201 KAR 2:010

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:010. Schools approved by the board

Section 1. An applicant for licensure as a pharmacist, shall have graduated and received a degree in an accredited pharmacy degree program which has been approved by the Board of Pharmacy. A program shall be considered approved if the program's standards are equivalent to the minimum standards for accreditation for a similar program established by:

(1) The American Council on Pharmaceutical Education in:

(a) “Accreditation Manual for Professional Programs” or

(b) “Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree” or

(2) The Canadian Council for Accreditation of Pharmacy Programs in “Accreditation Standards and Guidelines for Pharmacy Professional Degree Programs in Canada”

Section 2. An applicant for licensure as a pharmacist who shall have graduated and received a degree in a foreign pharmacy degree program, other than from a college or school accredited by the Canadian Council for Accreditation of Pharmacy Programs shall be deemed to be a graduate of a pharmacy degree program which has been approved by the Board of Pharmacy if the applicant has obtained a Foreign Pharmacy Graduate Examination Committee Certificate through the Foreign Pharmacy Graduate Examination Committee Certification Program which is administered by the National Association of Boards of Pharmacy Foundation.

Section 3. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) “Accreditation Manual for Professional Programs” 8th Edition (3rd Printing) January 1995, American Council on Pharmaceutical Education;

(b) “Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree,” June 14, 1997, American Council on Pharmaceutical Education; and

(c) “Accreditation Standards and Guidelines for Pharmacy Professional Degree Programs in Canada” Revised January 1998, Canadian Council for Accreditation of Pharmacy Programs.

(2) This material may be inspected, copied, or obtained at the Kentucky Board of Pharmacy, 1024 Capital Center Drive, Suite 210, Frankfort, Kentucky 40601-8204, Monday through Friday 8 a.m. to 4:30 p.m.

Adopted effective January 4, 1978; Amended effective June 4, 1985; Amended effective December 10, 1985; Amended effective January 12, 1990; Amended effective February 19, 1992; Amended effective October 8, 1992; Amended effective October 20, 1999.

HISTORICAL NOTES

RELATES TO: KRS 315.050

STATUTORY AUTHORITY: KRS 315.050, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.050(1) requires the board to approve the schools or colleges of pharmacy whose curricula or course of studies are acceptable. This administrative regulation establishes the educational standards for an applicant for licensure as a pharmacist in Kentucky and identifies the acceptable and approved colleges or schools of pharmacy from which an applicant shall graduate.

201 Ky. Admin. Regs. 2:010, 201 KY ADC 2:010

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:015

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:015. Continuing education

Section 1. Definition. “Continuing education unit” or “CEU” is defined by KRS 315.010(7).

Section 2. (1) Continuing education hours for credit may be compiled in the following areas if the sponsor grants the participant a certificate of completion:

(a) Cassette and audiovisual presentation;

(b) In-company professional seminars;

(c) Accredited school of pharmacy continuing education programs;

(d) Postgraduate courses in pharmaceutical sciences;

(e) Correspondence courses;

(f) Programs granted continuing education credit by other states;

(g) The Accreditation Council for Pharmacy Education;

(h) Continuing education television series;

(i) Programs sponsored by allied professional groups; or

(j) Professional society and association sponsored programs.

(2) The board approval of each program shall expire at the end of three (3) years.

Section 3. Continuing education sponsors shall be responsible for submitting to the board for final accreditation continuing education programs for participants.

(1) A sponsor shall be any person, school, association, company, corporation or group who wishes to develop a continuing education program.

(2) Programs shall be submitted to the board at least sixty (60) days prior to planned participation so the participants can know the value of the experience prior to actual participation.

(3) Program changes shall be made to and accredited by the board, or the evaluation and accreditation of the program shall be void.

(4) Continuing education credit shall be given only once for each program per participant.

(5) Sponsors shall retain a file of each participant's program completion for three (3) years.

Section 4. (1) Sponsors and pharmacists requesting approval of continuing pharmacy education shall submit Kentucky Board of Pharmacy Continuing Education Program Approval Form. Pharmacists shall keep valid records, receipts, and certifications of continuing pharmacy education programs completed for three (3) years, except the pharmacist shall keep a copy of his or her HIV/AIDS CE certificate for ten (10) years, and submit the certification to the board on request.

(2) Submission of a fraudulent statement or certificate concerning continuing pharmacy education shall subject the pharmacist to discipline as provided in KRS 315.121.

Section 5. (1) A pharmacist shall:

(a) Complete a minimum of one and five-tenths (1.5) CEU (fifteen (15) contact hours) annually between January 1 and December 31; and

(b) Not transfer or apply excess hours or units for future years.

(2) A pharmacist may be granted a deferral on a year-to-year basis at the discretion of the board for illness, incapacity, or other extenuating circumstances.

(3) A pharmacist first licensed by the board within twelve (12) months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

Section 6. All pharmacists shall keep the board informed of their correct addresses.

Section 7. CEU may be transferred from another state to Kentucky if the transfer state recognizes Kentucky

CEU.

Section 8. A licensee who failed to timely renew his license shall:

(1) Comply with the applicable provisions of KRS 315.120(2) or (3); and

(2) Complete fifteen (15) hours of continuing education for each year the applicant failed to renew his license, up to a maximum of seventy-five (75) hours.

Section 9. (1) At least once every ten (10) years, a pharmacist shall successfully complete a continuing education course of not less than one (1) contact hour (0.1 CEU) concerning HIV/AIDS that complies with KRS 214.610(1).

(2) The continuing education course shall be:

(a) Approved by the Cabinet for Health and Family Services HIV/AIDS Branch; or

(b) Conducted by a provider approved by the Accreditation Council for Pharmacy Education (ACPE).

Section 10. Incorporation by Reference. (1) The Kentucky Board of Pharmacy Continuing Education Program Approval Form, 2002, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 23 Millcreek Park, Frankfort, Kentucky 40601-0230, Monday through Friday, 8 a.m. to 4:30 p.m.

Adopted effective January 4, 1978; Amended effective June 4, 1985; Amended effective January 12, 1990; Amended effective March 28, 2002; Amended effective May 6, 2011.

HISTORICAL NOTES

RELATES TO: KRS 214.610, 315.065, 315.116, 315.120

STATUTORY AUTHORITY: KRS 315.110(1), 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.065(2) and (3) require the board to establish continuing education requirements for pharmacists. This administrative regulation establishes requirements for the continuing pharmacy education of registered pharmacists and

requires all registered pharmacists holding a license issued by the board to participate in continuing pharmacy education as a means of renewal of their licenses.

201 Ky. Admin. Regs. 2:015, 201 KY ADC 2:015

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:020

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:020. Examination

Section 1. The examination for licensure shall include:

(1) The North American Pharmacist Licensure Examination (NAPLEX); and

(2) The Multistate Pharmacy Jurisprudence Examination (MPJE).

Section 2. The passing score on the required examinations shall be:

(1) At least seventy-five (75) on the basis of the NAPLEX and the MPJE grades shall not be used in computing the NAPLEX; and

(2) At least seventy-five (75) on the basis of the MPJE.

Section 3. If an applicant fails to obtain the necessary scores in any of the tests described in Section 2 of this administrative regulation, the applicant may upon proper application retake the tests upon the payment of the fee set forth in 201 KAR 2:050 plus any direct costs for test materials and supplies. An applicant who has failed any test may retake that test within one (1) year of the date the applicant first failed the test without having to reapply.

Section 4. All results of examinations shall be preserved according to the Board of Pharmacy Record Retention Schedule.

Section 5. Fees submitted with an application shall be nonrefundable.

Section 6. Prior to approval for examination, an applicant shall:

(1) Submit to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police and the Federal Bureau of Investigation; and

(2) Submit to a query to the National Practitioner Data Bank of the United States Department of Health and

Human Services.

Section 7. License, Fee. An applicant shall submit:

(1) An Initial Application for Pharmacist Licensure pursuant to KRS 315.050; and

(2) As appropriate, the fee established by 201 KAR 2:050, Section 1(1).

Section 8. Incorporation by Reference. (1) “Initial Application for Pharmacist Licensure” Form 1, 7/2012, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday 8:00 a.m. to 4:30p.m.

Adopted effective September 11, 1974; Amended effective December 3, 1980; Amended effective August 11, 1982; Amended effective June 4, 1985; Amended effective January 12, 1990; Amended effective October 8, 1992; Amended effective December 15, 1999; Amended effective May 5, 2006; Amended effective February 1, 2013; Amended effective August 21, 2013.

HISTORICAL NOTES

RELATES TO: KRS 218A.205(7), 315.050

STATUTORY AUTHORITY: KRS 218A.205(7), 315.050(2), 315.191(1), (2), (4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.050(2) and 315.191(1)(c) authorize the board to promulgate administrative regulations to prescribe the time, place, method, manner, scope, and subjects of examinations.KRS 218A.205(7) requires the board to establish requirements for background checks for licensees. This administrative regulation establishes the examination and application requirements for obtaining a license to practice pharmacy in Kentucky.

201 Ky. Admin. Regs. 2:020, 201 KY ADC 2:020

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:030

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:030. License Transfer

Section 1. Definitions. (1) “Board” is defined by KRS 315.010(3).

(2) “License transfer” means a license to practice pharmacy in Kentucky issued by the board to a pharmacist licensed in another jurisdiction.

(3) “NABP” means the National Association of Boards of Pharmacy.

Section 2. An applicant licensed in another jurisdiction shall be eligible for license transfer, if the:

(1) Requirements for licensure of the jurisdiction that granted his or her license met or exceeded Kentucky requirements for licensure at the time the license in the other jurisdiction was granted;

(2) Applicant has held in good standing, an active license to practice pharmacy during the entire year preceding the time of filing an application;

(3) Applicant has:

(a) Completed and certified the NABP Preliminary Application for Transfer of Pharmacist License form; and

(b) Received an NABP Official Application for Transfer of Pharmacist License;

(4) Applicant is currently in good standing in the jurisdiction from which he or she has applied;

(5) Applicant has successfully completed an examination in jurisprudence;

(6) Applicant has submitted to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police and the Federal Bureau of Investigation; and

(7) Applicant has submitted to a query to the National Practitioner Data Bank of the United States Department of Health and Human Services.

Section 3. Required Information. An applicant shall provide the information required by the NABP Preliminary Application for Transfer of Pharmacist License form, including:

(1) Name, maiden, and other names used currently or previously;

(2) Address, telephone number;

(3) Date and place of birth, and current age;

(4) Social Security number;

(5) Citizenship;

(6) Gender;

(7) State of original license by examination, including:

(a) License number;

(b) Original date of issue;

(c) Current status of original licensure; and

(d) State for which license transfer is requested;

(8) Pharmacy education, including:

(a) Name and location of pharmacy school;

(b) Name of pharmacy degree;

(c) Date degree was received;

(d) Other professional degrees, including the information specified by paragraphs (a) to (c) of this subsection;

(9) Whether the applicant has earned certification by the Foreign Pharmacy Graduate Examination Committee, and, if so, the examination equivalency number assigned;

(10) Total hours of practical experience prior to licensure as a pharmacist, including the State Board of Pharmacy with which the hours are filed;

(11) States, dates, and results of pharmacist licensure examinations;

(12) Pharmacist licenses obtained by:

(a) Score transfer; and

(b) Licensure transfer;

(13) Practice and employment, including nonpharmacist employment, from initial licensure to the date of filing the application; and

(14) Record of charges, convictions, and fines imposed, or certification that the applicant has not been convicted, fined, disciplined, or had a license revoked.

Section 4. The board shall accept a license transfer from a jurisdiction that:

(1) Is an active member of the NABP; and

(2) Grants license transfer to a pharmacist pursuant to conditions and requirements that are the equivalent of conditions and requirements established by the board.

Section 5. An applicant shall take and pass the Multistate Pharmacy Jurisprudence Examination administered by the NABP.

Section 6. Fee. An applicant shall include the fee specified by 201 KAR 2:050, Section 1(2), (20).

Section 7. (1) “NABP Preliminary Application for Transfer of Pharmacist License” 3/06, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

Adopted effective December 11, 1974; Amended effective March 8, 1990; Amended effective March 16, 1998; Amended effective June 16, 1999; Amended effective April 12, 2000; Amended effective May 5, 2006; Amended effective February 1, 2013; Amended effective August 21, 2013.

HISTORICAL NOTES

RELATES TO: KRS 315.210

STATUTORY AUTHORITY: KRS 218A.205(7), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.210 requires the board to establish conditions for licensure by reciprocity.KRS 218A.205(7) requires the board to establish requirements for background checks for licensees. This administrative regulation establishes conditions, forms, and examination requirements for licensure by reciprocity.

201 Ky. Admin. Regs. 2:030, 201 KY ADC 2:030

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:040

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:040. Registration of pharmacist interns

Section 1. Definitions. (1) “Academic experience program” means a course or series of courses taken by a pharmacist intern at a school or college of pharmacy approved by the board that involves actual practice of pharmacy experiences.

(2) “Preceptor” means the pharmacist who is responsible to the board for the practice of pharmacy experiences of a pharmacist intern.

Section 2. An applicant for registration as a pharmacist intern shall:

(1) File an Application for Registration as a Pharmacist Intern, Form I, with the board;

(2) Attach a recent head and shoulders passport photograph, that is not a proof copy or plastic identification; and

(3) Submit proof of acceptance by a college or school of pharmacy approved by the board.

Section 3. An applicant for examination for licensure as a pharmacist shall:

(1) Complete 1,500 hours of internship;

(2) Be awarded credit for internship for hours worked in a pharmacy or in related research during the time the pharmacist intern is enrolled in an approved school or college of pharmacy;

(3) Not be awarded credit for hours worked in a pharmacy or in related research during the period the pharmacist intern is completing the academic experience program;

(4) Be limited to internship credit:

(a) Of forty-eight (48) hours per week during non-academic sessions if the pharmacist intern is in good

standing with a college or school of pharmacy and the board; and

(b) Of twenty (20) hours per week during academic sessions in a college or school of pharmacy. The maximum credit allowed for this enrolled time shall be 500 hours;

(5) Be given credit for the following forms of internship:

(a). Completion of an academic experience program;

(b). Work performed in a pharmacy under the supervision of a preceptor;

(c). Work or research related to the practice of pharmacy that was performed under the supervision of a preceptor for a government body, college or university, pharmacy business, or other entity if the pharmacist intern has received prior approval by the board. The maximum credit allowed for this time shall be 400 hours and the pharmacist intern shall also file an essay of at least 500 words describing the work or research experience and the relation of the work or research to the practice of pharmacy, which shall be approved by the board president; or

(d) An internship performed outside of Kentucky if the:

1. Requirements for internship in that state are at least equivalent to the requirements established in this administrative regulation; and

2. Board of licensure in that state has certified that the preceptor, pharmacy, government body, college or university, pharmaceutical business, or other entity is in good standing; and

(6) Not be awarded credit for an internship completed prior to registration with the board.

Section 4. A pharmacist intern shall:

(1) Be issued a Registration Identification Card;

(2) Carry the Registration Identification Card when on duty; and

(3) Show it upon request to a member of the board or its authorized agent.

Section 5. The registration of a pharmacist intern shall be revoked if the pharmacist intern is not:

(1) Currently enrolled in a college or school of pharmacy approved by the board;

(2) A current applicant for licensure as a pharmacist in Kentucky; or

(3) Awaiting the results of an examination.

Section 6. The registration of a pharmacist intern shall not be revoked when the intern is not currently enrolled in a college or school of pharmacy approved by the board if the board finds that:

(1) The intern is on a semester break; or

(2) Personal or family health concerns or other reasons beyond the control of the pharmacist intern necessitate a temporary absence from enrollment and the absence is approved by the board.

Section 7. A person who is not registered as a pharmacist intern shall not:

(1) Hold himself out as a pharmacist intern; or

(2) Perform the duties of a pharmacist intern.

Section 8. (1) A preceptor shall be a pharmacist:

(a) Whose license is in good standing;

(b) Has been licensed by the board for at least one (1) year; and

(c) Has requested in writing to be designated as a preceptor.

(2) A preceptor shall be actively engaged in the practice of pharmacy in the location where the pharmacist intern performs his internship.

(3) The preceptor shall supervise only one (1) pharmacist intern at a time for the purpose of the intern obtaining credit for the practice of pharmacy experience, unless the pharmacist is supervising interns as a faculty member at a school or college pharmacy approved by the board during an academic experience program.

Section 9. Credit for Non-Academic Experience Programs. (1) Within ten (10) days of beginning an internship

credit for non-academic experience program, a pharmacist intern shall submit a Pharmacist Preceptor's Affidavit, Form II.

(2) On or before graduation from a college or school of pharmacy, a pharmacist intern shall submit an Internship Report, Form III.

Section 10. Credit for Academic Experience Programs. (1) For a Doctor of Pharmacy degree, credit shall be awarded for each hour of successful completion of an academic experience program at a college or school of pharmacy approved by the board.

(2) An academic experience program shall be reported on an Academic Experience Affidavit, Form IV, which shall be filed with the board upon completion of the academic experience program or prior to certification for examination.

Section 11. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) “Application for Registration as a Pharmacist Intern” Form I, 11/2012;

(b)Pharmacist Preceptor's Affidavit, Form II, 11/2012;

(c)Internship Report, Form III, 11/2012; and

(d)Academic Experience Affidavit, Form IV, 11/2012.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

Adopted effective September 11, 1974; Amended effective September 8, 1982; Amended effective March 12, 1985; Amended effective January 12, 1990; Amended effective June 16, 1999; Amended effective January 12, 2000; Amended effective February 1, 2008; Amended effective February 1, 2013.

HISTORICAL NOTES

RELATES TO: KRS 315.010(16), 315.020(3), (4), 315.050(4), (5), 315.191(1)(h)

STATUTORY AUTHORITY: KRS 315.050(4), (5), 315.191(1)(a), (h)

201 KAR 2:040

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy is required by KRS 315.050(4) to establish standards for pharmacy intern certification.KRS 315.191(1)(h) authorizes the board to establish an apprentice program for training, qualifications, and registration of applicants for registration of pharmacist interns. This administrative regulation establishes the standards for training, qualifications, and registration of pharmacist interns.

201 Ky. Admin. Regs. 2:040, 201 KY ADC 2:040

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END OF DOCUMENT

201 KAR 2:045

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:045. Technicians

Section 1. A person shall be recognized by the board as a certified pharmacy technician, if:

(1)(a) He has successfully completed the National Certification Examination administered by the Pharmacy Technician Certification Board or the Institute for the Certification of Pharmacy Technicians (ICPT); and

(b) The certificate issued by the Pharmacy Technician Certification Board or the ICPT is current; or

(2) He has successfully completed the Nuclear Pharmacy Technician Training Program at the University of Tennessee.

Section 2. A certified pharmacy technician, subject to the supervision, as defined by KRS 315.010(25), of a pharmacist may perform the following functions:

(1) Certify for delivery unit dose mobile transport systems that have been refilled by another technician;

(2) Within a nuclear pharmacy, receive diagnostic orders; and

(3)(a) Initiate or receive a telephonic communication from a practitioner or practitioner's agent concerning refill authorization, after he clearly identifies himself as a certified pharmacy technician;

(b) If a practitioner or practitioner's agent communicates information that does not relate to the refill authorization:

1. A technician shall immediately inform the pharmacist; and

2. The pharmacist shall receive the communication.

Section 3. (1) A technician who has not been certified by the Pharmacy Technician Certification Board or the ICPT may perform the functions specified by Section 2 of this administrative regulation under the immediate

supervision of a pharmacist.

(2) A function performed by a certified pharmacy technician or pharmacy technician shall be performed subject to the review of the pharmacist who directed the technician to perform the function.

(3) A pharmacist who directs a certified pharmacy technician or pharmacy technician to perform a function shall be responsible for the technician and the performance of the function.

Adopted effective June 16, 1997; Amended effective June 12, 2000; Amended effective August 12, 2009.

HISTORICAL NOTES

RELATES TO: KRS 315.010(18), (25), 315.020(4)(b), 315.191(1)(a), (g), (l)

STATUTORY AUTHORITY: KRS 315.010(18), (25), 315.020(4)(b), 315.191(1)(a), (g), (l)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations governing pharmacy technicians.KRS 315.010(18) authorizes the board to permit a pharmacy technician to work under the general supervision of a pharmacist.KRS 315.191(1)(l) authorizes the board to promulgate administrative regulations establishing the qualifications a pharmacy technician is required to obtain prior to practicing under the general supervision of a pharmacist. This administrative regulation establishes the qualifications required for a pharmacy technician to practice under the general supervision of a pharmacist, and establishes the scope of practice for a pharmacy technician.

201 Ky. Admin. Regs. 2:045, 201 KY ADC 2:045

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END OF DOCUMENT

201 KAR 2:050

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:050. Licenses and permits; fees

Section 1. The following fees shall be paid in connection with pharmacist examinations and licenses, pharmacy permits, intern certificates and the issuance and renewal of licenses and permits:

(1) Application for a licensee for pharmacist examination—$150;

(2) Application and initial license for a pharmacist license by license transfer—$250;

(3) Certifying the grades of a licentiate of Kentucky to the licensing agency of another state—ten (10) dollars;

(4) Annual renewal of a pharmacist license—seventy (70) dollars;

(5) Delinquent renewal penalty for a pharmacist license—seventy (70) dollars;

(6) Annual renewal of an inactive pharmacist license—ten (10) dollars;

(7) Pharmacy intern certificate valid six (6) years—twenty-five (25) dollars;

(8) Duplicate of original pharmacist license wall certificate—seventy -five (75) dollars;

(9) Application for a permit to operate a pharmacy—$100;

(10) Renewal of a permit to operate a pharmacy—$100;

(11) Delinquent renewal penalty for a permit to operate a pharmacy—seventy-five (75) dollars;

(12) Change of location or change of ownership of a pharmacy or manufacturer permit—seventy-five (75) dollars;

(13) Application for a permit to operate as a manufacturer—$100;

(14) Renewal of a permit to operate as a manufacturer—$100;

(15) Delinquent renewal penalty for a permit to operate as a manufacturer—$100;

(16) Change of location or change of ownership of a wholesale distributor license—seventy-five (75) dollars;

(17) Application for a license to operate as a wholesale distributor—$100;

(18) Renewal of a license to operate as a wholesale distributor—$100;

(19) Delinquent renewal penalty for a license to operate as a wholesale distributor—$100;

(20) Query to the National Practitioner Data Bank of the United States Department of Health and Human Services—twenty-five (25) dollars;

(21) Application for a license to operate as a home medical equipment supplier—$200;

(22) Renewal for a license to operate as a home medical equipment supplier—$200; and

(23) Delinquent renewal penalty for a license to operate as a home medical equipment supplier—$150.

Adopted effective September 11, 1974; Amended effective November 2, 1977; Amended effective October 7, 1981; Amended effective August 11, 1982; Amended effective April 6, 1983; Amended effective November 9, 1992; Amended effective June 16, 1999; Amended effective May 5, 2006; Amended effective June 5, 2009; Amended effective February 1, 2013.

HISTORICAL NOTES

RELATES TO: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.0351(1), 315.036(1), 315.050(5), 315.060, 315.110, 315.120, 315.402, 315.518(1), 315.520(4)

STATUTORY AUTHORITY: KRS 218A.205(3)(g), 315.191(1), 315.035(1), (2), (4), 315.036(1), 315.050(5), 315.060, 315.110(1), 315.120(4), 315.402(1), 315.518(1), 315.520(4)

201 KAR 2:050

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(i) authorizes the board to assess reasonable fees for services rendered to perform its duties and responsibilities. This administrative regulation provides reasonable fees for this agency to perform all the functions for which it is responsible.

201 Ky. Admin. Regs. 2:050, 201 KY ADC 2:050

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END OF DOCUMENT

201 KAR 2:061

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:061. Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints

Section 1. (1) A complaint against a licensee may:

(a) Be submitted orally or in writing; and

(b) Originate from a consumer, competitor, health professional, government or provider agency, or other interested party.

(2) A complaint shall be accepted anonymously if the complaint is accompanied by sufficient corroborating evidence as would allow the board to believe, based upon a totality of the circumstances, that a reasonable probability exists that the complaint is meritorious.

(3) A complaint shall not be required to be sworn to or notarized.

Section 2. (1) Except as provided by subsection (2) of this section, upon receipt of a complaint, the board shall instruct its staff to:

(a) Conduct an investigation; and

(b) Report the conclusions and recommendations of the investigation to the:

1. Executive director; and

2. Board member assigned by the board to review conclusions and recommendations relating to an investigation.

(2) If the complaint pertains to the improper, inappropriate, or illegal dispensing of controlled substances, the board shall:

(a) File a report with the Attorney General's office, the Office of Inspector General's office, and the

Department of the Kentucky State Police within three (3) business days;

(b) Commence an investigation within seven (7) days of the complaint; and

(c) Produce a charging decision within 120 days of the complaint, unless an extension for a definite time period is requested in writing by a law enforcement agency due to an ongoing criminal investigation.

Section 3. (1) A panel consisting of the assigned board member, the executive director, and the pharmacy drug inspector shall review the conclusions and recommendation relating to an investigation.

(2) The panel shall recommend one (1) of the following options to the board:

(a) A reprimand restricting the licensee, permit or certificate holder;

(b) The issuance of a formal complaint, order, and notice of hearing;

(c) Dismissal of the case with or without prejudice; or

(d) Returning the case to the inspector for further investigation.

(3) Documentation of a board reprimand shall be maintained in the appropriate board files.

Section 4. (1) With the approval of the board, the executive director shall notify the licensee, permittee, or certificate holder, in writing, that he or she may request an administrative conference before the executive director and the pharmacy drug inspector to be held prior to the hearing.

(2) The licensee, permit or certificate holder shall be notified that he or she may appear with counsel.

(3) An administrative conference shall be held to determine whether an agreement may be reached to resolve the complaint that is acceptable to all parties.

(4) If an agreement is reached, it shall be submitted to the board for approval and board order.

Section 5. (1) A settlement conference may be requested by the licensee, permit or certificate holder, or the attorney for that person.

(2) If a settlement conference is requested, it shall be scheduled. The settlement conference shall include the

board's attorney, the licensee, permit or certificate holder, and the attorney for that person.

(3) If the parties to a settlement conference agree on stipulations, proposed terms, and conditions for an agreed order to resolve the complaint, they shall forward the agreed order to the board for approval.

(4) If the proposed agreed order is approved by the board, the complaint shall be considered resolved and a hearing shall not be held.

Section 6. Hearings. All hearings shall be conducted in accordance with the provisions of KRS 315.131(1).

Section 7. Posthearing Proceedings. (1) The board shall deliberate on all cases in closed session.

(2) Board counsel shall not attend, or be involved in any manner with, the closed session.

(3) The specific findings of the board shall be made in open session following the board's deliberation.

Section 8. Penalties. (1) Pursuant to KRS 218A.205(3)(e)1., a licensee convicted of a felony offense related to dispensing a controlled substance shall, at a minimum, be permanently banned from dispensing any controlled substance.

(2) Pursuant to KRS 218A.205(3)(e)2., the board shall impose restrictions short of a permanent ban from dispensing controlled substances on a licensee convicted of a misdemeanor offense relating to the dispensing of a controlled substance.

(3) Pursuant to KRS 218A.205(3)(e)3., a licensee disciplined by the licensing board of another state relating to the improper, inappropriate, or illegal dispensing of a controlled substance shall, at a minimum, have the same disciplinary action imposed in Kentucky as the disciplinary action imposed by the licensing board of the other state.

(4) Pursuant to KRS 218A.205(3)(f), the board shall submit all disciplinary actions to the National Practitioner Data Bank of the United States Department of Health and Human Services either directly or through a reporting agent.

Adopted effective March 4, 1992; Amended effective February 1, 2013.

HISTORICAL NOTES

RELATES TO: KRS 218A.205, 315.131, 315.191(4)

201 KAR 2:061

STATUTORY AUTHORITY: KRS 218A.205(3)(e), (f), (5), 315.191(1), (4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to the practice of pharmacy, including a process for complaints and hearings. KRS 218A.205(3)(e), (f), and (5) require the board to promulgate administrative regulations relating to complaints, licensure standards, and disciplinary actions. This administrative regulation establishes board procedure for investigations, the administrative hearings process, and the penalties for violations.

201 Ky. Admin. Regs. 2:061, 201 KY ADC 2:061

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:070

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:070. Prescription intermediary services restricted

Section 1. No pharmacist shall fill and dispense prescriptions obtained from an establishment or place which offers to the public, in any manner, its services as a “pickup station” or “intermediary” for the purpose of having prescriptions filled or delivered unless such establishment or place has a registered pharmacist in full charge of such services.

Adopted effective September 11, 1974.

HISTORICAL NOTES

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.020(2), 315.121(1), 315.191(2),(8)

NECESSITY, FUNCTION, AND CONFORMITY: By the authority of KRS 315.191(2) the Board of Pharmacy is responsible to control all matters relating to pharmacies and pharmacists with respect to drugs sold by prescriptions only. This administrative regulation assures the public that a registered pharmacist is present and that prescription drugs distribution is curtailed.

201 Ky. Admin. Regs. 2:070, 201 KY ADC 2:070

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:074

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:074. Pharmacy services in hospitals or other organized health care facilities

Section 1. Definitions. (1) “Automated pharmacy system” means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information and shall be either:

(a) A decentralized automated pharmacy system that is located outside the pharmacy department, but within the same institution, and under the supervision of a pharmacist; or

(b) A centralized automated pharmacy system from which medications are prepared for final distribution that require the approval of a pharmacist.

(2) “Institutional pharmacy” means that portion of an acute care hospital licensed pursuant to 902 KAR 20:016 or a pharmacy serving an other organized health care facility engaged in the manufacture, production, sale, or distribution of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, or disease.

(3) “Investigational drug” means a drug that has not been approved for use in the United States, but for which an investigational drug application has been approved by the FDA.

(4) “Other organized health care facility” means a facility:

(a) With a primary purpose to provide medical care and treatment to inpatients; and

(b) That is:

1. An intermediate care facility;

2. A skilled nursing facility;

3. A hospital other than an acute care hospital licensed pursuant to 902 KAR 20:016;

4. A licensed personal care home;

5. A licensed family care home;

6. A nursing home;

7. A nursing facility;

8. An intermediate care facility for mental retardation; or

9. An Alzheimer's nursing home.

(5) “Unit dose distribution” means a system in which drug therapy profiles are maintained in the pharmacy and doses are scheduled, prepared, and delivered in a ready-to-administer form to the patient care area as the doses are needed.

Section 2. Pharmacy Administration. (1) General.

(a) The pharmacy, organized as a separate department or service, shall be directed by a pharmacist, who shall be thoroughly knowledgeable about institutional pharmacy practice and management.

(b) The director of pharmacy services shall be responsible for departmental management and the development and implementation of goals and objectives to meet the needs of the institution and shall be responsible to the chief executive officer of the institution or the chief executive officer's designee.

(c) If the director of pharmacy services is not employed full time, the institution shall establish an ongoing arrangement in writing with a pharmacist to provide services required by this administrative regulation and KRS 315.020(1).

(d) If a hospital pharmacy is decentralized, each decentralized section or separate organizational element shall be under the immediate supervision of a pharmacist responsible to the director of pharmacy services.

(2) Pharmacy personnel.

(a) The institutional pharmacy shall maintain additional pharmacists in cooperation with the institution's administration, either full time or part time, as required to operate safely and effectively to meet the needs of the patients.

(b) If nonpharmacist personnel are employed, nonpharmacist personnel shall perform all duties under the supervision of a pharmacist and shall not be assigned and shall not perform duties that are to be performed only by a pharmacist.

(3) Responsibilities.

(a)1. Lines of authority and areas of responsibility within the pharmacy shall be clearly defined.

2. Written job descriptions for all categories of pharmacy personnel shall be prepared and revised as necessary.

(b)1. There shall be policies and procedures to provide for selection of drugs as well as a distribution system to serve the needs of the patient.

2. Provision for procurement of drugs in an emergency situation shall be provided for.

(4) Supportive personnel.

(a) Sufficient supportive personnel (technical, clerical, and other) shall be available in order to optimize the participation of pharmacists in activities requiring professional judgment.

(b) The training and supervision of supportive personnel shall be the responsibility of the pharmacist.

(5) Availability.

(a) The services of a pharmacist shall be available continuously. If around-the-clock operation of the pharmacy is not feasible, the pharmacist shall be available on an on-call basis, and an adequate night drug cabinet shall be established. The pharmacy itself shall not be designated as the night drug cabinet.

(b) A hospital not having a full-time pharmacist, but in which drugs are prepackaged or relabeled or transferred from one (1) container to another, shall obtain a pharmacy permit and have at least a part-time pharmacist designated to perform those functions or to provide personal supervision of those functions.

Section 3. Physical Facility. (1) The institutional pharmacy shall have adequate space, equipment, and supplies sufficient to provide for safe and efficient drug storage, preparation, and distribution, patient education and consultation, drug information services, and proper management of the department.

(2) Legal requirements. The physical facility shall meet state and federal regulations and shall be accessible by authorized pharmacy personnel only.

(3)(a) A currently licensed hospital shall be exempt from the provisions of subsection (2) of this section if it:

1. Is authorized by the Department for Health and Human Services to provide pharmacy services; and

2. Does not currently possess a pharmacy permit.

(b) A currently licensed hospital exempt from the provisions of subsection (2) of this section shall permit access by authorized personnel only.

(4) Location. Locked storage or locked medication carts shall be provided for use in each nursing unit or service area.

(5) Reference materials. The pharmacy shall have current pharmaceutical reference materials in accordance with 201 KAR 2:090. References related to the following subjects shall also be available:

(a) Drug identification;

(b) Toxicology;

(c) Drug interactions;

(d) Parenteral drug compatibility; and

(e) Microbiology.

Section 4. Drug Distribution and Control. (1) General. The institutional pharmacy shall be responsible for the procurement, distribution, and control of all drugs and parenteral solutions used within the institution. Policies and procedures governing these functions shall be developed by the pharmacist with input from other involved hospital or other organized health care facility staff (for example, nurses) and committees (for example, pharmacy and therapeutics committee and patient care committee).

(2) Dispensing. The pharmacist shall dispense medications only on the order of a licensed medical practitioner.

(3) Prescriber's order. The pharmacist shall review the medication order within a reasonable amount of time.

(4) Recordkeeping. The pharmacist shall maintain appropriate records of each medication order. The records shall be retained for the time and in the manner prescribed by state and federal law.

(5) Patient medication profile. A medication profile shall be maintained for all inpatients and for those ambulatory patients routinely receiving care at the institution. The pharmacist shall utilize this profile to properly review, schedule, prepare, and distribute medications except in an emergency situation.

(6) Labeling and packaging.

(a) Each licensee shall comply with U.S.P. Standards established pursuant to federal law and all state and federal laws and regulations regarding labeling and packaging.

(b) Labeling and packaging of medications used for outpatients shall meet the requirements of state and federal law.

(7) Dispensing. The pharmacist shall dispense medications by the unit dose distribution system if feasible. If the unit dose distribution system is not utilized, adequate safeguards shall be in place to protect patients.

(8) Stop orders. There shall be established written stop order policies or other methods of assuring that drug orders are not continued inappropriately in accordance with the status of the patient.

(9) Administration.

(a) Drugs shall be administered only upon order of a licensed medical practitioner.

(b) The institutional pharmacy shall participate in the establishment of policies and procedures regarding the administration of medications. Specific procedures shall be developed in cooperation with appropriate hospital or other health care facility personnel and shall include personnel authorized to schedule, prepare, and administer medications.

(10)(a) Unused medication. The institutional pharmacy shall establish policies and procedures for the disposition of patients' unused medications.

(b) Medication in unit dose form may be reissued if package integrity has been maintained and the product has not expired.

(11) Hospital floor stocks.

(a) Floor stocks of drugs shall be kept as small as possible. The pharmacist in charge shall be responsible for authenticating the need for floor stock.

(b) A pharmacist shall review all orders distributed through floor stock within a reasonable amount of time.

(c) The pharmacist in charge shall be responsible for defining those areas of the hospital requiring floor stock (for example, emergency room, surgery, critical care, or medical or surgical wards).

(d) All drug storage areas within the hospital shall be routinely inspected by pharmacy personnel at least monthly, and documentation shall be maintained to ensure that:

1. Unusable items shall not be present; and

2. All stock items shall be properly labeled and stored.

(e) This subsection shall not apply to other organized health care facilities.

(12) Drug recall. There shall be a system for removing from use a drug that has been recalled.

(13) Sample medications. The institutional pharmacy shall establish policies and procedures regarding medical representatives and the obtaining, storage, and dispensing of complimentary packages of medications.

(14) Emergency drugs.

(a) The institutional pharmacy shall establish policies and procedures for supplying emergency drugs.

(b) For expediency and efficiency, emergency drugs shall be limited in number to include only those whose prompt use and immediate availability are generally regarded by physicians as essential in the proper treatment of sudden and unforeseen patient emergencies.

(c) Emergency stocks shall be routinely inspected by pharmacy personnel on a monthly basis and documentation maintained to determine if contents have become outdated and if the stocks are being maintained at adequate levels.

(15) Investigational drugs.

(a) Policies and procedures controlling the use of investigational drugs (if used in the institution) shall be developed and followed.

(b) The pharmacy shall be responsible for storing, packaging, labeling, distributing, maintaining inventory records (including lot numbers and expiration date), and providing information about investigational drugs

(including proper disposal).

(16) Controlled substances. All permit holders shall comply with state and federal laws regarding controlled substances.

Section 5. Assuring Rational Drug Therapy. (1) Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice activities.

(2) The pharmacist shall be a member of the pharmacy and therapeutics committee and any other committees where input concerning the use of drugs is required.

(3) The pharmacist shall provide a means to ensure that patients receive adequate information about the drugs they receive. Patient education activities shall be in coordination with the nursing and medical staffs and patient education department, if any.

Section 6. Responsibility. The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for:

(1) An initial validation of system accuracy prior to use for distribution to patients;

(2) Ensuring the system:

(a) Is properly maintained;

(b) Is in good working order;

(c) Accurately dispenses the correct strength, dosage form, and quantity of drug prescribed; and

(d) Complies with the recordkeeping, access, and security safeguards pursuant to all applicable state and federal laws;

(3) Assuring medications are reviewed prior to loading into an automated pharmacy system and distribution;

(4) Implementing an ongoing quality assurance program that monitors performance of the pharmacy compounding robotics, which is evidenced by written policies and procedures and requires a continued documented validation of doses distributed on a routine basis and annual review of the quality assurance program;

(5) Establishing policies and procedures if there is a system failure of an automated pharmacy system;

(6) Providing the board with prior written notice of installation or removal of an automated pharmacy system. This notification shall include the:

(a) Name and address of the pharmacy; and

(b) Initial location of the automated pharmacy system;

(7) Oversight for assigning, discontinuing, or changing personnel access to the system, including establishment of written policies and procedures for security and control;

(8) Reviewing personnel access on at least an annual basis;

(9) Assuring that the decentralized automated pharmacy system stock is checked at least monthly in accordance with established policies and procedures, including checking for:

(a) Accuracy;

(b) Integrity of packaging; and

(c) Expiration dates;

(10) Maintaining in the pharmacy the following documentation relating to an automated pharmacy system:

(a) The name and address of the pharmacy or inpatient health care facility where the system is being used;

(b) The automated pharmacy system manufacturer's name, model, serial number, and software version;

(c) A description of how the system is used;

(d) Written quality assurance procedures and accompanying documentation of use to determine continued appropriate use of the system as established in subsections (7) and (8) of this section; and

(e) Written policies and procedures for system operation, safety, security, accuracy, emergency medication access, access, and malfunction which includes clearly defined down time and procedures;

and

(11) Maintaining adequate security systems and procedures, evidenced by written policies and procedures to:

(a) Prevent unauthorized access;

(b) Maintain patient confidentiality;

(c) Allow user access modification; and

(d) Comply with federal and state laws.

Section 7. Standards. (1) (a) All events involving the contents of the automated pharmacy system shall be recorded electronically.

(b) Records shall be maintained by the pharmacy and be available to the board and shall include the following:

1. The date, time, and location of the system accessed;

2. Identification of the individual accessing the system;

3. Type of transaction;

4. Name, strength, dosage form, and quantity of drug accessed; and

5. Name of the patient for whom the drug was ordered, if applicable.

(2) All medications to be stocked into the centralized automated pharmacy system shall have been previously validated for bar code accuracy by a pharmacist, pharmacist intern, or certified pharmacy technician. Integrity and accuracy shall be validated by a pharmacist.

(3) The stocking of medications in a decentralized automated pharmacy system utilizing bar code technology shall be done by a pharmacist, pharmacist intern, or a certified pharmacy technician.

(4) The stocking of medications in a decentralized automated pharmacy system without bar code technology

shall be done by a pharmacist, pharmacist intern, or a certified pharmacy technician. Integrity and accuracy shall be validated by a pharmacist.

(5) If a hospital licensed pursuant to 902 KAR 20:016 utilizes technology that validates appropriate drug, dose, dosage form, route of administration, time of administration, and patient at the exact time of medication administration, the stocking of the decentralized automated pharmacy system shall be done by a pharmacist, pharmacist intern, or certified pharmacy technician.

(6) A record of medications stocked in an automated pharmacy system shall be maintained for at least five (5) years and shall include:

(a) The name of the person repacking the medications; and

(b) Documentation of the pharmacist checking the medications.

(7) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.

(8) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with federal and state laws.

(9) All medications initially received in the pharmacy for use in an automated pharmacy system shall be quarantined until validation of bar code accuracy and existence of the item in the database powering automated pharmacy system by a certified pharmacy technician, pharmacist intern, or pharmacist.

(10) If a medication needs to be repackaged:

(a) A pharmacist, pharmacist intern, or certified pharmacy technician shall:

1. Perform the repackaging and validate the presence of an accurate bar code on the unit dose packaging; and

2. Document the repackaging process including:

a. Manufacturer;

b. Date and time of repackaging;

c. The person repackaging;

d. The lot number or batch number;

e. The expiration date; and

f. The quantity repackaged; and

(b) A pharmacist shall:

1. Validate for accuracy and integrity prior to the addition to the automated pharmacy system; and

2. Document the validation including:

a. The date and time of the validation;

b. The name of the pharmacist validating;

c. The lot number or batch number;

d. The expiration date; and

e. The quantity validated.

(11) A medication returned to the pharmacy from a patient care area shall follow the processes established pursuant to Section 4(10) of this administrative regulation.

(12) A medication distributed by the centralized automated pharmacy system shall be distributed in the delivery device utilized by that system.

(13) A medication distributed by an automated pharmacy system shall be accessed and administered by a professional licensed to administer medications.

Adopted effective December 13, 1990; Amended effective August 20, 2003; Amended effective June 19, 2013.

HISTORICAL NOTES

201 KAR 2:074

RELATES TO: KRS 315.010, 315.020, 315.030, 315.121

STATUTORY AUTHORITY: 315.002, 315.005, KRS 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies.KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and requires the board to insure the safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in hospitals or other organized health care facilities.

201 Ky. Admin. Regs. 2:074, 201 KY ADC 2:074

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:076

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:076. Parenteral pharmaceutical compounding

Section 1. A policy and procedure manual for parenteral pharmaceutical compounding shall be available at a pharmacy for inspection purposes. The manual shall include policies and procedures for:

(1) Oncology drugs;

(2) Disposal of unused supplies and medications;

(3) Drug destruction and return;

(4) Drug dispensing;

(5) Drug labeling;

(6) Storage;

(7) Duties and qualifications for staff;

(8) Equipment;

(9) Handling of hazardous wastes;

(10) Investigation drug protocol;

(11) Safety;

(12) Recordkeeping;

(13) Reference material;

(14) Sanitation;

(15) Security;

(16) Transportation; and

(17) Quality assurance, as relates to:

(a) Recall procedures;

(b) Storage and dating;

(c) Educational procedures for staff and patient;

(d) Sterile procedures, to include routine maintenance and hood certification; and, if necessary,

(e) Sterile testing of end products, operator procedures, and environment.

The manual shall be reviewed and revised on an annual basis.

Section 2. The following physical requirements are in addition to other requirements set forth in KRS 217.055 and 315:020:

(1) The licensed pharmacy shall have a designated area for preparing compounded parenteral pharmaceuticals. This area shall be designed to withstand routine disinfecting procedures and shall be kept free of particulate generators, e.g., corrugated cardboard containers. This area shall be designed to avoid unnecessary traffic and airflow disturbances. It shall be used only for the preparation of sterile products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(2) The minimum equipment shall be:

(a) Laminar airflow hood or Class 100 clean room;

(b) Sink with hot and cold running water which is convenient to the compounding area;

(c) Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic and hazardous wastes from preparation of said agents;

(d) A Class II vertical flow biological safety cabinet, if oncology agents are prepared;

(e) Refrigerator or freezer with a thermometer; and

(f) A temperature controlled delivery container (not required if delivered in the same facility).

(3) The minimum supplies shall be:

(a) Disposable needles, syringes, and other supplies needed for aseptic parenteral compounding;

(b) Disinfectant cleaning solutions;

(c) Hand-washing agent with bactericidal action;

(d) Disposable, lint-free towels or equivalent;

(e) Appropriate filters and filtration equipment;

(f) Oncology drug spill kit; and

(g) Disposable gowns, and sterile disposable gloves.

(4) This area of the pharmacy shall not be accessible to the public and no one shall have access without supervision of the pharmacist.

(5) The pharmacy shall have current reference materials related to sterile products.

Section 3. Each licensed pharmacy shall be managed by a pharmacist licensed to practice pharmacy in the Commonwealth and who is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. The pharmacist in charge shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all drugs and pharmaceuticals. The pharmacist shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and the quality assurance programs, as well as participation in those aspects of the facility's patient care evaluation program relating to pharmaceutical material utilization and effectiveness. The pharmacist in charge may be assisted by additional personnel

adequately trained in this area of practice. A pharmacist shall be accessible at all times at each licensed facility to respond to patients' and other health professionals' questions and needs.

Section 4. (1) The pharmacist shall receive a written or verbal prescription or direct copy order from a prescriber before dispensing any compounded, sterile parenteral product. These prescriptions or direct copy orders shall contain the following:

(a) Patient's name;

(b) Patient's address on controlled substances prescriptions or location (room number);

(c) Drug name and strength;

(d) Directions for use;

(e) Date;

(f) Authorized prescriber's name;

(g) Prescriber's address and DEA number, if applicable;

(h) Refill instructions, if applicable; and

(i) Dispensing quantity, if applicable.

(2) A pharmacy generated profile shall be maintained separate from the prescription file. The patient profile shall be maintained under the control of the pharmacist in charge for a period of two (2) years following the last dispensing activity. In addition, a medication administration record (MAR) as part of the medical record shall be retained for a period of five (5) years from date of the patient's discharge from the facility, or in the case of a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longer. Supplemental records may also be employed as necessary. The patient profile shall contain:

(a) Patient's name;

(b) Sterile product dispensed;

(c) Date dispensed;

(d) Drug content and quantity; and

(e) Patient's directions.

(3) Each sterile pharmaceutical dispensed to patients shall be labeled with the following information:

(a) Name, address, and telephone number of the licensed pharmacy, if product will leave the premises;

(b) Date;

(c) Identifying number;

(d) Patient's full name;

(e) Name of each drug, strength, and amount;

(f) Directions for use, including infusion rate;

(g) Required controlled substances transfer warnings, where applicable;

(h) Expiration date;

(i) Identity of dispensing pharmacist;

(j) Storage requirements, when applicable; and

(k) Auxiliary labels, when applicable.

(4) The pharmacist in charge shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety, and welfare. Records shall be readily available, maintained for two (2) years at facility not computerized, but for five (5) years at facility utilizing computerized recordkeeping, and subject to inspection by the Board of Pharmacy or its agents. These shall include the following:

(a) Patient profile;

(b) Purchase records;

(c) Biennial controlled substances inventories;

(d) Policy and procedures manual;

(e) Policies and procedures for cytotoxic wastes, if applicable;

(f) Quality assurance records; and

(g) Such other records and reports as may be required by law and rules and administrative regulations of the Kentucky Board of Pharmacy.

Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's records. Release of this information shall be in accordance with federal and state laws.

(5) The pharmacist in charge shall be responsible for the environmental control of all products shipped. Any compounded, sterile pharmaceutical that is frozen or requires refrigeration shall be shipped or delivered to a patient in appropriate temperature controlled delivery containers, if the product leaves the premises.

(6) The pharmacist in charge shall be responsible for assuring that there is a system for the disposal of hazardous waste in a manner that does not endanger the public health.

(7) A quality assurance program documented by the pharmacist shall be available to provide accountability for the manufacturing and distribution of sterile parenteral products.

Section 5. Licensed pharmacies that prepare oncology agents shall meet the following additional requirements in order to insure the protection of the personnel involved:

(1) All oncology agents shall be compounded in a vertical flow, Class II, biological safety cabinet, and other products may be compounded in this cabinet;

(2) Protective apparel shall be worn by personnel compounding oncology drugs, and this shall include disposable gloves and gowns;

(3) Proper aseptic and safety techniques shall be used by personnel compounding oncology agents;

(4) Appropriate disposable procedures for cytotoxic waste shall be developed that comply with applicable state and federal regulations;

(5) Written procedures for handling both major and minor spills of cytotoxic agents shall be developed; and

(6) Prepared doses of oncology drugs shall be dispensed, shipped, or delivered in a manner to minimize the risk of accidental rupture of the primary container and labeled with a distinctive cautionary label as being hazardous.

Section 6. There shall be a documented, ongoing quality control program that monitors personnel performance, equipment, and facilities. Quality assurance procedures, at a minimum, shall include:

(1) Recall procedures;

(2) Storage and dating;

(3) Educational procedures for staff;

(4) Sterile procedures;

(5) Hood or clean room annual certification by an independent contractor in accordance with federal standard 209B and NSF standard No. 49;

(6) Prefilter cleaning and replacement when appropriate;

(7) Justification of the chosen expiration dates for compounded parenteral products; and

(8) Documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits.

Section 7. Violation of any provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121.

Adopted effective June 10, 1990.

HISTORICAL NOTES

RELATES TO: KRS 315.020

STATUTORY AUTHORITY: KRS 315.020(1), (2), 315.065(1), (2), 315.191(1)

201 KAR 2:076

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy is responsible to insure minimum standards of practice of parenteral compounding by pharmacies. The board is also responsible to insure the safety of all products provided to the citizens of the Commonwealth.

201 Ky. Admin. Regs. 2:076, 201 KY ADC 2:076

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:080

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:080. Prescription substitution

Section 1. Except as provided in KRS 217.822, whenever any registered pharmacist is requested to sell, furnish, or compound any drug, medicine, chemical or pharmaceutical preparation by means of a prescription and substitutes or causes to be substituted therefore, any other drug, medicine, chemical, or pharmaceutical preparation without specific or express permission, approval, or consent of the prescriber, the board may find such person guilty of engaging in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public, and may revoke or suspend his license as prescribed by law.

Section 2. If approval or consent is obtained from the prescriber, the brand name or the name of the manufacturer of the drug, medicine, chemical or pharmaceutical preparation dispensed must be stated on the prescription by the pharmacist.

Adopted effective December 11, 1974; Amended effective January 12, 1990.

HISTORICAL NOTES

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.191(2)

NECESSITY, FUNCTION, AND CONFORMITY: Although KRS 217.819 permits the exercise of product selection when there is no prohibition for such selection listed in the nonequivalent drug product formulary, this administrative regulation protects the public and practitioners in assuming that the medications and drugs dispensed are acceptable.

201 Ky. Admin. Regs. 2:080, 201 KY ADC 2:080

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:090

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:090. Reference material and prescription equipment

Section 1. (1) A pharmacy located within the Commonwealth that receives a pharmacy permit shall be required to maintain at least one (1) current reference from each of the following categories:

(a) Category I—Pharmacology;

(b) Category II—Drug Interactions;

(c) Category III—Drug Product Composition; and

(d) Category IV—State and Federal Laws and Regulations.

(2) References shall be relevant to the professional practice of pharmacy at the permitted pharmacy.

(3) Electronic references shall be acceptable if the information is readily retrievable such that the pharmacist is not required to exit the dispensing program to obtain information from the electronic references. The existence of drug information on the Internet and the mere ability of the pharmacist to connect to the Internet shall not be sufficient to meet the requirements of this administrative regulation.

Section 2. (1) The following shall be deemed as minimum equipment required of a pharmacy:

(a) A prescription balance with a sensitivity not less than that of a Class 3 balance;

(b) Weights—metric or apothecary—complete set;

(c) Graduates capable of accurately measuring from 1 ml to 250 ml;

(d) Mortars and pestles—glass, porcelain, or wedgewood;

(e) Spatulas—steel and nonmetallic;

(f) Filtration funnel with filter papers;

(g) A heating unit;

(h) Suitable refrigeration unit for proper storage of drugs; and

(i) Ointment slab or ointment papers.

(2) All equipment shall be maintained in a clean condition.

Section 3. The pharmacy shall have other reference material and equipment as dictated by experience to meet the needs of the particular pharmacy and necessary to compound and dispense in a safe manner.

Section 4. A pharmacy may be granted an exemption to required reference material and prescription equipment upon written petition to the board.

Section 5. The prescription counter upon which prescriptions are dispensed shall be used for the prime purpose of dispensing prescriptions. All pharmacies shall comply with all sanitation laws and administrative regulations.

Adopted effective December 11, 1974; Amended effective April 13, 1984; Amended effective February 7, 2002.

HISTORICAL NOTES

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035(6), 315.19(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035(6) authorizes the Board of Pharmacy to promulgate administrative regulations regarding reference material and equipment suitable for pharmaceutical practice. This administrative regulation establishes the minimum reference material and equipment required for pharmaceutical practice.

201 Ky. Admin. Regs. 2:090, 201 KY ADC 2:090

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

201 KAR 2:090

END OF DOCUMENT

201 KAR 2:095

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:095. Dispensing responsibilities

Section 1. Pursuant to KRS 315.020(4), a pharmacist intern shall perform professional acts within the practice of pharmacy under the immediate supervision and direction of a registered pharmacist.

Section 2. A pharmacist intern who has successfully completed his first professional year coursework of a Bachelor's of Science in Pharmacy or Doctor of Pharmacy degree program at an accredited school or college of pharmacy may, at the discretion of the supervising pharmacist, engage in delegated acts of professional practice pursuant to supervision as defined by KRS 315.010(25).

Section 3. A pharmacist shall be responsible for all the actions of the pharmacist intern.

Adopted effective September 10, 1975; Amended effective June 4, 1985; Amended effective December 15, 1999.

HISTORICAL NOTES

RELATES TO: KRS 315.010(19), (25), 315.020, 315.050

STATUTORY AUTHORITY: KRS 315.020(4), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to promulgate administrative regulations necessary to regulate and control the practice of pharmacists. This administrative regulation establishes the professional responsibilities of a pharmacist and a pharmacist intern under supervision.

201 Ky. Admin. Regs. 2:095, 201 KY ADC 2:095

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:100

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:100. Security and control of drugs and prescriptions

Section 1. A pharmacy must provide adequate security and control of its controlled substances and prescription legend drugs and in the absence of a pharmacist the pharmacy must be closed. If a pharmacy is located within a larger establishment which is open to the public for business at times when a pharmacist is not present then the pharmacy must be enclosed by a floor to ceiling partition which may be either solid or solid transparent secured by lock from other departments of the store. In the absence of a pharmacist such pharmacies must be locked and secured. Employees of the establishment cannot be authorized to enter the closed pharmacy during those hours when a pharmacist is not present. Owners of prescription departments, which are to be closed at times the merchandise area of the same establishment remains open, must request permission from the Kentucky Board of Pharmacy, submit a detailed plan of the prescription department barrier and obtain written approval before enclosing the prescription department.

Section 2. All prescription files, all legend drugs and other items which are restricted to sale either by or under the personal supervision of a pharmacist must be kept in the pharmacy area.

Section 3. Written prescription orders and refill requests can be delivered to a pharmacy at any time. But if no pharmacist is present then the prescription order(s) must be deposited, by the patient or his agent delivering the prescription order or refill request to the establishment, into a “mail slot” or “drug box” such that the prescription order is stored in the pharmacy area.

Section 4. Prepared prescription medications shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place. Emergency drugs shall be available throughout a hospital as deemed necessary by the pharmacist and under the overall control of the pharmacist. A night drug cabinet shall be maintained for the provision of emergency drugs in the absence of a pharmacist.

Section 5. It shall be regarded as unprofessional conduct under KRS 315.121(1)(f) for any pharmacist or employer of pharmacists to refrain from reporting to the board a pharmacist who:

(1) Has been convicted of a misdemeanor of felony which involved acts that bear directly on the qualifications or ability of the applicant or licensee to practice pharmacy; or

(2) Commits fraud or deceit in procuring or attempting to procure a license to practice pharmacy; or

(3) Negligently or willfully acts in a manner inconsistent with the practice of pharmacy or willfully repeatedly violates any provisions of this chapter; or

(4) Has a license to practice as a pharmacist denied, limited, suspended, probated or revoked in another jurisdiction on grounds sufficient to cause a license to be denied, limited, suspended, probated or revoked in this Commonwealth; or

(5) Is practicing pharmacy without a current active license issued by the board.

Adopted effective September 10, 1975; Amended effective June 4, 1985.

HISTORICAL NOTES

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy is authorized by KRS 315.191(1) to adopt rules and administrative regulations necessary to regulate and control pharmacists and pharmacies. This administrative regulation is to assure adequate security and control of drugs and prescriptions.

201 Ky. Admin. Regs. 2:100, 201 KY ADC 2:100

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:105

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:105. Licensing and drug distribution requirements for wholesale distributors

Section 1. Definition. “Drug sample” means unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

Section 2. Requirements. (1) A wholesale distributor engaged in wholesale distribution in the Commonwealth shall apply for a license from the board in accordance with KRS 315.402, 315.406, and this administrative regulation.

(2) A separate license shall be required for each wholesale distributor's facility that distributes within the Commonwealth regardless of whether joint ownership or control exists.

(3) An agent or employee of a licensee shall not be required to obtain a license under this section when the agent or employee is acting in the usual course of business or employment.

(4) A license shall not be issued or renewed unless the applicant demonstrates or continues to demonstrate acceptable operational procedures, including:

(a) Adequate maintenance and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or official United States Pharmacopoeia (USP) compendium requirements. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs;

(b) Physical separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated or otherwise recalled merchandise until they are destroyed or returned;

(c) Providing accurate and precise records of all goods shipped or received including source or recipient, date, quantity, itemized description, and any other information pertinent to the transaction; and

(d) Providing proof of registration with the state controlled substance authority, and with the U.S. Drug Enforcement Administration and shall comply with all DEA regulations.

201 KAR 2:105

Section 3. Qualifications for License. (1) The minimum qualifications shall include:

(a) The Kentucky Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the Commonwealth:

1. Any convictions of the applicant under any federal, state, or local laws relating to drug samples and wholesale or retail drug distribution of controlled substances;

2. Any felony convictions of the applicant under federal, state, or local laws;

3. The applicant's past experience in the wholesale distribution of prescription drugs, including controlled substances;

4. The furnishing by the applicant of false or fraudulent material in any application made in connection with wholesale distribution;

5. Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant for wholesale distribution of any drugs, including controlled substances;

6. Compliance with the requirements under any previously granted license or permit, if any; and

7. Compliance with requirements to maintain or make available to the Kentucky Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section.

(b) The Kentucky Board of Pharmacy shall have the right to deny a license to an applicant if it determines that the granting of that license would not be in the public interest based on health and safety considerations.

(2) A license shall not be issued pursuant to this administrative regulation unless the applicant has furnished proof satisfactory to the Board of Pharmacy:

(a) That the applicant is in compliance with all applicable federal and state laws and regulations relating to drugs; and

(b) That the applicant is equipped as to land, buildings, and security to properly carry on the business described in his application.

(3) A license issued pursuant to this administrative regulation may be suspended or revoked for failure to

comply with the provisions of KRS 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412, or this administrative regulation.

Section 4. Application, Fees, Renewals. (1) An application for a license shall be submitted to the Board of Pharmacy on "Application for a License to Operate as a Wholesale Distributor (KBP W 9:08)"

(2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.

(3) An application shall include:

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business name used by the licensee;

(c) Addresses, telephone numbers, and the names of contract persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);

(e) The name(s) of the owner and operator of the licensee, including;

1. If a person, the name and Social Security number of the person;

2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;

3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

4. If a sole proprietorship, the full name and Social Security number of the sole proprietor and the name of the business entity; and

(f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(4) All licenses shall:

(a) Expire on September 30 following date of issuance; and

(b) Be renewable annually thereafter upon renewal application accompanied by the renewal fee set forth in 201 KAR 2:050 and shall be nontransferable.

Section 5. Standards. (1) Facilities.

(a) All buildings in which legend drugs are held for wholesale distribution, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

(b) Buildings shall meet all applicable federal, state, and local standards. The facility shall have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.

(c) A facility shall not be located in a residence.

(2) Security.

(a) A wholesale distributor shall be equipped with an alarm system to detect entry after hours.

(b) A wholesale distributor shall ensure that access from outside their premises is well-controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where legend drugs are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A licensee shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of prescription drugs.

(3) Recordkeeping.

(a) Inventories and other records of transactions regarding the receipt and disposition of legend drugs shall be maintained and readily available for inspection or photocopying by authorized law enforcement officials for a period of two (2) years following disposition of the drugs. These records shall include:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other distribution of the drugs.

(b) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(4) Written policies and procedures.

(a) A Wholesaler Distributor distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and to assure that the wholesale distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(b) There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.

(c) There shall be written policies and procedures to assure that any outdated stock or any stock with an expiration date that, in the wholesale distributor's view, does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise destroyed, and this shall be documented.

(d) There shall be written policies and procedures by which the wholesale distributor exercises control over the shipping and receiving of all stock within the operation.

(5) Returned, damaged, and outdated prescription drugs. A wholesale distributor shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods if conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(6) Handling recalls. A wholesale distributor shall maintain and follow written policy for handling recalls and withdrawals of products. The policy shall cover all recalls and withdrawals of drug products due to:

(a) Any voluntary action on the part of the manufacturer;

(b) The direction of the Food and Drug Administration, or any other federal, state, or local government agency; and

(c) Replacement of existing merchandise with an improved product or new package design.

(7)(a) A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock.

(b) Procedures for distribution of approved stock shall provide for a rotation whereby the oldest inventory is distributed first.

(c) A wholesale distributor shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

Section 6. Pedigree. (1) Effective July 1, 2009 and in accordance with KRS 315.406, each person or entity engaged in the wholesale distribution of prescription drugs that leave or that have ever left the normal distribution channel shall, prior to the distribution of the prescription drug, provide a pedigree to the person receiving the prescription drug.

(2) The pedigree shall include the following information concerning the prescription drug:

(a) The proprietary and established name of the prescription drug;

(b) The dosage;

(c) The size of the container;

(d) The number of containers;

(e) The lot number of control number of the prescription drug;

(f) The business name and address of all parties to each prior transaction involving the drug, starting with

the manufacturer; and

(g) The date of each previous transaction.

(3) Pedigree records shall be maintained and readily be available for inspections or photocopying by authorized law enforcement officials for a period of two (2) years.

Section 7. Violations. (1) A wholesale distributor shall not distribute legend drugs directly to a consumer or a patient or operate in a manner that endangers the public health.

(2) Violation of any of these provisions shall be grounds for the suspension or revocation of the license.

Section 8. Incorporation by Reference. (1) “Application for a License to Operate as a Wholesale Distributor” (KBP W 9:08) is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, Spindletop Administration Building Suite 302, 2624 Research Park Drive, Lexington, Kentucky 40511 , Monday through Friday, 8 a.m. to 4:30 p.m.

Adopted effective August 11, 1982; Amended effective June 4, 1985; Amended effective April 12, 1990; Amended effective March 25, 1992; Amended effective October 8, 1992; Amended effective July 15, 2002; Amended effective February 18, 2009.

HISTORICAL NOTES

RELATES TO: KRS 315.010, 315.402, 315.406

STATUTORY AUTHORITY: KRS 315.010, 315.191(1), 315.402, 315.406

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.402 and 315.406 authorizes the board to promulgate administrative regulations to regulate wholesale distributors of drugs. This administrative regulation establishes the requirements for the regulation of wholesale distributors.

201 Ky. Admin. Regs. 2:105, 201 KY ADC 2:105

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

201 KAR 2:105

END OF DOCUMENT

201 KAR 2:106

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:106. Pharmacy, manufacturer, or distributor closures

Section 1. Definitions. As used in this administrative regulation:

(1) “Permanent closure” means a licensee:

(a) Ceases to do business and permanently closes; and

(b) Does not file application for a pharmacy license for the same location;

(2) “Voluntary closure” means a closing or abandonment of premises resulting from:

(a) Chronic mental or physical deterioration; or

(b) A deviation from the business hours listed on the current permit application or amendments filed thereto; or

(c) Cessation of the practice of pharmacy at the licensed location for a reason other than permanent or involuntary closure.

(3) “Involuntary closure” means an interruption of formal business activity resulting from:

(a) Acute illness or incapacitation;

(b) Death;

(c) Fire, flood or other natural disaster;

(d) Bankruptcy proceedings; or

(e) Court, government, or Board of Pharmacy action.

201 KAR 2:106

Section 2. Procedures for Closure. (1) Permanent closure.

(a) A licensee shall conspicuously place a sign notifying the public thirty (30) days in advance of the:

1. Termination date of business; and

2. Name and address of the licensee to which prescription files or other pertinent records will be transferred.

(b) Except when prevented by the exercise of another party's legal rights:

1. The sign shall remain in place for a period of thirty (30) days after the closure; and

2. All efforts shall be undertaken to assure a smooth transition of uninterrupted service to those affected by the closure.

(c) A licensee shall inform the Board of Pharmacy, Drug Enforcement Administration, and the Cabinet for Human Resources by written notice fifteen (15) days prior to the anticipated closing and include the following information:

1. Date of business termination; and

2. Name, address, and DEA number of registrant to whom the prescription or controlled drugs are to be transferred.

(d) In the absence of directives to the contrary from the Drug Enforcement Administration, the Board of Pharmacy, or the Cabinet for Human Resources, the transfer shall be effected on the assigned date.

(e) The transferor and the transferee shall each maintain copies of the following documents relating to transferred controlled substances for at least two (2) years:

1. U.S. Official Order Forms, DEA-222 Schedule II; and

2. Schedules III, IV, and V Invoices for a period of at least two (2) years.

(f) Upon termination, a licensee shall:

1. Remove all signs pertinent to pharmacy or drugs from the building and premises; and

2. Return the voided permits, the Drug Enforcement Administration registration, and unused Schedule II Order Forms to their respective office of issue.

(g) The posting of the sign required by paragraph (a) of this subsection shall not be required if:

1. An application for a pharmacy license for the same location is filed; or

2. During a sale of a pharmacy, prescription records are transferred to another permitted pharmacy that is within five (5) miles of the location of the pharmacy that is sold and owned by the purchasing entity.

(2) Voluntary closure.

(a) A pharmacy or distributor licensed by the Kentucky Board of Pharmacy whose hours of operation have deviated over a period of five (5) consecutive working days from those of record at the Board of Pharmacy office shall immediately notify the board, verbally and in writing of the reason for the deviation and the anticipated period of continuance.

(b) Upon receipt of the notice, the Board of Pharmacy, with full cooperation of the licensee, shall make arrangements it deems necessary to provide adequate and continued security and control of all drugs, chemicals, poisons, and devices owned or controlled by the licensee.

(c) If normal operation cannot resume within sixty (60) days, or if satisfactory agreements cannot be reached between the Board of Pharmacy, the licensee, or his designated representative, the:

1. Permit shall be revoked; and

2. Board of Pharmacy shall notify the Cabinet for Human Resources to assume control and responsibility of any drug, chemical, poison, or device deemed necessary in any manner deemed appropriate.

(d) If the Board of Pharmacy or the Cabinet for Human Resources or its agents liquidate or arrange for the liquidation of items specified in paragraphs (b) and (c) of this subsection, the board or the Cabinet for Human Resources may retain a portion of the proceeds realized from the liquidation equal to the expenses incurred.

(3) Involuntary closure.

(a) Within five (5) days of involuntary closure, a licensee, or person authorized to act on his behalf, shall:

1. Notify the board in writing; and

2. Guarantee the safety and control of the licensed premises in a manner that will allow continued storage of controlled substances consigned to the board permittees for sixty (60) days after the effective date of the involuntary closure.

(b) Within sixty (60) days after the effective date of the involuntary closure, a licensee shall effect arrangements for the lawful sale or other disposition of drugs and substances requiring board licensure.

(c) The board may assume control and responsibility of substances it deems necessary for disposition, if after the expiration of the sixty (60) day period following the effective date of involuntary closure:

1. A sale or other disposition has not been effected; or

2. An agreement between the board, and the licensee or person authorized to act on behalf of the licensee, has not been reached.

Section 3. Duties and Responsibilities of Licensee. A licensee or person authorized to act on his behalf shall:

(1) Fully cooperate with the board to promote the efficient administration of action required by the provisions of this administrative regulation; and

(2) Be financially liable to the board for expenses incurred by the board in its implementation of the provisions of this administrative regulation.

Adopted effective April 12, 1990; Amended effective June 18, 1997.

HISTORICAL NOTES

RELATES TO: KRS 315.035, 315.036

STATUTORY AUTHORITY: KRS 315.036, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to promulgate administrative regulations relating to subject matters governed by KRS Chapter 315. This administrative regulation establishes requirements relating to closure of business by licensees.

201 Ky. Admin. Regs. 2:106, 201 KY ADC 2:106

201 KAR 2:106

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:115

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:115. Controlled release tablets, capsules and injectables

Section 1. The following are determined to be noninterchangeable: controlled release tablets, capsules and injectables—these dosage forms are subject to bioavailability and bioequivalence difference, primarily because different manufacturers developing controlled release products for the same active ingredient do not employ the same approach to formulating their controlled release products. Approved controlled release products for which bioequivalence data are available and considered as meeting necessary bioequivalence requirements are exempted from this administrative regulation.

Adopted effective January 6, 1983.

HISTORICAL NOTES

RELATES TO: KRS Chapter 217

STATUTORY AUTHORITY: KRS 217.814(7), (8), 217.819(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.819 directs the Kentucky Board of Pharmacy to prepare a nonequivalent drug product formulary of drugs which should not be interchanged by pharmacists. In conformance with the publication cited, “Approved Prescription Drug Products with Therapeutic Equivalence Evaluations,” this administrative regulation lists controlled release tablets, capsules and injectables as noninterchangeable.

201 Ky. Admin. Regs. 2:115, 201 KY ADC 2:115

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:116

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:116. Drug products with therapeutic problems

Section 1. The following have been determined by the board to be noninterchangeable: drugs, drug products, or dosage formulations considered by the United States Food and Drug Administration not to be therapeutically equivalent as published in the "Approved Drug Products with Therapeutic Equivalence Evaluations." $

Section 2. The following have been determined by the board to be noninterchangeable unless the United States Food and Drug Administration considers them therapeutically equivalent as published in the "Approved Drug Products with Therapeutic Equivalence Evaluations"

(1) Digitalis glycosides;

(2) Antiepileptic drugs;

(3) Antiarrhythmic agents;

(4) Conjugated estrogens;

(5) Esterified estrogens;

(6) Warfarin anticoagulants;

(7) Theophylline products; and

(8) Thyroid preparations.

Section 3. "Approved Drug Products with Therapeutic Equivalence Evaluations," 11th Edition, 1991, U.S. Food and Drug Administration is incorporated by reference.

Adopted effective May 13, 1990; Amended effective April 5, 1991.

201 KAR 2:116

HISTORICAL NOTES

RELATES TO: KRS 217.819

STATUTORY AUTHORITY: KRS 217.814(5), (6), (7), (8), 217.819(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.819 directs the Kentucky Board of Pharmacy to prepare a drug product formulary of drugs which should not be interchanged by pharmacists. This administrative regulation lists drug products with active ingredients or dosage forms with potential bioequivalence problems, drugs characteristically possessing a narrow therapeutic index, or categories of agents for which there is either documented evidence of inequivalent therapeutic effect or a potential for it based on differences in bioavailability.

201 Ky. Admin. Regs. 2:116, 201 KY ADC 2:116

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END OF DOCUMENT

201 KAR 2:160

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:160. Licensees; inactive status

Section 1. A pharmacist may apply for inactive status by:

(1) Completing annual renewal application; and

(2) Paying annual fee for inactive status.

Section 2. Pharmacists maintaining an active license to practice in another state or jurisdiction are ineligible for inactive status in Kentucky.

Section 3. Pharmacists seeking relicensure form inactive to active status must fulfill the following requirements:

(1) If the pharmacist has been inactive for no more than five (5) consecutive years, he must:

(a) Provide written notice to the board requesting their consideration to active status. The board shall act upon such request within sixty (60) days.

(b) Satisfy the board's continuing education requirements for each year of inactive status.

(c) Successfully complete a jurisprudence examination given by the board.

(d) Pay all cumulative annual renewal fees required for active licensees.

(2) If a pharmacist has had inactive status for more than five (5) consecutive years, he must:

(a) Provide written notice to the board requesting their consideration to active status. The board shall act upon such request within sixty (60) days.

(b) Successfully complete a satisfactory examination before the board.

(c) Pay all cumulative annual renewal fees required of active licensees.

Adopted effective December 1, 1982.

HISTORICAL NOTES

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.065, 315.110, 315.120, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: Senate Bill 241 of the General Assembly, Commonwealth of Kentucky, Regular Session 1982, provided for changes in KRS Chapter 315. This necessitated requirements for licensees to be issued inactive status and for those who desire to apply for renewal of a license to return to active practice.

201 Ky. Admin. Regs. 2:160, 201 KY ADC 2:160

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:165

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:165. Transfer of prescription information

Section 1. (1) The transfer of prescription information for any noncontrolled substance prescription for the purpose of refill dispensing may occur if:

(a) It is orally communicated directly between two (2) pharmacists in the Commonwealth or between a pharmacist and an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District;

(b) It is made through an on-line real-time computer system that provides documentation of the presence of a pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District when the information is transferred;

(c) It is made through the use of a facsimile machine and all the information required by this administrative regulation is provided to the sending and receiving pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District; or

(d) It is made through the use of voice recording technology and all information required by this administrative regulation is provided to the sending and receiving pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District.

(2) If in the Commonwealth the transferring pharmacist shall record the following information:

(a) That the prescription is void;

(b) The name and address of the pharmacy or the establishment located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by that state or U.S. Territory or District to which it was transferred and the name of the pharmacist or the individual located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacist by that state or U.S. Territory or District receiving the prescription information; and

(c) The date of the transfer and the name of the pharmacist transferring the information.

(3) If in the Commonwealth the pharmacist receiving the transferred prescription shall record the following information:

(a) That the prescription is a transfer;

(b) The date of issuance of the original prescription;

(c) The refill authorization on the original prescription;

(d) The date of original dispensing;

(e) The refill authorization remaining and the date of the last refill;

(f) The name and address of the pharmacy or the establishment located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by that state or U.S. Territory or District and the original prescription number from which the prescription was transferred; and

(g) The name of the transferor pharmacist or the individual located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacist by that state or U.S. Territory or District.

(4) Both the original prescription and the transferred prescription shall be maintained for a period of five (5) years from the date of the last refill.

(5) Pharmacies electronically accessing the same prescription record shall satisfy all information of a manual mode for a prescription transfer.

Section 2. The transfer of prescription information for a controlled substance prescription, except a Schedule II controlled substance, for the purpose of refill dispensing may occur if the transfer complies with the requirements of 21 C.F.R. 1306.25.

Section 3. Violation of a provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121(2)(d), (f), and (g).

Adopted effective June 1, 1983; Amended effective January 12, 1990; Amended effective May 19, 1999; Amended effective February 7, 2002; Amended effective February 4, 2011.

201 KAR 2:165

HISTORICAL NOTES

RELATES TO: KRS 217.215(2), 315.191(1)(f)

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(f) authorizes the Board of Pharmacy to promulgate administrative regulations to control the transfer of prescription drug orders between pharmacists and pharmacies. This administrative regulation establishes the procedures by which a prescription may be transferred between pharmacies in the Commonwealth or between a pharmacy and an establishment located in a state or United States Territory or District outside the Commonwealth and similarly credentialed as a pharmacy by that state or U.S. Territory or District for the purpose of dispensing.

201 Ky. Admin. Regs. 2:165, 201 KY ADC 2:165

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:170

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:170. Computerized recordkeeping

Section 1. The following information shall be entered into the system:

(1) All information pertinent to a prescription shall be entered into the system, including, but not limited to, each of the following:

(a) The prescription number;

(b) The patient's name and address;

(c) The prescriber's name and address;

(d) The prescriber's Federal Drug Enforcement Administration number, if appropriate;

(e) Refill authorization;

(f) Any prescriber's instructions or patient's preference permitted by law or administrative regulation;

(g) The name, strength, dosage form, and quantity of the drug dispensed originally and upon each refill; and

(h) The date of dispensing of the prescription and the identifying designation of the dispensing pharmacist for the original filling and each refill.

(2) The entries shall be made into the system at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that the data already entered may appear for the prescription or refill without reentering that data. Records that are received or sent electronically may be kept electronically. The dispensing pharmacist shall be responsible for the completeness and accuracy of the entries.

(3) The original prescription and a record of each refill, if received written or oral, shall be preserved as a hard copy for a period of three (3) years and thereafter be preserved as a hard copy or electronically for no less than an additional two (2) years. The original prescription and a record of each refill, if received by facsimile, shall be preserved as a hard copy, the original electronic image, or electronically for a period of three (3) years and thereafter be preserved as a hard copy, the original electronic image, or electronically for no less than an additional two (2) years. The original and electronic prescription shall be subject to inspection by authorized agents. An original prescription shall not be obstructed in any manner.

(4) The original prescription and a record of each refill, if received as an e-prescription, shall be preserved electronically for a period of no less than five (5) years. The electronic prescription shall be subject to inspection by authorized agents. An original prescription shall not may be obstructed in any manner.

(5) The required information shall be entered into the system for all prescriptions filled at the pharmacy.

(6) The system shall provide adequate safeguards against improper manipulation or alteration of the data.

(7) The system shall have the capability of producing a hard-copy printout of all original and refilled prescription data as required in Section 1 of this administrative regulation. A hard-copy printout of the required data shall be made available to an authorized agent within forty-eight (48) hours of the receipt of a written request.

(8) The system shall maintain a record of each day's prescription data as follows:

(a) This record shall be verified, dated, and signed by the pharmacist(s) who filled those prescription orders either:

1. Electronically;

2. Manually; or

3. In a log.

(b) This record shall be maintained for no less than five (5) years; and

(c) This record shall be readily retrievable and shall be subject to inspection by authorized agents.

(9) An auxiliary recordkeeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription order and that the maximum number of refills is not

exceeded. If the automated data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated data processing system within seventy-two (72) hours.

(10) Controlled substance data shall be identifiable apart from other items appearing in the record.

(11) The pharmacist shall be responsible to assure continuity in the maintenance of records throughout any transition in record systems utilized.

Section 2. A computer malfunction or data processing services provider's negligence shall not be not a defense against charges of improper recordkeeping.

Section 3. This administrative regulation is not applicable to the recordkeeping for drugs prescribed for and administered to patients confined as inpatients in an acute care facility.

Adopted effective June 1, 1983; Amended effective January 18, 2012.

HISTORICAL NOTES

RELATES TO: KRS 217.215, 217.216, 315.191

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1),(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.215(2) provides for the board to establish administrative regulations relating to the storage and retrieval of prescriptions records, including computerized recordkeeping. This administrative regulation provides standards for those desiring to use computerized recordkeeping.

201 Ky. Admin. Regs. 2:170, 201 KY ADC 2:170

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:175

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:175. Emergency/seventy-two (72) hour prescription refills

Section 1. If a pharmacist receives a request for a prescription refill with no refill authorized and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one (1) time emergency refill of up to a seventy-two (72) hour supply of the medication when:

(1) The prescription refill is not for a controlled substance;

(2) The medication is essential to the maintenance of life or to the continuation of therapy in chronic conditions;

(3) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may be detrimental to the patient's welfare and cause physical or mental discomfort;

(4) The pharmacist notes on the prescription record the date, the quantity dispensed, and his name or initials; and

(5) In all situations an emergency refill must be followed by authorization from the prescriber for continued therapy.

Section 2. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

Adopted effective June 1, 1983; Amended effective January 12, 1990.

HISTORICAL NOTES

RELATES TO: KRS Chapters 217, 315

STATUTORY AUTHORITY: KRS 217.215(3), 315.191

201 KAR 2:175

NECESSITY, FUNCTION, AND CONFORMITY: This administrative regulation sets out the conditions whereby a prescription may be refilled in an emergency situation and the prescriber is unavailable.

201 Ky. Admin. Regs. 2:175, 201 KY ADC 2:175

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:180

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:180. Pharmacies sanitation

Section 1. The designated pharmacy area(s) shall be used exclusively for the compounding and dispensing of drugs and other usual procedures incidental to compounding and dispensing of drugs. This area shall be maintained in a clean and sanitary condition, adequately lighted and ventilated.

Section 2. No compounding or dispensing of drugs shall be carried on in any room used as a dwelling or for usual household purposes.

Section 3. Hot and cold water shall be readily accessible. Adequate facilities, separate and distinct from toilets and washrooms, shall be provided for maintaining clean and sanitary conditions.

Section 4. All equipment used in the storage, compounding, and dispensing of drugs or medicines shall be kept in a clean and sanitary manner.

Section 5. Proper temperatures shall be maintained for compounding and dispensing of drugs and medicines. Controlled room temperatures shall be fifteen (15) to thirty (30) degrees Centigrade, fifty-nine (59) to eighty-six (86) degrees Fahrenheit. Refrigeration temperatures shall be two (2) to eight (8) degrees Centigrade, thirty-six (36) to forty-six (46) degrees Fahrenheit. Freezer temperatures shall be minus twenty (-20) to minus ten (-10) degrees Centigrade, minus four (-4) to fourteen (14) degrees Fahrenheit. Under nonspecific conditions, it is to be understood that the storage conditions include protection from moisture, freezing, and excessive heat.

Section 6. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

Adopted effective February 1, 1984.

HISTORICAL NOTES

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035(6), 315.191(1), (5)

201 KAR 2:180

NECESSITY, FUNCTION, AND CONFORMITY: There is no existing uniform administrative regulation for which the Kentucky Board of Pharmacy can monitor a pharmacy for cleanliness. Existing administrative regulations pertain only to food handling facilities. The purpose of this administrative regulation is to provide the board with the authority to require standards for compliance.

201 Ky. Admin. Regs. 2:180, 201 KY ADC 2:180

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:185

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:185. Noncontrolled substance prescription drug refills

Section 1. (1) A pharmacist shall not refill a prescription for a noncontrolled substance prescription drug unless authorized by the prescribing practitioner.

(2) A pharmacist shall record all refills by writing the date of the refill together with his name or initials on the original prescription.

(3) If an alternate approved automated data processing system is used, refills and records shall be maintained in compliance with 201 KAR 2:170.

Section 2. (1) The use of the terms “prn” and “ad lib” in relation to authorization for refilling prescriptions shall mean the prescription may be refilled for a maximum period of one (1) year from the date prescribed.

(2) After one (1) year from the date prescribed, the prescribing practitioner shall issue a new prescription.

Section 3. If the authorized refills are expressed solely as a number, the prescription shall be refilled for the authorized limit of refills within one (1) year of the date prescribed.

Section 4. Violation of a provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121(2)(d), (f), (g).

Adopted effective February 1, 1984; Amended effective May 19, 1999.

HISTORICAL NOTES

RELATES TO: KRS 215.191(f), (g), 315.191(1)(f)

STATUTORY AUTHORITY: KRS 217.215, 315.191(1)(f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.010, 315.191 and 217.215(2) require the Board of Pharmacy to promulgate administrative regulations necessary to regulate the practice

of pharmacists and the recordkeeping systems associated with prescriptions. This administrative regulation establishes the responsibilities of pharmacists and practitioners relating to prescription drug refills.

201 Ky. Admin. Regs. 2:185, 201 KY ADC 2:185

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:190

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:190. Return of prescription drugs prohibited

Section 1. No pharmacy, pharmacist, or agent thereof shall accept for reuse or resale a prescription drug. This administrative regulation shall not apply to sealed/unopened unit dose, unit of use or tamper resistant drug packaging.

Section 2. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

Adopted effective February 1, 1984; Amended effective March 12, 1985; Amended effective January 12, 1990.

HISTORICAL NOTES

RELATES TO: KRS Chapters 217 and 315

STATUTORY AUTHORITY: KRS 315.010(5), 315.191(1), (5)

NECESSITY, FUNCTION, AND CONFORMITY: To prevent the dispensing of drugs that have been adulterated, contaminated or misbranded.

201 Ky. Admin. Regs. 2:190, 201 KY ADC 2:190

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:205

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:205. Pharmacist-in-charge

Section 1. Definition. “Pharmacist-in-charge” means a pharmacist licensed in the Commonwealth of Kentucky, or in the appropriate jurisdiction of an out-of-state pharmacy holding a Kentucky Board of Pharmacy permit, who accepts responsibility for the operation of a pharmacy in conformance with all laws and administrative regulations pertinent to the practice of pharmacy and the distribution of prescription drugs and who is personally in full and actual charge of the pharmacy.

Section 2. Duties and Responsibilities. (1) The pharmacist-in-charge shall be so designated in the application for a permit to operate a pharmacy and in each application for renewal of that permit thereafter.

(2) A pharmacist shall not serve as a pharmacist-in-charge:

(a) For more than one (1) pharmacy at a time, except upon written approval from the Kentucky Board of Pharmacy; and

(b) Unless he or she is physically present in that pharmacy for a minimum of ten (10) hours per week or the amount of time appropriate to provide supervision and control.

(3) The pharmacist-in-charge shall be responsible for:

(a) Quality assurance programs for pharmacy services designed to objectively and systematically monitor care, pursue opportunities for improvement, resolve identified problems as may exist, and detect and prevent drug diversion;

(b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services;

(c) Assuring that all pharmacists and interns employed by the pharmacy are currently licensed;

(d) Providing notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in the:

1. Employment of the pharmacist-in-charge;

2. Employment of staff pharmacists; or

3. Schedule of hours for the pharmacy;

(e) Making or filing of any reports required by state or federal laws and regulations;

(f) Responding to the Kentucky Board of Pharmacy regarding identified violations or deficiencies; and

(g) Filing of any report of a theft or loss to:

1. The U. S. Department of Justice Drug Enforcement Agency as required by 21 C.F.R. 1301.76(b);

2. The Department of the Kentucky State Police as required by KRS 315.335; and

3. The board by providing a copy to the board of each report submitted.

Section 3. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) “Application for Permit to Operate a Pharmacy in Kentucky” Form 1, 07/2012;

(b) “Application for Non-Resident Pharmacy Permit” Form 1, 07/2012;

(c) “Application for Resident Pharmacy Renewal” Form 2, 07/2012; and

(d) “Application for Non-Resident Pharmacy Permit Renewal” Form 2, 07/2012.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

Adopted effective November 30, 1992; Amended effective September 11, 2000; Amended effective February 1, 2013.

HISTORICAL NOTES

201 KAR 2:205

RELATES TO: KRS 315.020, 315.0351, 315.191, 315.300, 315.335

STATUTORY AUTHORITY: KRS 315.020(1), 315.0351, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the board to promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers.KRS 315.020(1) and 315.0351(7) require applicants for pharmacy permits to place a pharmacist in charge as a prerequisite to compounding and dispensing privileges granted by the Kentucky Board of Pharmacy. This administrative regulation establishes the requirements relating to a pharmacist-in-charge.

201 Ky. Admin. Regs. 2:205, 201 KY ADC 2:205

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:210

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:210. Patient records and patient counseling

Section 1. Patient Records. (1)(a) A patient record system shall, with the exercise of professional judgment, be maintained by a pharmacy for patients for whom prescriptive drug orders are dispensed at that pharmacy location.

(b) A pharmacist, with the exercise of professional judgment, shall establish a procedure for obtaining, recording, and maintaining information required for a patient record.

(c) A pharmacist, or his designee, shall obtain, record, and maintain the information for a patient record.

(d) A patient record shall:

1. Be readily retrievable by manual or electronic means;

2. Enable the pharmacist to identify previously dispensed drugs and known disease conditions;

3. Enable the pharmacist to determine the impact of previously dispensed drugs and known disease conditions upon the newly submitted prescriptive drug order; and

4. Be maintained for not less than 180 days from the date of the last entry.

(2) A patient record shall include:

(a) Full name of patient for whom the drug is intended;

(b) Address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender;

(e) A list of all prescriptions obtained by the patient at that pharmacy location for the past twelve (12) months by:

1. Prescription number;

2. Name and strength of medication;

3. Quantity;

4. Date received;

5. Identity of prescriber; and

6. Comments or other information as may be relevant to the specific patient or drug; and

(f) Individual medical history if significant, including known disease states, known allergies, idiosyncrasies, reactions or conditions relating to prospective drug use and drug regimen reviews.

Section 2. Patient Counseling. (1) The pharmacist shall offer to counsel a patient on matters which he believes will optimize drug therapy with each patient or caregiver:

(a) Upon the presentation of an original prescription order; and

(b) On refill prescriptions, as professional discretion dictates.

(2)(a) The offer shall be made by the pharmacist in a face-to-face communication with the patient or caregiver, unless, in the professional judgment of the pharmacist, it is deemed impractical or inappropriate.

(b) If deemed impractical or inappropriate, the offer to counsel may be made:

1. By the pharmacist designee;

2. In written communication;

3. By telephone through access to a telephone service that is toll-free for long distance calls, unless the primary patient population is accessible through a local, measured, or toll-free exchange; or

4. In another manner determined by the pharmacist to be appropriate.

(3) Patient counseling shall be:

(a) In person when practical; or

(b) With reasonable effort, by telephone.

(4) The pharmacist shall include the following elements of patient counseling that he has determined are appropriate:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of therapy;

(c) Special directions and precautions;

(d) Common and clinically significant adverse effects, interactions, or contraindications that may be encountered, including their avoidance and the action required should they occur;

(e) Techniques for self-monitoring of drug therapy;

(f) Proper storage;

(g) Refill information;

(h) Action to be taken in event of a missed dose;

(i) His comments relevant to the individual's therapy; and

(j) Any other information peculiar to the specific patient or drug.

(5) If a pharmacist determines that it is appropriate, he may supplement patient counseling with additional forms of patient information, such as:

(a) Written or printed information leaflets;

(b) Pictogram labels; and

(c) Video programs.

(6) Mail-order pharmacies shall be subject to the same counseling requirements as any other pharmacy.

Section 3. Confidentiality. (1) A patient record shall be held in confidence.

(2) It shall be communicated or released:

(a) To the patient;

(b) As the patient directs; or

(c) As prudent, professional discretion dictates.

Section 4. Prospective Drug Use Review. (1) A prospective drug use review shall be conducted by a pharmacist prior to dispensing.

(2) It shall include an assessment of a patient's drug therapy and the prescription order.

(3) A prospective drug use review shall include a review by the pharmacist of the following:

(a) Known allergies;

(b) Rationale for use;

(c) Proper dose, route of administration, and directions;

(d) Synergism with currently employed modalities;

(e) Interaction or adverse reaction with applicable:

1. Drugs;

2. Foods; or

3. Known disease states;

(f) Proper utilization for optimum therapeutic outcomes; and

(g) Clinical misuse or abuse.

Section 5. Documentation of Counseling. (1) A record that the patient refused the pharmacist's offer to counsel shall be maintained for one (1) year.

(2) If there is no record that the patient refused the pharmacist's offer to counsel, there shall be a presumption that:

(a) The offer to counsel, as required in Section 2 of this administrative regulation, was made and accepted; and

(b) The counseling was provided.

Section 6. The provisions of this administrative regulation shall not apply:

(1) To inpatients of a hospital or institution, if other licensed health-care professionals are authorized to administer the drugs; or

(2) If there is documentation that the patient or caregiver refused consultation.

Adopted effective February 17, 1993.

HISTORICAL NOTES

RELATES TO: KRS 315.191(1), (5), (6), 42 C.F.R. Part 456

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1), (5), 42 C.F.R. Part 456

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1), (56), 42 CFR Part 456 mandates that pharmacists implement drug utilization reviews and provide patient counseling to those recipients of health-care benefits for which federal funds are allocated. This administrative regulation provides for this mechanism and broadens its magnitude by rendering this valuable service available to all Kentucky's citizenry, equitably.

201 KAR 2:210

201 Ky. Admin. Regs. 2:210, 201 KY ADC 2:210

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:215

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:215. Nuclear pharmacy services

Section 1. Definitions. (1) “Nuclear pharmacy” means a pharmacy providing radiopharmaceutical services.

(2) “Radiopharmaceutical services” means those acts, services, operations and transactions necessary in the conduct, operation, management and control of a nuclear pharmacy, including, for example:

(a) The compounding, dispensing, labeling and delivery of radiopharmaceuticals;

(b) The participation in radiopharmaceutical utilization reviews; and

(c) The proper and safe storage and distribution of radiopharmaceuticals.

(3) “Radiopharmaceutical” means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(4) “Radiopharmaceutical quality assurance” means the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, and it shall include, for example, internal test assessment, authentication of product history and the keeping of proper records.

(5) “Internal test assessment” means conducting those tests necessary to insure the integrity of the test.

(6) “Authentication of product history” means identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.

(7) “Authorized practitioner” means a practitioner duly authorized by applicable federal and state law to possess, use and administer radiopharmaceuticals. This person shall be named on a radioactive materials license issued by the Radiation Control Branch of the Cabinet for Human Resources.

(8) “Designated agent” means an individual who shall be under the direct supervision of an authorized practitioner and who shall be authorized to communicate that practitioner's instructions to a nuclear pharmacy.

(9) “Nuclear pharmacist” means a pharmacist licensed to practice in the Commonwealth of Kentucky and who meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Control Branch of the Cabinet for Human Resources.

(10) “Direct supervision” means that the supervising nuclear pharmacist shall be physically present in the general area or location where the supportive personnel are performing supportive duties and shall conduct in-process and final checks.

Section 2. General Requirements for Pharmacies Providing Radiopharmaceutical Services. (1) A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a pharmacy operating under the direct supervision of a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist shall be responsible for all operations of the licensed area and in personal attendance at all times that the pharmacy is open for business.

(2) Nuclear pharmacies may be exempted from the general space requirements for pharmacies, but shall:

(a) Have adequate space, commensurate with the scope of services required and meeting Radiation Control Branch, Cabinet for Human Resources, requirements established for all radioactive material licensees in the Commonwealth;

(b) Be separate from the pharmacy areas for nonradioactive drugs;

(c) Be inaccessible to all unauthorized personnel; and

(d) Have a radioactive storage and decay area.

(3) The process used for handling radioactive materials by any license holder shall involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials as approved in a Kentucky radioactive materials license. In order to ensure the public health and safety in this respect, a nuclear pharmacy shall first meet the following general environmental requirements where the handling of radiopharmaceutical materials takes place:

(a) Proper ventilation so that radioactive materials cannot be airborne from that environment to other nonoccupationally unrestricted areas;

(b) Proper location so that the receipt and dispersal of radioactive materials do not result in inadvertent and undesired contamination of other nonoccupationally labeled areas; and

(c) Proper design to allow radioactive materials to be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to ensure proper operation of the corresponding assay equipment.

(4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with administrative regulations of the Radiation Control Branch of the Cabinet for Human Resources.

(5) A nuclear pharmacy, upon receiving an oral prescription for a radiopharmaceutical, shall immediately have the prescription reduced to writing or recorded in a data processing system, which writing or record shall contain at least the following:

(a) The name of the authorized user or his agent;

(b) The date of distribution and the time of administration of the radiopharmaceutical;

(c) The name of the procedure;

(d) The name of the radiopharmaceutical;

(e) The dose or quantity of the radiopharmaceutical;

(f) The serial number assigned to the order for the radiopharmaceutical;

(g) Any specific instructions; and

(h) The patient's name, whenever an order is for a therapeutic or blood-product radiopharmaceutical.

(6) The immediate outer container (shield) of a radioactive drug to be dispensed shall be labeled with the:

(a) Standard radiation symbol;

(b) Words, “Caution-Radioactive Material”

(c) Radionuclide;

(d) Chemical form;

(e) Amount of radioactive material contained in millicuries or microcuries;

(f) Volume in cubic centimeters, if a liquid;

(g) Requested calibration time for the radioactivity contained;

(h) Name, address, and telephone number of the nuclear pharmacy;

(i) Prescription number;

(j) Date; and

(k) Space for patient's name.

(7) The immediate container shall be labeled with the:

(a) Standard radiation symbol;

(b) Words, “Caution-Radioactive Material”

(c) Prescription number; and

(d) Name of the radiopharmaceutical.

(8) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(9) A nuclear pharmacist may transfer to authorized persons, in accordance with the provisions of a Kentucky radioactive materials license, radioactive materials not intended for drug use and radiopharmaceuticals intended for individual patient use.

(10) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies including those laws and regulations governing nonradioactive drugs. For nuclear pharmacies handling

radiopharmaceuticals exclusively, the Kentucky Board of Pharmacy may waive regulations pertaining to pharmacy licenses for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.

(11) Radioactive drugs are to be dispensed only upon a nonrefillable prescription order from a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.

(12) Prescription orders for delivery of radioactive drugs for use in the medical practice of a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.

(13)(a) A nuclear pharmacist in charge of a nuclear pharmacy shall have the authority to delegate to any qualified and properly trained person or persons, acting under his direct supervision, any nuclear pharmacy act which a reasonable and prudent nuclear pharmacist would find is within the scope of sound pharmaceutical judgment to delegate.

(b) The delegation shall only occur if, in the professional opinion of the delegating nuclear pharmacist-in-charge, the act may be properly and safely performed by the person to whom the act is delegated.

(c) The delegated act shall only be performed in its customary manner and not in violation of other statutes.

(d) Persons to whom nuclear pharmacy acts are delegated shall not hold themselves out to the public as being authorized to practice pharmacy.

Section 3. Minimum Requirements for Space, Equipment, Supplies, and Library. (1) Each nuclear pharmacy must meet the following requirements for space:

(a) The area for the storage, compounding, and dispensing of radioactive drugs shall be completely separate from pharmacy areas for nonradioactive drugs;

(b) Hot lab and storage area shall be a minimum of 120 square feet; and

(c) The compounding and dispensing area shall be a minimum of 300 square feet.

(2) Each nuclear pharmacy shall be equipped with at least the following items of equipment:

(a) Dose calibrator;

(b) Refrigerator;

(c) Drawing station;

(d) Well scintillation counter;

(e) Microscope;

(f) Chromatagraphic apparatus or comparable means of effectively assuring tagging efficiency;

(g) Portable radiation survey meter; and

(h) Other equipment deemed necessary for radiopharmaceutical quality assurance for products compounded or dispensed as shall be determined by the Radiation Control Branch, Cabinet for Human Resources, and the Kentucky Board of Pharmacy.

(3) Each nuclear pharmacy shall have on the premises current editions or revisions of the following reference materials:

(a) United States Pharmacopedia-National Formulary with supplements;

(b) State statutes and administrative regulations relating to pharmacy;

(c) State and federal regulations governing the use of applicable radioactive materials; and

(d) Text relating to the practice of nuclear pharmacy and radiation safety.

Section 4. Radiopharmaceutical Quality Assurance. The holder of a nuclear pharmacy license shall be responsible for the radiopharmaceutical quality assurance of all radiopharmaceuticals, including biologicals, dispensed or manufactured.

Adopted effective January 27, 1993.

HISTORICAL NOTES

RELATES TO: KRS Chapter 315

201 KAR 2:215

STATUTORY AUTHORITY: KRS 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy shall be responsible for imposing minimum standards in all settings where drug products are dispensed and to ensure the safety of all drug products provided to the citizens of the Commonwealth. This administrative regulation applies to pharmacies as defined in KRS 315.010. The requirement of these administrative regulations are in addition to, and not in substitution of, other applicable administrative regulations promulgated by the Cabinet for Human Resources for radioactive materials and applicable administrative regulations promulgated by the Kentucky Board of Pharmacy.

201 Ky. Admin. Regs. 2:215, 201 KY ADC 2:215

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:220

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:220. Collaborative care agreements

Section 1. A collaborative care agreement shall:

(1) Be in writing;

(2) Be signed and dated by the:

(a) Individual practitioner;

(b) Individual pharmacist; and

(c) Patient or care giver;

(3) Provide that upon termination of the agreement the individual practitioner or individual pharmacist shall notify the patient in writing;

(4) State the method for termination of the agreement; and

(5) Contain the information specified by Section 2 of this administrative regulation.

Section 2. A collaborative care agreement shall contain the following information:

(1) Patient name;

(2) Patient address and telephone number;

(3) Protocol, criteria, standing orders, or other method by which services are authorized;

(4) The method established for the assessment of patient outcomes, if appropriate; and

(5) Lab tests that may be ordered.

Section 3. The following information relating to a collaborative care agreement shall be maintained by a pharmacist and shall be provided to the collaborating practitioner:

(1) Emergency notification contact;

(2) Date of birth, weight, height, and gender;

(3) Prescription regimen;

(4) Nonprescription regimen;

(5) Medical history; including:

(a) Known diseases;

(b) Known allergies; and

(c) Reactions and conditions relating to:

1. Prescription regimens; and

2. Nonprescription regimens;

(6) Lab tests ordered, including results of lab tests;

(7) Assessments of patient outcomes;

(8) Notes relating to contacts between the individual pharmacist and the individual practitioner concerning the care and course of therapy of the patient; and

(9) Documentation of the specific counseling information provided to the patient or care giver.

Section 4. A collaborative care agreement, and information and records required by the provisions of this administrative regulation, shall be maintained:

(1) At the pharmacist's practice site; and

(2) For at least five (5) years after termination.

Adopted effective June 16, 1997; Amended effective August 1, 2008.

HISTORICAL NOTES

RELATES TO: KRS 315.010(4), 315.040(4), 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations to regulate and control matters relating to pharmacists, pharmacist interns, pharmacist technicians, pharmacies, wholesale distributors, and manufacturers. This administrative regulation establishes minimum requirements for the development and maintenance of collaborative care agreements between an individual pharmacist and an individual practitioner.

201 Ky. Admin. Regs. 2:220, 201 KY ADC 2:220

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:225

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:225. Special pharmacy permit

Section 1. Definitions. (1) “Special pharmacy permits” means a permit issued to a pharmacy that provides miscellaneous specialized pharmacy service and functions.

(2) “Medical gasses” means oxygen United States Pharmacopoeia and nitrous oxide.

Section 2. General Requirements. (1)(a) An applicant for a special pharmacy permit for medical gasses shall comply with the requirements of 201 KAR 2:180 and 201 KAR 2:205, except that the pharmacist-in-charge designated on the special permit shall be exempt from the requirements of 201 KAR 2:205, Section 2(2).

(b) The pharmacist-in-charge shall review the records of the special pharmacy permit for medical gasses not less than once each quarter.

(2) An applicant for a special pharmacy permit for medical gasses shall prepare and adopt a policy and procedures manual that sets forth a detailed description of how the:

(a) Operation will comply with applicable federal, state, or local laws or administrative regulations; and

(b) Licensee will maintain the premises so that the medical gasses remain secure and comply with applicable compendial monographs of official pharmacopoeias specified by KRS 217.015(5)(a).

(3) An applicant for a special pharmacy permit for medical gasses shall be inspected by the board prior to the issuance of the license.

Section 3. Qualifications for License. (1) The board shall consider the following in reviewing the qualifications of an applicant for a special permit for medicinal gasses:

(a) The applicant's experience in the sale or distribution of prescription drugs, including controlled substances;

(b) A felony conviction of the applicant under federal, state, or local laws;

(c) The furnishing by the applicant of false or fraudulent material in a previous application for:

1. A special permit for medical gasses; or

2. A federal or state medical assistance program;

(d) Suspension or revocation of an applicant's license or permit by federal, state, or local government; and

(e) Compliance with requirements under a previously granted license or permit.

(2) The board shall deny an application for a special permit for medical gasses, if an applicant has:

(a) Been convicted for a violation of federal, state, or local laws relating to:

1. The practice of pharmacy;

2. Drugs; or

3. Federal or state medical assistance programs.

(b) Furnished false or fraudulent material in the application for a special permit for medical gasses;

(c) Failed to maintain or make available required records to the:

1. Board; or

2. Federal, state, or local law enforcement officials;

(d) Failed to comply with applicable federal, state, and local laws and regulations relating to medical gasses; or

(e) Failed to provide appropriate land, buildings, and security necessary to properly carry on the business described in his application.

Section 4. License Fees; Renewals. An applicant shall submit:

(1) An initial or renewal application for a special permit for medicinal gasses on “Application for Permit to Operate A Pharmacy In Kentucky” and

(2) As appropriate, the:

(a) Initial application fee established by Section 1(10), 201 KAR 2:050; or

(b) Renewal fee established by Section 1(11), 201 KAR 2:050.

Section 5. Incorporation By Reference. (1) “Application for Permit to Operate A Pharmacy In Kentucky (11/92)” is incorporated by reference.

(2) This form may be obtained, inspected, or copied at the Kentucky Board of Pharmacy, 1024 Capital Center Drive, Suite 210, Frankfort, Kentucky 40601-8204, 8 a.m. to 4:30 p.m., Monday through Friday.

Adopted effective July 16, 1997.

HISTORICAL NOTES

RELATES TO: KRS 217.015(5)(a), 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.020, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: This administrative regulation establishes, consistent with the requirements of KRS 315.191(1)(a), minimum requirements for the permitting of those entities that distribute medical gasses.

201 Ky. Admin. Regs. 2:225, 201 KY ADC 2:225

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:230

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:230. Special limited pharmacy - central refill pharmacy

Section 1. Definition. “Central refill pharmacy” means a pharmacy located in the Commonwealth that provides packaging, labeling and delivery of a refill prescription product to another pharmacy for the purpose of the refilling of a valid prescription.

Section 2. The central refill pharmacy shall:

(1) Either:

(a) Have a written contract with the pharmacy which has custody of the original prescription authorization for refill dispensing; or

(b) Be under common ownership with that pharmacy;

(2) Prepare the label for the refill prescription product which clearly identifies the name and address of the pharmacy preparing the product for refill dispensing and the name and address of the pharmacy that will receive the prepared product for dispensing to the patient;

(3) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the preparation of the refilled prescription product, including the name of the:

(a) Pharmacist who verified the accuracy of the refilled prescription product;

(b) Pharmacy preparing the refilled prescription product; and

(c) Pharmacy to which the prepared refill prescription product is delivered;

(4) Provide the originating pharmacy with written information that describes how a patient may contact the central refill pharmacy if the patient has any questions about the preparation of the prescription refill; and

(5) Be responsible for ensuring that the order has been properly prepared and verified by a pharmacist.

Section 3. The pharmacy to which a prepared prescription refill product is delivered shall:

(1) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the receipt and dispensing of the centrally refilled prescription product, including the name of the:

(a) Pharmacist who verified the accuracy of the refilled prescription product prior to its dispensing; and

(b) Pharmacy preparing the refilled prescription product;

(2) Be responsible for ensuring that the refill has been properly prepared, packaged and labeled;

(3) Provide the patient with written information that described how a patient may contact either:

(a) The central refill pharmacy if the patient has any questions about the preparation of the prescription refill; or

(b) the dispensing pharmacy if the patient has any questions about the use of the medication; and

(4) Be responsible for adherence to the requirements of 201 KAR 2:210.

Adopted effective June 12, 2000; Amended effective March 11, 2009.

HISTORICAL NOTES

RELATES TO: KRS 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.020, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.020 requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist.KRS 315.035 requires that all pharmacies hold a permit issued by the board. This administrative regulation establishes, consistent with the requirements of KRS 315.191(1)(a), minimum requirements for the permitting of those pharmacies that package, label and distribute refill prescriptions to pharmacies in the Commonwealth.

201 KAR 2:230

201 Ky. Admin. Regs. 2:230, 201 KY ADC 2:230

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:240

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:240. Special limited pharmacy - charitable pharmacy

Section 1. Definitions. (1) “Charitable organization” means an organization qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code.

(2) “Legend drug sample” means an unopened package of a manufacturers legend drug product that has been distributed to either a practitioner or the charitable pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987.

(3) “Qualified indigent patient” means a patient of the charitable pharmacy that has been screened and approved by the charitable organization as meeting the organization's mission of providing pharmaceutical care to those who are without sufficient funds to obtain needed legend drugs.

Section 2. (1) A charitable pharmacy:

(a) Shall comply with all pharmacy permit requirements except those specifically exempted by the board pursuant to paragraph (b) of this subsection; and

(b) May petition the board in writing to be exempted from those pharmacy permit requirements that do not pertain to the operation of that charitable pharmacy.

(2) The charitable pharmacy only shall dispense prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.

(3) The charitable pharmacy shall not charge any fee for the dispensing of prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.

(4) A charitable pharmacy may accept prescription legend drugs in their unbroken original packaging from pharmacies, wholesalers, or manufacturers, provided appropriate records of receipt and dispensing are maintained.

(5) A charitable pharmacy shall not:

(a) Accept controlled substances from pharmacies, wholesalers, or manufacturers; or

(b) Dispense controlled substances.

(6) A pharmacy that requests a charitable pharmacy permit shall submit to the board for prior approval, a plan describing the method by which the charitable pharmacy and the pharmacy will maintain a separate and distinct prescription drug stock. The failure of either pharmacy to follow the plan shall result in revocation of the special limited pharmacy permit and the pharmacy permit.

Adopted effective September 11, 2000.

HISTORICAL NOTES

RELATES TO: KRS 315.035

STATUTORY AUTHORITY: KRS 315.020, 315.030, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.020, 315.030, and 315.191(1)(a) requires the board to promulgate administrative regulations to prescribe the criteria for obtaining a pharmacy permit to dispense legend drugs and the procedures for the safe dispensing of legend drugs to citizens of the Commonwealth. This administrative regulation identifies the manner and procedure by which a charitable organization can be permitted to obtain a pharmacy permit and dispense legend drugs in the Commonwealth.

201 Ky. Admin. Regs. 2:240, 201 KY ADC 2:240

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:250

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:250. Pharmacist Recovery Network Committee

Section 1. The board's Pharmacist Recovery Network Committee (PRNC) consultant shall be a pharmacist licensee of the board. The consultant shall assist the Case Review Committee (CRC) and the PRNC in carrying out their respective responsibilities. This shall include working with the board's inspectors and investigators to determine whether a pharmacist or intern is in fact impaired.

Section 2. If a pharmacist or intern self reports impairment as a result of the misuse or abuse of alcohol or drugs, or both; or if the board receives a legally sufficient complaint alleging that a pharmacist or intern is impaired as a result of the misuse or abuse of alcohol or drugs, or both, and no complaint against the pharmacist or intern other than impairment exists, the reporting of any impairment information to the board shall be forwarded to the consultant and shall not constitute grounds for discipline, if the PRNC finds the pharmacist or intern has:

(1) Acknowledged the impairment problem;

(2) Voluntarily enrolled in an appropriate, approved treatment program;

(3) Voluntarily withdrawn from practice or limited the scope of practice as required by the consultant, in each case, until the PRNC is satisfied the licensee has successfully completed an approved treatment program; and

(4) Executed releases for medical records, authorizing the release of all records of evaluations, diagnoses, and treatment of the licensee, including records of treatment for emotional or mental conditions, to the consultant. The consultant shall not make copies or reports of records that do not regard the issue of the licensee's impairment and his or her participation in a treatment program.

Section 3. (1) A treatment provider shall disclose to the consultant or board if applicable all information in its possession regarding the issue of a pharmacist's or intern's impairment and participation in the treatment program. Failure of the treatment provider to provide information to the consultant shall be a basis for the withdrawal of the use of the program or provider.

(2) If in the opinion of the consultant or PRNC, an impaired pharmacist or intern has not progressed satisfactorily in a treatment or recovery program, all information regarding the issue of a pharmacist's or intern's

impairment and participation in a treatment or recovery program in the consultant's possession shall be disclosed to the board. That disclosure shall constitute a complaint.

Section 4. All information concerning a pharmacist or intern held by the consultant, PRNC, CRC, or board shall remain confidential.

Section 5. (1) The PRNC shall be comprised of eleven (11) members. The members shall include:

(a) The President of the Board of Pharmacy;

(b) The Chair of the PRNC;

(c) The Executive Director of the Board of Pharmacy; and

(d) Eight (8) other members, of which seven (7) shall be pharmacists and one (1) shall be a citizen member.

(2)(a) All members shall have the same rights, which include voting privileges.

(b) A member of the PRNC shall not be on the board, except the President of the Board.

(c) Any criminal conviction or disciplinary action by a licensure board against a proposed member shall be reported to the board prior to consideration for appointment.

(d) There may be no more than four (4) members in successful recovery on the PRNC.

(e) A pharmacist under a Pharmacist Recovery Network Agreement shall not serve on the PRNC.

(3)(a) A PRNC member may be appointed by the board a maximum of three (3), four (4) year terms.

(b) A PRNC member shall not serve more than (2) terms consecutively.

(c) After serving two (2) consecutive terms a PRNC member shall rotate off the PRNC for at least two (2) years.

(d) A committee member shall serve no more than twelve (12) years on the PRNC.

(e) The President of the Board, the PRNC Consultant, and the Executive Director of the Board membership

on the PRNC shall not constitute a twelve (12) year term.

(f) Membership of the PRNC shall be selected by the board from a list of qualified candidates submitted by an interested individual or entity.

(4) A member of the PRNC who becomes impaired, relapses, has any criminal conviction, or has any disciplinary action by a licensure board shall immediately resign from the PRNC.

(5) The board by majority vote, with the recusal of the President of the Board, may remove a member of the PRNC for any of the following reasons:

(a) Refusal or inability of a committee member to perform duties as a member of the committee in an efficient, responsible, and professional manner;

(b) Misuse of the committee by a member to obtain personal, pecuniary, or material gain or advantage for the member or others; and

(c) Violation of any provision of KRS Chapter 315.

Adopted effective February 7, 2002; Amended effective August 16, 2007.

HISTORICAL NOTES

RELATES TO: KRS 315.121(1)(d), 315.126

STATUTORY AUTHORITY: KRS 315.126(3), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.126(1) requires the Board of Pharmacy to establish a pharmacy recovery network committee (PRNC). This administrative regulation establishes minimum requirements for the establishment and operation of the PRNC. This administrative regulation specifies the manner by which the board's PRNC consultant works with the board in intervention, evaluating and treating a pharmacist or intern, and providing for continuing care and monitoring by the consultant through a treatment provider.

201 Ky. Admin. Regs. 2:250, 201 KY ADC 2:250

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

201 KAR 2:250

END OF DOCUMENT

201 KAR 2:260

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:260. Automated Pharmacy System in Residential Hospice Facilities

Section 1. Definitions. (1) “Automated Pharmacy System” is defined by KRS 315.295(1)(a).

(2) “Residential Hospice Facility” is defined by KRS 315.295(1)(b).

Section 2. Responsibility. The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for all of the following:

(1) Assuring that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of drug prescribed and complying with the recordkeeping and security safeguards pursuant to Section 3 of this administrative regulation;

(2) Assuring medications are reviewed by a pharmacist prior to access;

(3) Implementing an ongoing quality assurance program that monitors performance of the automated system, which is evidenced by written policies and procedures; and

(4) Notifying the board with prior written notice of the installation or removal of an automated pharmacy system. This notification shall include the following:

(a) Name and address of pharmacy;

(b) Initial location of the automated pharmacy system. The automated pharmacy system may thereafter be relocated within the pharmacy or health care facility without providing subsequent notification to the board; and

(c) Pharmacist-in-charge.

(5) Assigning, discontinuing or changing personnel access to the system;

(6) Assuring that access to the medications comply with state and federal laws; and

(7) Assuring that the automated pharmacy system is stocked accurately and that the automated pharmacy system stock is checked monthly in accordance with established written policies and procedures, including the following:

(a) Accuracy;

(b) Integrity; and

(c) Expiration date.

Section 3. Standards. An automated pharmacy system shall comply with the following provisions:

(1) A pharmacy shall maintain on-site the following documentation relating to an automated pharmacy system:

(a) Name and address of the pharmacy or inpatient health care facility where the system is being used;

(b) The automated pharmacy system manufacturer's name, model, and serial number;

(c) Description of how the system is used;

(d) Written quality assurance procedures to determine continued appropriate use of the system; and

(e) Written policies and procedures for system operation, safety, security, accuracy, access and malfunction.

(2) All written policies and procedures shall be maintained in the pharmacy responsible for the automated pharmacy system.

(3) An automated pharmacy system shall maintain adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.

(4) Records and data kept by the automated pharmacy system shall meet the following requirements:

(a) All events involving the contents of the automated pharmacy system shall be recorded electronically; and

(b) Records shall be maintained by the pharmacy and be available to the Board and shall include the following:

1. The time and location of the system accessed;

2. Identification of the individual accessing the system;

3. Type of transaction;

4. Name, strength, dosage form and quantity of drug accessed;

5. Name of the patient for whom the drug was ordered;

6. The prescription number;

7. The name of the prescriber; and

8. All events involving user database modifications shall be recorded electronically and maintained.

(5) The stocking of all medications in the automated pharmacy system shall be done by a pharmacist, pharmacist intern, or pharmacy technician, who shall be under the general supervision of a pharmacist on-site.

(6) A record of medications stocked into an automated pharmacy system shall be maintained for five (5) years and shall include identification of the person stocking and pharmacist checking for accuracy.

(7) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.

(8) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with federal and state laws.

(9) The automated pharmacy system shall provide a mechanism for securing and accounting for medications returned to the system and accounting for wasted medications in accordance with federal and state laws.

201 KAR 2:260

Adopted effective June 20, 2007.

HISTORICAL NOTES

RELATES TO KRS 315.010(9), 315.020, 315.035, 315.295, 315.300, 216B3195

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a), 315.295

NECESSITY, FUNCTION, AND CONFORMITY: KRS 335.020(1) requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist.KRS 315.295 authorizes the board to regulate an automated pharmacy system in a residential hospice facility. This administrative regulation establishes the standards for the operation of this type of system.

201 Ky. Admin. Regs. 2:260, 201 KY ADC 2:260

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END OF DOCUMENT

201 KAR 2:270

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:270. Expungement

Section 1. Definition. “Expungement” means that:

(1) The affected records shall be sealed;

(2) The proceedings to which they refer shall be deemed not to have occurred; and

(3) The affected party may properly represent that no record exists regarding the matter expunged.

Section 2. Minor Violations and Expungement Procedure. (1) The following violations are to be considered minor in nature:

(a) Failure to timely renew a license or permit;

(b) Failure to timely obtain required continuing education; and

(c) Failure to timely obtain required HIV/AIDS continuing education.

(2) A pharmacist seeking expungement of a record of a disciplinary action resulting from a violation designated in subsection (1) of this section shall, in accordance with KRS 315.121(6):

(a) Not have been the subject of a subsequent violation of the same nature for a period of three (3) years after the date of completion of disciplinary sanctions imposed for the violation sought to be expunged; and

(b) Submit a written request to the board.

(3) The board shall consider each request and shall, if the conditions of subsection (2) of this section are satisfied, expunge every record relating to the subject disciplinary order.

Adopted effective April 11, 2003.

201 KAR 2:270

HISTORICAL NOTES

RELATES TO: KRS 315.121(6), 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.121(6), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to pharmacists.KRS 315.121(6) requires the board to promulgate administrative regulations to establish violations that are considered minor and subject to expungement. This administrative regulation establishes the violations considered minor and the criteria and procedure for expungement.

201 Ky. Admin. Regs. 2:270, 201 KY ADC 2:270

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:280

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:280. Prescription dispensing for formulary Compliance

Section 1. Dispensing. (1) A pharmacist may dispense a therapeutic equivalent drug product under the following conditions:

(a) The ordering practitioner has indicated “formulary compliance approval” on the prescription, in one of the following ways:

1. In the practitioner's own handwriting; or

2. By checking a “formulary compliance approval” box on a preprinted form;

(b) The pharmacist receives a formulary change as a consequence of the patient's third-party plan; and

(c) The product designated as “preferred” by the third-party formulary is in the same therapeutic class as the prescribed drug.

(2) The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner, in an original writing or by facsimile:

(a) That the pharmacist engaged in formulary compliance; and

(b) The therapeutic equivalent drug product that was dispensed.

Section 2. The pharmacist may make adjustments in the quantity and directions to provide for an equivalent dose of the preferred formulary therapeutic alternative.

Adopted effective April 11, 2003.

HISTORICAL NOTES

201 KAR 2:280

RELATES TO: KRS 217.814, 315.191

STATUTORY AUTHORITY: KRS 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists.KRS 315.191(1)(f) authorizes the board to promulgate administrative regulations to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between qualifying pharmacists and pharmacies. This administrative regulation establishes procedural and substantive requirements for dispensing an equivalent drug product pursuant to a practitioner declaration of formulary compliance approval.

201 Ky. Admin. Regs. 2:280, 201 KY ADC 2:280

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:300

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:300. Common database

Section 1. Definition. “Common Database” means information shared among pharmacists and pharmacies for the purpose of dispensing medications or providing other forms of pharmacist care to a patient.

Section 2. The use of a common database shall not constitute a transfer as established in 201 KAR 2:165, provided that the following conditions are met:

(1) All pharmacies involved in the transactions pursuant to which the prescription is dispensed shall be under common ownership and utilize a common database;

(2) All pharmacies involved in the transactions pursuant to which the prescription is dispensed and all pharmacies engaging in dispensing functions shall be properly permitted in Kentucky pursuant to KRS 315.035 or 315.0351.

(3) A pharmacist who provides a pharmacy service on a prescription dispensed in Kentucky shall be licensed in Kentucky;

(4) The common database shall maintain a record of all pharmacists, pharmacist interns, and pharmacy technicians involved in the process of dispensing a prescription;

(5) The owner of the common database shall maintain a policy and procedure manual that governs its participating pharmacies, pharmacists, and pharmacy employees and that is available to the board or its agents upon request within five (5) business days and which shall include:

(a) A procedure detailing how each pharmacy and each pharmacist accessing the common database shall comply with applicable federal and state laws, rules, and regulations;

(b) The procedure for maintaining appropriate records for regulatory oversight for tracking a prescription during each stage of the filling and dispensing process, identifying the pharmacists involved in filling and dispensing the prescription and counseling the patient, and responding to any requests for information made by the board;

(c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and

(d) A quality assurance program designed to objectively and systemically monitor, evaluate, and improve the quality and appropriateness of patient care through the use of a common database; and

(6) A pharmacist dispensing a prescription shall at all times exercise independent professional judgment and shall be responsible for his or her actions and the professional actions of those individuals the pharmacist is required to supervise.

Adopted effective June 6, 2008.

HISTORICAL NOTES

RELATES TO: KRS 315.020, 315.035, 315.0351

STATUTORY AUTHORITY: KRS 315.035, 315.0351, 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035 and 315.0351 require that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist.KRS 315.191(1)(a) and (f) authorize the Kentucky Board of Pharmacy to promulgate administrative regulations pertaining to pharmacies; pharmacists; and the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders. This administrative regulation establishes minimum requirements for prescription drug orders within and between pharmacists and pharmacies.

201 Ky. Admin. Regs. 2:300, 201 KY ADC 2:300

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:310

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:310. Compounding for a practitioner's office or institutional administration

Section 1. A pharmacist, pharmacist intern, or pharmacy technician may prepare a compounded drug for a practitioner's office administration or institutional administration.

Section 2. A compounded drug that contains a controlled substance shall not be compounded for office or institutional administration.

Section 3. The pharmacist shall receive a written, verbal, facsimile, or electronic request for a compounded drug from a practitioner, indicating the formulation, strength, and quantity ordered.

Section 4. Label Requirements. A label shall be generated for the compounded drug and shall include:

(1) The name of the practioner;

(2) The designated name and strength of the compounded drug;

(3) The quantity dispensed;

(4) A lot or batch number of the compounded drug;

(5) The beyond use date for the compounded drug;

(6) The date the compounded is dispensed;

(7) The pharmacy's name, address, and telephone number;

(8) Any special storage requirements;

(9) A notation stating “For Office or Institutional Administration Only-Do Not Dispense to Patient;

(10) Any auxiliary label required for the compounded drug.

Section 5. The compounded drug shall be administered in the practitioner's office or institution and shall not be dispensed to the patient.

Section 6. The prescription for the compounded drug shall be kept pursuant to 201 KAR 2:170.

Adopted effective March 11, 2009.

HISTORICAL NOTES

RELATES TO KRS 315.191(1)(a).

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to promulgate administrative regulations to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. This administrative regulation addresses compounding for use by a practitioner's office administration or institutional administration.

201 Ky. Admin. Regs. 2:310, 201 KY ADC 2:310

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:320

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:320. Permit requirements for manufacturers

Section 1. Requirements. (1) A manufacturer shall apply for a permit from the board in accordance with KRS 315.036 and this administrative regulation.

(2) A separate permit shall be required for each facility within the Commonwealth regardless of whether joint ownership or control exists.

(3) An agent or employee of a permit holder shall not be required to obtain a permit under this section when the agent or employee is acting in the usual course of business or employment.

(4) A permit shall not be issued or renewed unless the applicant or its officers demonstrates or continues to demonstrate acceptable operational procedures, including:

(a) Adequate maintenance and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or current year United States Pharmacopoeia (USP) compendium requirements. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs;

(b) Physical separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated, or otherwise recalled merchandise until they are destroyed or returned;

(c) Providing accurate and precise records of all goods shipped or received including source or recipient, date, quantity, itemized description, and any other information pertinent to the transaction;

(d) Providing proof of registration with the state controlled substance authority, and with the U.S. Drug Enforcement Administration and compliance with all DEA regulations.

Section 2. Qualifications for Permit. (1)(a) The Kentucky Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in manufacturer of prescription drugs within the Commonwealth:

1. Any convictions of the officers of the applicant under any federal, state, or local laws;

2. The applicant's past experience in the manufacture of prescription drugs, including controlled substances;

3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing;

4. Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant or its officers for the manufacture of any drugs, including controlled substances;

5. Compliance with the requirements under any previously granted license or permit, if any; and

6. Compliance with requirements to maintain or make available to the Kentucky Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section.

(b) The Kentucky Board of Pharmacy shall have the right to deny a permit to an applicant or its officers if it determines that the granting of that permit would not be in the public interest for any reason established in KRS 315.121.

(2) A permit shall not be issued pursuant to this administrative regulation unless the applicant or its officers has furnished proof satisfactory to the Board of Pharmacy:

(a) That the applicant and its officers are in compliance with all applicable federal and state laws and regulations relating to drugs; and

(b) That the applicant and its officers are equipped as to land, buildings, and security to properly carry on the business described in the application.

(3) A permitted manufacturer may sell or distribute federal legend drugs only to the following:

(a) A currently permitted manufacturer;

(b) A currently licensed wholesale distributor;

(c) A currently permitted pharmacy;

(d) A currently licensed practitioner;

(e) A currently licensed hospital, but only for use by or in that hospital; or

(f) A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes.

(4) A permit holder may be disciplined for failure to comply with the provisions of KRS 315.036, pursuant to KRS 315.121, or this administrative regulation.

Section 3. Application, Fees; Renewals. (1) An application for a permit shall be submitted to the Board of Pharmacy on Application for a Permit to Operate as a Manufacturer (KBP M 5:09).

(2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.

(3) An application shall include:

(a) The name, full business address, and telephone number of the applicant;

(b) All trade or business name used by the applicant;

(c) Addresses, telephone numbers, and the names of the contact persons for the facility used by the permittee for the storage, handling, and manufacturing of prescription drugs;

(d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);

(e) The name(s) of the owner and operator of the permittee, including;

1. If a person, the name and Social Security number of the person;

2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;

3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

4. If a sole proprietorship, the full name and social security number of the sole proprietor and the name of the business entity; and

(f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to

manufacture or possess prescription drugs.

(4) All permits shall:

(a) Expire on September 30 following the date of issuance; and

(b) Be:

1. Renewable annually thereafter upon proper application accompanied by the renewal fee set forth in 201 KAR 2:050; and

2. Nontransferable.

Section 4. Standards. (1) Facilities.

(a) All buildings in which legend drugs are repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

(b) Buildings shall meet all applicable federal, state, and local standards. The facility shall have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.

(c) A facility shall not be located in a residence.

(2) Security.

(a) A manufacturer shall be equipped with an alarm system to detect entry after hours.

(b) A manufacturer shall ensure that access from outside their premises is well-controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where legend drugs are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A permit holder shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the manufacturer of prescription drugs.

(e) Lists of officers, directors, managers and other persons in charge of distribution, storage, and handling of prescription drugs, including a description of their duties and summary of their qualifications, shall be maintained for purpose of review.

(3) Recordkeeping.

(a) Inventories and other records of transactions regarding the receipt and disposition of legend drugs shall be maintained and readily available for inspection or photocopying by authorized law enforcement officials for a period of two (2) years following disposition of the drugs. These records shall include:

1. The source of the drugs including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other distribution of the drugs.

(b) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(4) Written policies and procedures.

(a) A manufacturer shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and to ensure that the manufacturer prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(b) There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.

(c) There shall be written policies and procedures to assure that any outdated stock or any stock with an expiration date that, in the manufacturer's view, does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return or otherwise destroyed, and this shall be documented.

(d) There shall be written policies and procedures by which the manufacturer exercises control over the shipping and receiving of all stock within the operation.

(5) Returned, damaged, and outdated prescription drugs. A manufacturer's operation shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods. If conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the manufacturer shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(6) Handling recalls. A manufacturer shall adopt, maintain, and follow a written policy for handling recalls and withdrawals of products. The policy shall cover all recalls and withdrawals of drug products due to:

(a) Any voluntary action on the part of the manufacturer;

(b) The direction of the Food and Drug Administration, or any other federal, state, or local government agency; and

(c) Replacement of existing merchandise with an improved product or new package design.

(7)(a) A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock.

(b) Procedures for distribution of approved stock shall provide for a rotation whereby the first expiration inventory is distributed first.

(c) A manufacturer shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

Section 5. Pharmacist-in-charge. A manufacturer shall designate a pharmacist-in-charge of the facility who shall be responsible to the board for security and recordkeeping. The pharmacist-in-charge shall review the security and records by conducting an on-site inspection not less than quarterly.

Section 6. Violations. (1) A drug manufacturer shall not distribute legend drugs directly to a consumer or a patient or operate in a manner that endangers the public health.

(2) Violation of any of these provisions shall be grounds for the discipline of the permit pursuant to KRS 315.121.

Section 7. Incorporation by Reference. (1) “Application for a Permit to Operate as a Manufacturer” 6/09, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, Spindletop Administrative Building, Suite 302, 2624 Research Park Drive, Lexington, Kentucky 40511, Monday through Friday, 8 a.m. through 4:30 p.m.

Adopted effective October 21, 2009.

HISTORICAL NOTES

RELATES TO: KRS 315.020(2), 315.036, and 315.191(1)

STATUTORY AUTHORITY: KRS 315.020(2), 315.036, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.036 and 315.191(1) authorizes the board to promulgate administrative regulations to regulate the manufacturers of drugs.KRS 315.036 authorizes the board to promulgate administrative regulations regarding manufacturer permits and the maintenance and reporting of accurate records of all drugs manufactured, received and sold. KRS 315.020(2) authorizes the Board to promulgate administrative regulations regarding the pharmacist-in-charge. This administrative regulation establishes the requirements for a manufacturer permit and for functioning as a manufacturer.

201 Ky. Admin. Regs. 2:320, 201 KY ADC 2:320

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:330

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:330. Emergency pharmacy powers

Section 1. If a pharmacist receives a request for a prescription refill with no refill authorized and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense an emergency refill of up to a thirty (30) day supply of the medication if:

(1) The Governor has issued an executive order as authorized by KRS 315.500 for the county where the pharmacy is located;

(2) The pharmacist obtains prescription information from:

(a) A prescription label;

(b) A prescription record within the pharmacy;

(c) A prescription record from another pharmacy;

(d) A common database;

(e) The patient; or

(f) Any other healthcare record;

(3) The prescription refill is not for a controlled substance;

(4) The prescription is for a maintenance medication;

(5) In the pharmacist's professional judgment, the interruption of therapy may produce undesirable consequences or may be detrimental to the patient's welfare and cause physical or mental discomfort; and

(6) The pharmacist notes on the prescription record the date, the quantity dispensed, and the pharmacist's

name or initials.

Section 2. (1) A pharmacy may temporarily relocate to and operate at a new location if:

(a) It is not safe or practicable to operate a pharmacy at the address listed on the permit; and

(b) The Governor has issued an executive order as authorized by KRS 315.500 for the county where the pharmacy is located.

(2) The pharmacy owner shall:

(a) Maintain confidentiality of patient records;

(b) Secure all drugs; and

(c) Notify the board of the temporary address as soon as practicable.

(3) The following regulatory requirements shall not apply for this temporary location:

(a) The requirement to maintain references as listed in 201 KAR 2:090, Section 1;

(b) The requirement to maintain equipment as listed in 201 KAR 2:090, Section 2; and

(c) The requirement that the pharmacy be enclosed by a floor to ceiling partition if it is located within a larger establishment which is open to the public for business when a pharmacist is not present.

Adopted effective October 20, 2010.

HISTORICAL NOTES

RELATES TO KRS 39A.100, 315.500

STATUTORY AUTHORITY: KRS 315.191, 315.505

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.500 establishes the conditions under which a pharmacy may operate temporarily in an area not designated on the pharmacy permit pursuant to an executive order issued by the Governor pursuant to KRS 39A.100. 315.191

201 KAR 2:330

authorizes the Board of Pharmacy to promulgate administrative regulations governing pharmacists and pharmacies. This administrative regulation sets out the conditions whereby a prescription may be refilled pursuant to an executive order issued by the Governor as authorized by KRS 315.500 when the prescriber is unavailable. This administrative regulation sets out the conditions whereby a pharmacy may operate temporarily in an area not designated on the pharmacy permit pursuant to an executive order issued by the Governor as authorized by KRS 315.500.

201 Ky. Admin. Regs. 2:330, 201 KY ADC 2:330

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:340

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:340. Special pharmacy permit for clinical practice

Section 1. Definition. “Special pharmacy permit for clinical practice” means a permit issued to a pharmacy that maintains patient records and other information for the purpose of engaging in the practice of pharmacy and does not dispense prescription drug orders.

Section 2. General Requirements. (1) An applicant for a special pharmacy permit for clinical practice shall:

(a) Prepare and adopt a policy and procedure manual that is updated annually;

(b) Maintain pharmacy references as outlined in 201 KAR 2:090;

(c) Maintain a physical pharmacy address;

(d) Designate a Pharmacist-in-Charge (PIC) without a required minimum number of hours of physical presence;

(e) Maintain patient records for five (5) years in a manner that shall provide adequate safeguard against improper manipulation or alteration of the records; a computer malfunction or data processing services' negligence is not a defense against the charges of improper recordkeeping; and

(f) Maintain patient records by establishing:

1. A patient record system to be maintained for patients for whom non-dispensing pharmacy services and functions are being performed;

2. A procedure for obtaining, recording, and maintaining information required for a patient record by a pharmacist, pharmacist intern, or pharmacy technician; and

3. A procedure for a patient record to be readily retrievable by manual or electronic means.

(2) An applicant for a special pharmacy permit for clinical practice shall be exempt from the following:

(a) Prescription equipment requirements of 201 KAR 2:090, Section 2;

(b) Pharmacy sanitation requirements of 201 KAR 2:180; and

(c) Security and control of drugs and prescriptions requirements of 201 KAR 2:100, Sections 1, 2, 3, and 4.

Section 3. Pharmacy Closure. The permit holder shall provide notification to the board thirty (30) days prior to permanent pharmacy closure.

Section 4. License Fees; Renewals. An applicant shall submit:

(1) An initial or renewal application for a special pharmacy permit for clinical practice on either the Application for Special Pharmacy Permit for Clinical Practice or the Application for Special Pharmacy Permit for Clinical Practice Renewal; and

(2) As appropriate, the:

(a) Initial application fee established by 201 KAR 2:050, Section 1(9); or

(b) Renewal application fee established by 201 KAR 2:050, Section 1(10).

Section 5. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) “Application for Special Pharmacy Permit for Clinical Practice” Form 1, 5/2012; and

(b) “Application for Special Pharmacy Permit for Clinical Practice Renewal” Form 2, 5/2012.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8:00 a.m. to 4:30 p.m.

Adopted effective September 19, 2012.

HISTORICAL NOTES

RELATES TO KRS 315.010(9), 315.020, 315.035, 315.191(1)(a)

201 KAR 2:340

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035 authorizes the Board of Pharmacy issue a permit to a pharmacy.KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for the permitting of those entities that provide non-dispensing pharmacy services. This administrative regulation establishes the requirements for the special pharmacy permit for clinical practice.

201 Ky. Admin. Regs. 2:340, 201 KY ADC 2:340

Current with amendments included in the Administrative Register of Kentucky, Volume 40, Number 8, dated February 1, 2014.

END OF DOCUMENT

201 KAR 2:350

Kentucky Administrative Regulations Currentness
Title **201**. General Government Cabinet
Chapter 2. **Board** of **Pharmacy**
201 KAR 2:350. Home medical equipment service providers

Section 1. General Requirements. (1) A home medical equipment company engaged in providing services in the Commonwealth shall apply for a license from the board in accordance with KRS 315.518 and this administrative regulation.

(2) An agent or employee of a licensee shall not be required to obtain a license if the agent or employee is acting in the usual course of business or employment.

(3) A license shall not be issued or renewed unless the applicant demonstrates or continues to demonstrate acceptable operational procedures, including:

(a) Adequate maintenance and storage conditions to ensure proper lighting, ventilation, temperature, and humidity control, sanitation, space, and security;

(b) Establishing and providing records of annual continuing education for personnel engaged in the delivery, maintenance, repair, cleaning, inventory control, and financial management of home medical equipment and services; and

(c) Providing accurate and precise records of all goods shipped or received including source of receipt, date, quantity, itemized description, and any other information pertinent to the transaction.

(4) An applicant for a home medical equipment license shall prepare and adopt a policy and procedure manual that sets forth a detailed description of how the:

(a) Operation will comply with applicable federal, state, or local laws or administrative regulations; and

(b) Licensees will maintain the premises so that the home medical equipment remains secure.

Section 2. Sanitation and Safety Requirements. (1) An applicant for a home medical equipment license located in the Commonwealth of Kentucky shall be inspected by the board prior to the issuance of the license.

(2)(a) The designated business area shall be used exclusively for the sale, rental, and distribution of home medical equipment.

(b) Repairs and cleaning shall be done in a confined, properly ventilated area.

(c) All areas shall be adequately lighted and all areas kept in a clean and sanitary manner.

(3) A home medical equipment supplier shall comply with the maintenance and cleaning requirements established in this subsection. A home medical equipment supplier shall:

(a) Maintain documents demonstrating that a function and safety check of equipment was performed prior to set up;

(b) Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;

(c) Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;

(d) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment;

(e) Clean and disinfect equipment according to manufacturer's specifications;

(f) Instruct the patient on proper cleaning techniques as specified by the manufacturer; and

(g) Perform routine inspection, service, and maintenance of equipment located in the patient's or customer's home according to manufacturers' specifications.

(4) The supplier's services shall be available twenty-four (24) hours, seven (7) days per week if it is essential to the maintenance of life or lack of service might reasonably cause harm.

(5) The supplier shall:

(a) Demonstrate that each piece of equipment has been checked, is free of defects, and operates within the manufacturer's specifications;

(b) Maintain documentation, which shall include the following:

1. The type of equipment;

2. The manufacturer;

3. The model number;

4. The serial number;

5. The date of repair;

6. The specific repair made; and

7. The name of the person or company performing the repair;

(c) Refrain from modifying equipment to the extent that the modification might reasonably cause harm;

(d) Maintain all electrical components so that they do not present fire or shock hazard;

(e) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided;

(f) Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated; and

(g) Affix an identifying label that contains the name of the provider, address, and phone number.

(6) The supplier shall implement and maintain a written procedure at each location for handling complaints and problems. The procedure shall include a complaint file documenting complaints and problems and resolution of the complaints and problems.

Section 3. License Fee; Renewals. (1) A home medical equipment and services provider shall be licensed by the board prior to engaging in providing home medical equipment and services in the Commonwealth.

(2) An applicant shall submit:

(a)1. A completed Application for Home Medical Equipment License; and

2. The initial application fee established by 201 KAR 2:050, Section 1(21); or

(b)1. A completed Application for Home Medical Equipment License Renewal; and

2. The renewal application fee established by 201 KAR 2:050, Section 1(22).

Section 4. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) “Application for Home Medical Equipment License” Form 1, 10/2012; and

(b) “Application for Home Medical Equipment License Renewal” Form 2, 10/2012.

(2) This form may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8:00 a.m. to 4:30 p.m.

Adopted effective February 1, 2013.

HISTORICAL NOTES

RELATES TO: KRS 315.512, 315.514, 315.518, 314.520

STATUTORY AUTHORITY: KRS 315.191, 315.518(1), (4), 315.520(4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191 authorizes the Board of Pharmacy to promulgate administrative regulations governing home medical equipment and service providers. This administrative regulation establishes the minimum requirements for the licensing of a home medical equipment service provider.

201 Ky. Admin. Regs. 2:350, 201 KY ADC 2:350

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