him or her as provided by law in other contempt cases. In any proceeding brought under this paragraph, a circuit court may modify or set aside the subpoena.
(e) An investigation or inspection may include:
1. Inspection of a licensee's site, facility, vehicles, equipment, books, records, papers, documents, data, and other physical or electronic information;
2. Interviews of licensee's principal officers, board members, agents, employees, volunteers, or employee representatives;
3. Interviews of licensee's former principal officers, board members, agents, employees, volunteers, or employee representatives; and
4. Inspection of equipment, instruments, tools, machinery, and vehicles that are used to grow, process, package, transport, and test medicinal cannabis.
(f) The cabinet and its authorized agents shall have free access to review and, if necessary, make copies of books, records, papers, documents, data, or other physical or electronic information that relates to the business of the licensee, including financial data, sales data, shipping data, pricing data, and employee data.
(g) Failure of a licensee to provide the cabinet and its authorized agents immediate access to any part of a licensee's site or facility, requested material, physical or electronic information, or individual as part of an inspection or investigation may result in the imposition of a civil monetary fine, suspension, or revocation of its license, or an immediate cessation of operations pursuant to a cease-and-desist order issued by the cabinet if continued operations would present a risk to the health, safety, or welfare of cardholders or the public.
(h) The cabinet and its authorized agents shall have access to any area within a licensee's site or facility, including any area being used to store medicinal cannabis, and ***shall be*** ***[~~are~~]*** authorized to collect samples and test samples for testing.
(4) Training.
(a) Every principal, agent, employee, and volunteer of a licensee who has direct contact with cardholders, or physically handles cannabis seeds, seedlings, **tissue cultures, clones,** mature cannabis plants, medicinal cannabis, or medicinal cannabis products, shall complete applicable training required by the cabinet, which may include trainings for cultivating, processing, testing, and retail sale of medicinal cannabis and usage of the Commonwealth's designated electronic monitoring system and seed to sale tracking system required by KRS 218B.140. The cabinet shall provide written notice to licensees of the availability of any required training and the frequency to complete the training.
(b) The cabinet shall publish a Guide to Worker Safety and Health in the Kentucky Medical Cannabis Industry on the website of the Kentucky Medical Cannabis Program, https://kymedcan.ky.gov. Licensees shall maintain a physical copy of the Guide to Worker Safety and Health in the Kentucky Medical Cannabis Industry in their facility in a manner that is readily accessible to its employees or agents and ensure that employees receive annual training on the contents of the guide.
(c) A licensee shall train its principals, agents, employees, and volunteers on its established standard operating procedures within thirty (30) days of starting employment and once every calendar year thereafter.
(d) A licensee shall retain any training participation records of its principals, agents, employees, and volunteers and make them available for inspection by the cabinet upon request for a period

of five (5) years.
(5) Insurance requirements.
(a) A licensee shall obtain and maintain commercial general liability insurance for, at a minimum, $1,000,000 per occurrence and $2,000,000 per aggregate.
(b) A licensee shall obtain and maintain commercial automobile insurance as required by Kentucky law, specifically KRS 304.39-110, for any vehicle used to transport medicinal cannabis or medicinal cannabis products.
(c) A licensee shall obtain and maintain workers' compensation insurance coverage for employees in the Commonwealth and shall pay all required employer contributions to the Kentucky Office of Unemployment Insurance.
(d) The insurance requirements contained in this section shall begin prior to the licensee's first day of cannabis business activities in the Commonwealth and continue for as long as the licensee is operating under a license issued by the cabinet.
(6) Reports.
(a) The cabinet may require ongoing reporting of operational and financial information from the licensee in a form and manner prescribed by the cabinet.
(b) The cabinet shall require any reports necessary to carry out its responsibilities under KRS Chapter 218B and 915 KAR Chapter 1.

Section 6. Failure to be Operational.
(1) If a licensee has not met the timeline estimates provided in its initial license application to begin cannabis business activities in the Commonwealth, the licensee shall notify the cabinet ***by~~[via]~~*** electronic mail to kymedcanreporting@ky.gov within two (2) calendar days of determining a need to adjust its timeline. In its written notice to the cabinet, the licensee shall identify any operational deficiencies and provide an explanation for failing to adhere to its timeline estimates.
(2) Within seven (7) calendar days of providing the written notice required under this section, the licensee shall submit a corrective action plan to the cabinet that sets forth the licensee's updated timeline and a date certain for correcting the identified operational deficiencies.
(3) If the licensee fails to comply with its corrective action plan, the cabinet may impose penalties or sanctions as outlined in Section 12 of this administrative regulation.

Section 7. Closure of a Licensed Cannabis Business Location.
(1) A licensee shall notify the cabinet ***by~~[via]~~*** electronic mail to kymedcanreporting@ky.gov ***at least~~[immediately, but in no event fewer than]~~*** thirty (30) calendar days prior to the projected date of closure, upon making a determination that it intends to close a cannabis business location.
(2) A licensee shall not accept or purchase seeds, seedlings, **tissue cultures, clones,** medicinal cannabis plants, medicinal cannabis, medicinal cannabis products, medicinal cannabis accessories, equipment, or medicinal devices or instruments for the closing location as of the date of closure notice submitted to the cabinet.
(3) The notice shall be accompanied by the licensee's written plan for closing its cannabis business location that includes:
(a) The projected date of closure;
(b) How the licensee intends to notify, prior to the projected date for closure, any person or entity

to which the licensee provides medicinal cannabis or medicinal cannabis services from the closing location;
(c) How the licensee intends to dispose of seeds, seedlings, **tissue cultures, clones,** medicinal cannabis plants, medicinal cannabis, medicinal cannabis products, or other plant matter projected to still be at the closing location at the time of the projected closure; and
(d) How the licensee intends to dispose of equipment, devices, instruments, or medicinal cannabis accessories at the closing location.
(4) A licensee shall not remove or destroy any seeds, seedlings, **tissue cultures, clones,** medicinal cannabis plants, medicinal cannabis, other plant matter, medicinal cannabis products, equipment, medicinal cannabis accessories, or medicinal devices or instruments until the cabinet has approved its plan for closing the location and shall comply with all applicable requirements regarding disposal of medicinal cannabis contained in 915 KAR Chapter 1.
(5) The cabinet may enter and inspect the cannabis business location and facilities following receipt of the licensee's closure plan to determine whether to approve the closure plan. If the cabinet denies the closure plan, it shall notify the licensee in writing and require the licensee to submit a revised closure plan within seven (7) calendar days of the date of the denial notice. The cabinet shall review and consider the revised closing plan and issue a determination within seven (7) calendar days of receipt.
(6) If the cabinet approves the licensee's closure plan, the licensee shall surrender its license for the closing location to the cabinet on or before the date for closure provided in the plan.

Section 8. Request for Approval of a Change in Cannabis Business Ownership.
(1) If there is ***a pending*** ***~~an impending~~*** change in ownership of a licensee from the ownership listed in the initial license application, the licensee shall submit a written request for approval of a change in ownership to the cabinet ***by~~via~~*** electronic mail to kymedcanreporting@ky.gov. The cabinet shall consider the requirements for ownership of a cannabis business contained in KRS Chapter 218B and 915 KAR Chapter 1 as well as any other factors that the cabinet deems relevant in making its determination on the request. The cabinet shall review the request and notify the licensee in writing whether the request is approved or denied.
(2) For each new individual or entity that is part of the proposed change in ownership, the licensee shall include in its request the information required of owners in the initial license application. The licensee shall also provide the cabinet with the names of all outgoing individuals or entities previously listed as owners.
(3) If the cabinet determines that a request for approval of a change in ownership is lacking sufficient information upon which to make a determination, the cabinet shall notify the licensee in writing of the areas that require additional information and documentation. The licensee shall have fifteen (15) calendar days from the mailing date of the notice to provide the requested information and documentation to the cabinet. A licensee's failure to provide the required information and documentation to the cabinet by the deadline shall be grounds for the denial of the requested change in ownership.

Section 9. Request for Approval of a Change in Cannabis Business Location.
(1) A licensee desiring to change the location of a site or facility shall submit a written request for approval of a change in location to the cabinet ***by~~via~~*** electronic mail to

kymedcanreporting@ky.gov. A change in location of a site or facility shall not occur unless the cabinet approves the change in writing. The cabinet shall consider the location requirements for a cannabis business contained in KRS Chapter 218B and 915 KAR Chapter 1 in making its determination on the request, and any other factors that the cabinet deems relevant. The cabinet shall review the request and notify the licensee in writing whether the request is approved or denied.

(2) A written request for approval of a change in location shall include the reason(s) for requesting the change and other information about the proposed new location, including:

(a) The proposed new physical address of the cannabis business and the GPS coordinates for any proposed cultivation, processing, producing, testing, or dispensing activities;

(b) Evidence that the licensee has the authority to use the proposed site as a cannabis business;

(c) Confirmation that the proposed location is not within ***1,000*** ***~~[one thousand (1,000)]~~*** feet of an existing elementary or secondary school or a daycare center at the time the request is made; and

(d) A site plan for the cannabis business.

(3) If the cabinet in its discretion approves the request, the cabinet shall issue an amended license to the licensee reflecting the new physical address of the cannabis business. The expiration date of the amended license shall be the same as the expiration date of the previous license.

(4) Within ninety (90) calendar days of the issuance by the cabinet of an amended license under this section, the licensee shall change the location of its operation to the new location designated in the new license. Simultaneously, the licensee shall cease to operate at the former location and surrender its existing license to the cabinet. The following conditions shall apply:

(a) ***~~[At no time may]~~*** A licensee ***shall not*** operate or exercise any of the privileges granted under the license in both locations;

(b) The cabinet may extend the ninety (90) day deadline for relocation for up to an additional ninety (90) calendar days;

(c) The licensee shall notify the cabinet ***by~~[via]~~*** electronic mail to kymedcanreporting@ky.gov at least fifteen (15) calendar days prior to beginning cannabis business activities at the new location; and

(d) The cabinet may conduct an inspection to determine the appropriateness of the new location, and upon notification from the cabinet, the licensee shall immediately correct any deficiencies identified by the cabinet during this inspection and shall not commence operations at the new location until the deficiencies have been corrected and approved by the cabinet.

(5) For dispensary licenses, the cabinet shall not approve a change of location that is outside the boundaries of the medicinal cannabis region for which the license was issued or that otherwise is not in compliance with the location restrictions contained in Section 3(3) of this administrative regulation.

Section 10. Request to Sell Cannabis Business License.

(1) A licensee desiring to sell its cannabis business license shall submit ***to the cabinet by electronic mail to kymedcanreporting@ky.gov*** a written request for approval of the sale ***~~[to the cabinet via electronic mail to kymedcanreporting@ky.gov]~~***. The sale of a cannabis business license shall not occur unless the cabinet approves the sale in writing. The cabinet shall review the request and notify the licensee in writing whether the proposed sale is approved or

denied. The cabinet shall consider the initial license application requirements for a cannabis business contained in KRS Chapter 218B and 915 KAR 1:010, and any other factors that the cabinet deems relevant in making its determination on the request.
(2) A written request to approve a license sale shall include the sale price, the reason(s) for requesting the sale, and information about the proposed purchaser, including:
(a) All information and documentation required to be submitted by a cannabis business as part of the initial license application process ***[~~in order~~]*** to show the proposed purchaser would be eligible for entry into a license lottery conducted according to this administrative regulation;
(b) Signed attestations from the proposed purchaser that are required as part of the initial license application process;
(c) A transition plan for transferring the license from the licensee to the proposed purchaser; and
(d) A notarized affidavit from the proposed purchaser swearing ***or[~~and~~]*** affirming that all information and documentation provided to the cabinet along with the request is true and correct, and an acknowledgement that any false statement made to the cabinet as part of the proposed sale process is punishable under the applicable provisions of KRS 523.100.
(3) The cabinet shall approve a licensee's sale of a license if the proposed purchaser and any new location or facilities meet the requirements of KRS Chapter 218B and 915 KAR Chapter 1.
(4) The cabinet shall deny a licensee's sale of a license to any proposed purchaser who currently holds a license in a different cannabis business category than ***that being [~~the one~~]*** offered for sale (such as the proposed purchaser seeks to purchase a dispensary license while currently licensed as a tier I cultivator), except that a cultivator may sell its license to another licensed cultivator in the same or different cultivator tier (such as the proposed purchaser may purchase a tier II cultivator license while currently licensed as a tier I cultivator). Cultivators may hold licenses in more than one (1) cultivator tier at any given time ***if [~~as long as~~]*** each license contains a separate and distinct physical address where cultivator conducts licensed cannabis activities and the licensee is otherwise in compliance with the requirements of KRS Chapter 218B and 915 KAR Chapter 1.

Section 11. Issuance of Additional Cannabis Business Licenses.
(1) Beginning January 1, 2025, the cabinet shall, on a quarterly basis, review the need for issuance of new licenses in each cannabis business category.
(2) In making its determination whether to issue new licenses, the cabinet may consider:
(a) The population of the Commonwealth;
(b) The number of active cardholders;
(c) Changes to the list of qualifying medical conditions for medicinal cannabis;
(d) Market supply and demand;
(e) Geographic distribution of dispensaries and other cannabis businesses;
(f) Workforce development opportunities; and
(g) Any other factors that the cabinet deems relevant to its analysis.
(3) If the cabinet determines there exists a need for additional cannabis business licenses in the Commonwealth, the cabinet shall issue a notice documenting the basis for this determination, including a list of the factors it considered to arrive at that determination.
(4) The cabinet shall publish on the website of the Kentucky Medical Cannabis Program, https://kymedcan.ky.gov, the notice required by this Section as well as a notice of initial license

application availability. This notice shall provide the timeframe during which initial license applications shall be accepted by the cabinet and the category and number of cannabis business licenses available for distribution at the close of the application period. Applicants for new cannabis business licenses shall adhere to the requirements of 915 KAR 1:010 regarding initial license applications and follow the initial license application instructions. The process for issuing new licenses shall comply with the requirements of this administrative regulation.

Section 12. Penalties and Sanctions.
(1) In addition to any other penalty imposed by law for violations of KRS Chapter 218B and 915 KAR Chapter 1, the cabinet may take one (1) or more of the following actions:
(a) Suspend or revoke a license if ***[~~any of the following occur~~]***:
1. The licensee or any of its agents commit multiple violations or a serious violation of the requirements of KRS Chapter 218B and 915 KAR Chapter 1;
2. The licensee or any of its agents fail to maintain effective control against diversion of medicinal cannabis from its facility or under its control;
3. The licensee or any of its agents violate a provision of other state or local laws regarding the operation of its cannabis business;
4. The licensee or any of its agents engage in conduct, or an event occurs, that would have disqualified the cannabis business from being issued a license or having its license renewed; or
5. The licensee submitted false or misleading information on any application submitted to the cabinet.
(b) Impose a civil fine of not more than $10,000 for each violation and an additional fine of not more than $1,000 for each day of the continuing violation. In determining the amount of each fine, the cabinet shall ***consider*** ***[~~take the following into consideration~~]***:
1. The seriousness of the violation;
2. The potential harm resulting from the violation to cardholders or the general public;
3. The willfulness of the violation;
4. Previous violations, if any, by the licensee being assessed;
5. The economic benefit to the licensee being assessed for failing to comply with the requirements of KRS Chapter 218B, 915 KAR Chapter 1, or an order issued by the cabinet; and
6. The economic determent to the licensee.
(c) Issue a cease-and-desist order to immediately stop or restrict the operations of a licensee to protect the public's health, safety, and welfare. The following applies to issuing a cease-and-desist order:
1. An order may include a requirement that a licensee cease or restrict some or all of its operations. In addition, the order may prohibit the use of some or all of the medicinal cannabis grown, processed, or to be sold by the licensee;
2. An order may be issued by an authorized agent of the cabinet immediately upon the completion of an inspection or investigation if the agent observes or suspects an operational failure or determines that the conditions will likely create a diversion of medicinal cannabis, contamination of medicinal cannabis, or a risk to cardholders or the general public;
3. An order may be issued by an authorized agent of the cabinet in circumstances where a licensee fails to provide timely notice of closure of a cannabis business location in accordance with Section 7 of this administrative regulation and the cabinet suspects the imminent closure of the cannabis

business shall likely create a diversion of medicinal cannabis or a risk to cardholders or the general public;
4. An order may include:
a. An immediate evacuation of the site and facility, and the sealing of the entrances to the facility;
b. A quarantine of some or all of the medicinal cannabis found at the facility; and
c. The suspension of the sale or shipment of some or all of the medicinal cannabis found at the facility.
(d) Issue a written warning if the cabinet determines that either:
1. The public interest shall be adequately served under the circumstances by the issuance of the warning; or
2. The violation does not threaten the safety or health of cardholders or the general public, and the licensee shall take immediate action to remedy the violation.
(e) Require a licensee develop and adhere to a corrective action plan approved by the cabinet. The cabinet shall monitor compliance with the corrective action plan. Failure to comply with the corrective action plan may result in the cabinet taking additional action under the applicable provisions of this section as it deems appropriate.
(2) A person who aids, abets, counsels, induces, procures, or causes another person to violate KRS Chapter 218B or 915 KAR Chapter 1, or an order issued by ***the*** cabinet, shall be subject to the civil penalties provided for under this section.
(3) Before the cabinet may revoke or suspend a license, the cabinet shall provide the licensee with written notice specifying the nature of the alleged violation(s) and allow the licensee an opportunity to appear and be heard pursuant to KRS Chapter 13B. Any resulting hearing shall be conducted in compliance with the requirements of KRS Chapter 13B.
(4) The cabinet shall provide a licensee with written notice of imposition of a civil fine, order of restitution, cease-and-desist order, written warning, or corrective action plan ***by[~~via~~]*** certified mail to the address on the license. The licensee may, within thirty (30) calendar days after the date of the mailing of the cabinet's notice, file a written request for an administrative hearing regarding the action taken. The hearing shall be conducted in compliance with the requirements of KRS Chapter 13B.

Section 13. Technical Advisories.
(1) The cabinet may issue technical advisories by memorandum to assist licensees in complying with the KRS Chapter 218B and 915 KAR Chapter 1.
(2) Technical advisories shall not have the force of law or regulation, but shall provide guidance on the cabinet's interpretation of, and how a licensee may maintain compliance with, KRS Chapter 218B and 915 KAR Chapter 1.
(3) Notice of the availability of a technical advisory shall be published on the website of the Kentucky Medical Cannabis Program, https://kymedcan.ky.gov.

Section 14. Minimal Performance Standards for Biennial Accreditation.
(1) As part of the license renewal process, licensees shall meet the minimum performance standards established in 915 KAR 1:010, Section 6 ***[~~in order~~]*** to be approved for a renewal license.
(2) If a licensee successfully meets the minimum performance standards established in 915 KAR 1:010, Section 6 over a two (2) year period, the cabinet shall recognize the licensee as an accredited

cannabis business in the Commonwealth.
(3) The recognition provided under this section shall expire two (2) years after the date of issuance, and shall be renewed if the licensee continues to:
(a) Operate in the Commonwealth as of the expiration date; and
(b) Meet the minimum performance standards established in 915 KAR 1:010, Section 6.

CONTACT PERSON: Oran S. McFarlan, III, Kentucky Medical Cannabis Program, Cabinet for Health and Family Services, 275 E. Main Street, 5th Floor, Frankfort, KY 40621; Phone Number: (502) 564-5313; Email: oran.mcfarlan@ky.gov.

Andy Beshear
GOVERNOR

CABINET FOR HEALTH AND FAMILY SERVICES

Eric Friedlander
SECRETARY

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October 14, 2024

Senator Stephen West, Co-Chair
Representative Derek Lewis, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
083, Capitol Annex
Frankfort KY 40601

Re: 922 KAR 1:350

Dear Co-Chairs West and Lewis:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 922 KAR 1:350, Requirements for public child welfare agency foster parents, adoptive parents, and respite care providers, the Cabinet for Health and Family Services proposes the attached suggested amendments to 922 KAR 1:350.

If you have any questions regarding this matter, please contact Rachael Ratliff, Department for Community Based Services, at (502) 229-5407.

Sincerely,

Mary Carey

Executive Staff Advisor
Office of Legislative and Regulatory Affairs

Staff-suggested Amendment
Final version 10/8/2024

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Community Based Services
Division of Protection and Permanency

922 KAR 1:350. Requirements for public child welfare agency foster parents, adoptive parents, and respite care providers.

Page 25
Section 11(1)(k)
Line 14

After "environment", insert ";".
Delete ".".

Page 26
Section 11(7)(d)
Line 17

After "cabinet", insert ";".
Delete ".".