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

The proposed amended or rescinded, it will have a heading of proposed amendment or proposed rescission. Rules which are proposed to be amended will have new matter printed in boldface type and matter to be deleted placed in brackets.

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

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

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

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

Proposed Amendment Text Reminder: Boldface text indicates new matter. [Bracketed text indicates matter being deleted.]

[Title 4-DEPARTMENT OF ECONOMIC DEVELOPMENT] [Division 220-State Board of Pharmacy] Title 20-DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2220-State Board of Pharmacy Chapter 2-General Rules

PROPOSED AMENDMENT

[4 CSR 220-2.010] 20 CSR 2220-2.010 Pharmacy Standards of Operation. The board proposes to add section (9).

PURPOSE: This amendment sets forth minimum standards of practice for Class I: Consultant Pharmacies located within a residence. (9) Class I: Consultant Pharmacies as defined in 20 CSR 2220-2.020(9)(I) and are approved by the board to be located within a residence shall be required to address and comply with the following minimum standards of practice:

(A) Location Requirements—

1. The pharmacy must be located in a separate room that provides for a door with a lock approved by the board;

2. Sufficient storage for securing confidential documents and any hardware used in accessing a central pharmacy by electronic connection must be provided;

3. Ceiling and walls must be constructed of plaster, drywall, brick or other substantial substance that affords a design that makes the room separate and distinct from the remainder of the domicile. Drop down ceilings that allow access into the room are not allowed; and

4. All locations must be inspected and have approval by the board prior to the initiation of services;

(B) Documentation-

1. Maintain a current policy and procedure manual that is attested by the signature and date of review of the pharmacist-incharge to its accuracy. All pharmacists employed and located at the pharmacy shall be required to sign the manual attesting to their review and understanding of all policies and procedures in force;

2. Maintain documentation that the pharmacist-in-charge or the permit holder has provided training to all personnel on all operations associated with the pharmacy; and

3. The permit holder must complete an audit of transactions completed by the pharmacy at a minimum of twice per year, through physical visits by representatives of the permit holder or by electronic means. Audit results must be maintained by the supervising (central) pharmacy for a period of three (3) years;

(C) Security-Records-

1. All electronic data processing systems used by the pharmacy to access another pharmacy's confidential data/information system must be void of any permanent storage capability;

2. Electronic data processing hardware, if used to access another pharmacy's record system, must be dedicated to a specific Class I: Consultant Pharmacy location;

3. Any exterior ports located on hardware of a data processing system must be made inoperable;

4. There must be a password enabled screensaver for all electronic data processing systems and the screen of any systems must be positioned away from all room entrances; and

5. No electronic or hard copy records shall be maintained on a permanent basis;

(D) Security-Internet-

1. System sign-on capability shall include a sequence involving a secure identification of the user with proper virtual private network (VPN) authentication that creates an encrypted connection;

2. Passwords and secure identification (ID) tokens must be maintained in order to ensure access only by authorized personnel;

3. The electronic data system must provide for an automatic time-out after any short period (less than five (5) minutes) of inactivity. The system must then provide for a re-log on process when any time-out situation occurs;

4. The electronic data system must operate within a dedicated connection system. If electronic mail is utilized, the capability of the system shall be limited to only the receipt of electronic mail and;

5. Software that is utilized by the pharmacy shall maintain up-to-date virus and anti-spyware protection; and

(E) Licensure and Inspection-

1. Each location must maintain and display a current Class I pharmacy permit;

2. Routine inspections for in-state pharmacies shall be arranged ahead of time. Notification by the inspector to either the permit holder or the pharmacist-in-charge will be provided a minimum of seventy-two (72) hours ahead of the scheduled inspection. The permit holder must arrange for a separate witness to be present that is not a resident of the location under inspection;

3. A pharmacy located outside the state must maintain a pharmacist-in-charge with a current and active pharmacist license with the state of Missouri;

4. The audits required in paragraph (9)(B)3. shall be available and provided to the board when requested. Compliance with this paragraph requires requested records to be produced within seven (7) business days of the request; and

5. The pharmacy shall provide copies of inspections completed by the state in which they are located if such inspections are required within seven (7) business days of the inspection date.

AUTHORITY: sections 338.010, 338.140, 338.240 and 338.280, RSMo 2000 and 338.210, RSMo Supp. [2004] 2005. Original rule filed July 18, 1962, effective July 28, 1962. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 21, 2006.

PUBLIC COST: This proposed amendment will cost state agencies and political subdivisions approximately three thousand four hundred fifty-four dollars and fifty-one cents (\$3,454.51) annually for the life of the rule with a continuous annual increase of fifty-two dollars and twenty-six cents (\$52.26). Additionally, this proposed amendment will cost approximately two thousand six hundred eighty-seven dollars and fifteen cents (\$2,687.15) biennially for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE COST: The proposed amendment will cost private entities approximately eighteen thousand eight hundred ninety-four dollars and fifty cents (\$18,894.50) annually with a continuous annual increase of three hundred two dollars and eighty-nine cents (\$302.89) for the life of the rule. Additionally, this proposed amendment will cost private entities approximately thirty-seven thousand three hundred four dollars (\$37,304) biennially with a continuous biennial increase of one thousand ninety-two dollars and sixteen cents (\$1,092.16). It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

PUBLIC ENTITY FISCAL NOTE

I. RULE NUMBER

Title 4 -Department of Economic Development

Division 220 - Missouri Board of Pharmacy

Chapter 2 - General Rules

Proposed Amendment - 4 CSR 220-2.010 Pharmacy Standards of Operation

Prepared June 20, 2006 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Annual Cost of Compliance		
Missouri Board of Pharmacy	\$3,454.51		
Total Annual Cost of for the Life of th	+ · · , · · · ·		
a Continuous Annual Increa			

Affected Agency or Political Subdivision	1	ted Biennial Cost Compliance
Missouri Board of Pharmacy		\$2,687.15
Total Biennial Cost of for the L	f Compliance fe of the Rule	+-,

III. WORKSHEET

FIRST YEAR OF IMPLEMENTATION OF THE RULE

Based on FY06 actuals, 8 active pharmacies currently hold the Class I classification, or combination of Class I and other classifications. This amendment only affects those pharmacies with this classification. For purposes of this fiscal note, it is estimated that approximately 50 entities will apply for a pharmacy permit with this classification per year. The board anticipates an annual growth rate of 1% in the number of applications received annually.

The figures below represent the expense and equipment costs:

CLASSIFICATION	Fee Amount	Number in Class	AGGREGATE C	DST
Letterhead	\$0.15	50		\$7.50
Envelope for Mailing Correspondence	\$0.03	50		\$1.50
Postage for Mailing Correspondence	\$0.39	50		\$19.50
Printing and Mailing of License	\$0.32	50		\$16.00
	Total ern	ense and equi	nment costs	\$44.50

Total expense and equipment costs

The figures below represent the personal service costs:

STAFF	ANNUAL SALARY	INCLUDE FRINGE		COST PER MINUTE	COST PER APPLICATION	TOTAL COST
Licensure Technician I	\$20,904	BENEFIT \$31,124	\$14.96	<u><u><u></u></u></u>		PE(1.13
Pharmaceutical Consultant	\$73,836					
Executive Director	\$69,144					+-,+

Total personal service costs \$3,410.01

BIENNIAL EXPENSES

The figures below represent the expense and equipment costs for the renewal applications:

CLASSIFICATION	Fee Amount	Number in Class	AGGREGATE COST	
Letterhead	\$0.15	50		7.50
Envelope for Mailing Correspondence	\$0.03	50		1.50
Postage for Mailing Correspondence	\$0.39	50	\$1	9.50
Printing and Mailing of License	\$0.32	50	\$1	6.00
T TINKING UNV FRANKING VI FRANK	Total ave	ance and equi	inment costs \$4	4.50

Total expense and equipment costs

The figures below represent the personal service costs:

STAFF	ANNUAL SALARY	SALARY TO INCLUDE FRINGE BENEFIT		COST PER MINUTE	COST PER RENEWAL	TOTAL COST
Pharmaceutical Consultant	\$73,836	\$109,934	\$52.85	\$0.88	\$52.85	\$2,642.65
Thathaeeddical Consultate				Total pers	onal service costs	\$2,642.65

IV. ASSUMPTIONS

- 1. The division's central processing unit will process the renewal applications. No cost are being calculated for the processing of the 50 additional renewal applications as the board believes the additional cost will be minimal.
- 2. Employee's salaries were calculated using their annual salary multiplied by 48.89% for fringe benefits and then were divided by 2080 hours per year to determine the hourly salary. The hourly salary was then divided by 60 minutes to determine the cost per minute. The cost per minute was then multiplied by the amount of time individual staff spent on the processing of applications. The total cost was based on the cost per application multiplied by the estimated number of applications.
- 3. The board anticipates the staff will perform the following duties:

Licensure Technician I - Review and process applications, update division licensing system, preparing correspondence, set up inspection with pharmaceutical consultant, issue permit, mail license, and prepare documents for optical imaging. (45 minutes per application)

Pharmaceutical Consultant - conduct initial and routine follow up inspections. (1 hour for initial inspection/2 hours for routine inspections)

Executive Director - Review and approval of application. (5 minutes per application)

4. The total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

NOTE: The public fiscal note for this rule only reflects the cost for this particular process. However, private entity fees are set at an amount to cover the total actual cost incurred by the board, which includes personal service, expense and equipment and transfers.

PRIVATE ENTITY FISCAL NOTE

I. RULE NUMBER

Title 4 -Department of Economic Development

Division 220 - Missouri Board of Pharmacy

Chapter 2 - General Rules

Proposed Amendment - 4 CSR 220-2.010 Pharmacy Standards of Operation

Prepared June 20, 2006 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Annual Costs

Estimate the number of entities by class which would likely be affected by the adoption of the proposed amendment:	Classification by type of the business entities which would likely be affected:	Estimated annual cost of compliance with the amendment by affected entities:
50	Applicants (initial application @ \$250)	\$12,500.00
50	Applicants (notary @ \$2.50)	\$125.00
50	Applicants (postage @ \$.39)	\$19.50
50	Applicants (lock for door @ \$25)	\$1,250.00
50	Applicants (locking storage cabinet @ \$100)	\$5,000.00
	Estimated Annual Cost for the Life of the Rule with an Annual Growth Rate of \$302.89	\$18,894.50

Biennial Costs

Estimate the number of entities	Classification by type of the	Estimated biennial cost of compliance
by class which would likely be	business entities which would	with the amendment by affected
affected by the adoption of	likely be affected:	entities:
the proposed amendment:		
50	Licensees (renewal application @ \$400)	\$20,000.00
50	Licensees (biannual audit @ \$346.08)	\$17,304.00
	Estimated Biennial Cost for the Life of the Rule with a Continous Biennial Increase of \$1,092.16	\$37,304.00

III. WORKSHEET

See table above.

IV. ASSUMPTION

- 1. Based on FY06 actuals, 8 active pharmacies currently hold the Class I classification, or combination of Class I and other classifications. This amendment only affects those pharmacies with this classification. For purposes of this fiscal note, it is estimated that approximately 50 entities will apply for a pharmacy permit with this classification per year. The board anticipates an annual growth rate of 1% in the number of applications received annually.
- 2. In addition to initial application and biennial renewal costs, the applicant/permit holder may incur initial costs involving construction and/or remodeling of his residence to comply with the requirements of subsection (9)(A), which involves a locking door, ceiling and walls constructed of plaster, drywall, brick or other substantial substance. Construction and remodeling costs will vary depending on the size of the room, the pharmacy location (rural vs. metropolitan), union vs. non-union labor, cost of building materials, to what extent remodeling is required, etc., therefore, an aggregate amount is not be calculated in this fiscal note. However, for purposes of this fiscal note, it is estimated that a lock for a door will cost \$25, and construction costs to be an average of \$150 per square foot.
- 3. Paragraph (9)(B)(D) requires an audit of transactions completed by the pharmacy at least twice per year, therefore, for purposes of this fiscal note, it is estimated that an audit will require approximately two hours of work and will be conducted by a licensed pharmacist whose annual salary is approximately \$90,000 (\$90,000 / 2,080 work hours per year = \$43.27 per hour) = \$86.54 X 2 audits per year = \$173.08 per pharmacy per year for auditing.
- 4. Subsections (9)(C) and (9)(D) require acquisition and maintenance of a very protected network, multi-layer security system, an encrypted software system, and virus/spy ware software. The board is unable to estimate aggregate costs associated with these requirements because too many unknown factors are involved, too many variances in existing computer systems at pharmacies and what additionally would be required in order to comply with this amendment. Thus, the board is not able to provide an estimate of costs involved with this aspect of this amendment.
- 5. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.
- NOTE: The board is statutorily obligated to enforce and administer the provisions of Chapter 338, RSMo. Pursuant to Section 338.070, RSMo, the board shall by rule and regulation set the amount of fees authorized by Chapter 338, RSMo so that the revenue produced is sufficient, but not excessive, to cover the cost and expense to the board for administering the provisions of Chapter 338, RSMo.

[Title 4-DEPARTMENT OF ECONOMIC DEVELOPMENT] [Division 220-State Board of Pharmacy] Title 20-DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2220-State Board of Pharmacy Chapter 2-General Rules

PROPOSED AMENDMENT

[4 CSR 220-2.020] 20 CSR 2220-2.020 Pharmacy Permits. The board proposes to amend subsections (9)(D) and (9)(H) and add subsection (9)(K).

PURPOSE: This amendment clarifies the definition and criteria for the Class D Pharmacy classification and provides a definition for Class K: Internet pharmacies.

(9) The following classes of pharmacy permits or licenses are hereby established:

(D) Class D: Non-Sterile Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a non-sterile compounded product as defined in [4 CSR 220-2.400] **20** CSR 2220-2.400(1) [which comprises five percent (5%) or more of the annual prescription volume of the pharmacy;] and meets one (1) of the following criteria:

1. A product which will act systemically, regardless of the route of administration, and is prepared from bulk ingredients; or

2. Any product that is produced in a batch quantity as defined in 20 CSR 2220-2.400(3).

(H) Class H: Sterile Product Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a sterile pharmaceutical as defined in [4 CSR 220-2.200] 20 CSR 2220-2.200(11)(I) and (AA). Pharmacies providing sterile pharmaceuticals within the exemptions outlined in [4 CSR 220-2.200] 20 CSR 2220-2.200(25) shall not be considered a Class H pharmacy;

(I) Class I: Consultant. A location where any activity defined in section 338.010, RSMo is conducted, but which does not include the procurement, storage, possession or ownership of any drugs from the location; *[and]*

(J) Class J: Shared Service. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions/./; and

(K) Class K: Internet. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the receipt, review, preparation, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for any prescription originating from the Internet. A prescription must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000 [and 338.220, RSMo Supp. 2004]. Original rule filed July 18, 1962, effective July 28, 1962. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 21, 2006.

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

[Title 4-DEPARTMENT OF ECONOMIC DEVELOPMENT] [Division 220-State Board of Pharmacy] Title 20-DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2220-State Board of Pharmacy Chapter 2-General Rules

PROPOSED AMENDMENT

[4 CSR 220-2.025] 20 CSR 2220-2.025 Nonresident Pharmacies. The board is proposing to add a new section (2) and renumber sections thereafter.

PURPOSE: This amendment requires pharmacists at nonresident pharmacies to be licensed by the board if they have access to pharmacy databases of a pharmacy located in Missouri.

(2) When access to the pharmacy database of a pharmacy located within this state is made available, any pharmacist utilizing the database and to provide services as defined in section 338.010, RSMo must be licensed by the state of Missouri. As used in this section, access means the ability to retrieve, review and execute changes or edits to the permanent records of a licensed pharmacy located within the state of Missouri.

[(2)] (3) To obtain a license as a pharmacy, a nonresident pharmacy must comply with each of the following:

(A) Maintain a license in good standing from the state in which the nonresident pharmacy is located;

(B) Submit an application as provided by the Missouri Board of Pharmacy for licensure in compliance with [4 CSR 220-2.020] 20 CSR 2220-2.020(2) and (3);

(C) Pay all appropriate licensing fees;

(D) Submit a copy of the state pharmacy license from the state in which the nonresident pharmacy is located; and

(E) Submit a copy of the state and federal controlled substance registrations from the state in which it is located, if controlled substances are to be shipped into Missouri.

[(3)] (4) When requested to do so by the Missouri Board of Pharmacy, each nonresident pharmacy shall supply any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state in which it is located concerning the operation of a nonresident pharmacy for review of compliance with state and federal drug laws.

[(4)] (5) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state that licenses and regulates nonresident pharmacies for the purpose of investigating complaints against pharmacies located in Missouri or the sharing of information and investigative reports, as long as the other state will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and 338.220, RSMo Supp. [2001] 2005. Original rule filed Jan. 16, 1990, effective May 11, 1990. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed Aug. 21, 2006.

PUBLIC COST: This proposed amendment will cost state agencies and political subdivisions approximately five hundred fifty-five dollars and forty-four cents (\$555.44) annually for the life of the rule with a continuous annual increase of twenty-two dollars and twentyone cents (\$22.21). It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE COST: This proposed amendment will cost private entities approximately twenty-two thousand two hundred twenty-one dollars (\$22,221) annually for the life of rule. It is anticipated that the costs will recur annually for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

PUBLIC ENTITY FISCAL NOTE

I. RULE NUMBER

Title 4 -Department of Economic Development

Division 220 - Missouri Board of Pharmacy

Chapter 2 - General Rules

Proposed Amendment - 4 CSR 220-2.025 Nonresident Pharmacies

Prepared June 20, 2006 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Annual (of Compliance	
Missouri Board of Pharmacy	\$555.44	
Total Annual Cost of Compli Life of the Rule with a Continous Annual Increa		\$555.44

III. WORKSHEET

FIRST YEAR OF IMPLEMENTATION OF THE RULE

The figures below represent the expense and equipment costs:

CLASSIFICATION	Fee Amount	Number in	AGGREGATE COST
		Class	
Letterhead (2 sheets)	\$0.30	25	\$7.50
Envelope for Mailing Correspondence	\$0.03	25	\$0.75
Postage for Mailing Correspondence	\$0.39	25	\$9.75
Printing and Mailing of Permit/License	\$0.64	25	\$16.00
	Total exp	ense and equ	lipment costs \$34.00

Total expense and equipment costs

The figures below represent the personal service costs:

STAFF	ANNUAL SALARY	SALARY TO INCLUDE FRINGE BENEFIT		COST PER MINUTE	COST PER APPLICATION	TOTAL COST
Licensure Technician I	\$23,376	\$34,805	\$16.73	\$0.28	\$16.73	\$418.32
Executive Director	\$69,144	\$102,949	\$49.49	\$0.82	\$4.12	\$103.11
	· · · · · · · ·			Total pers	onal service costs	\$521.44

IV. ASSUMPTIONS

- 1. Based on FY03-FY06 actuals, the board estimates approximately 25 applications will be will received during the first year of implementation of the rule with a continue annual growth rate of 1 application.
- 2. Employee's salaries were calculated using their annual salary multiplied by 48.89% for fringe benefits and then were divided by 2080 hours per year to determine the hourly salary. The hourly salary was then divided by 60 minutes to determine the cost per minute. The cost per minute was then multiplied by the amount of time individual staff spent on the processing of applications. The total cost was based on the cost per application multiplied by the estimated number of applications.

3. The board anticipates the staff will perform the following duties:

Licensure Technician I - Review and process licensure application; prepare and mail acknowledgement letter to applicant; update division's licensing system; monitor and process receipt and return of fax from/to national association which requests approval for the applicant to test; monitor and process receipt of examination score via internet; issue temporary license; issue and mail original license.(1 hour per application)

Executive Director - Review and approval of application. (5 minutes per application)

4. The total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

NOTE: The public fiscal note for this rule only reflects the cost for this particular process. However, private entity fees are set at an amount to cover the total actual cost incurred by the board, which includes personal service, expense and equipment and transfers.

PRIVATE ENTITY FISCAL NOTE

1. RULE NUMBER

Title 4 -Department of Economic Development

Division 220 - Missouri Board of Pharmacy

Chapter 2 - General Rules

Proposed Amendment - 4 CSR 220-2.025 Nonresident Pharmacies

Prepared June 20, 2006 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Annual Costs

Estimate the number of entities by class which would likely be affected by the adoption of the proposed amendment;	Classification by type of the business entitles which would likely be affected:	Estimated annual cost of compliance with the amendment by affected entities:
25	Applicants (National Association Preliminary Application Form @ \$300)	\$7,500.00
25	Applicants (National Association Registration Fee @ \$185)	\$4,625.00
25	Applicants (National Association Finalized Application Fee @ \$350)	\$8,750.00
25	Applicants (Identix Fingerprinting Service Fee @ \$50.95)	\$1,273.75
25	Applicants (notary @ \$2.50)	\$62.50
25	Applicants (postage @ \$.39)	\$9.75
	Estimated Annual Cost for the Life of the Rule	\$22,221.00

III. WORKSHEET

See table above.

IV. ASSUMPTION

- 1. For the purpose of this fiscal note, the board is estimating 25 applications will be received annually.
- 2. The various fees estimated above are paid directly to the board, the national association and Identix.
- 3. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.
- NOTE: The board is statutorily obligated to enforce and administer the provisions of Chapter 338, RSMo. Pursuant to Section 338.070, RSMo, the board shall by rule and regulation set the amount of fees authorized by Chapter 338, RSMo so that the revenue produced is sufficient, but not excessive, to cover the cost and expense to the board for administering the provisions of Chapter 338, RSMo.

[Title 4-DEPARTMENT OF ECONOMIC DEVELOPMENT] [Division 220-State Board of Pharmacy] Title 20-DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2220-State Board of Pharmacy Chapter 2-General Rules

PROPOSED AMENDMENT

[4 CSR 220-2.190] 20 CSR 2220-2.190 Patient Counseling. The board is proposing to amend section (1).

PURPOSE: This amendment establishes patient counseling requirements when an automated dispensing machine is used to provide medication to patients.

(1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist's immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained. If the patient or caregiver is not available, then a written offer to counsel with a telephone number of the dispensing pharmacy at no cost to the patient must be supplied with the medication so that the patient or caregiver may contact the pharmacist for counseling when necessary. In situations where automated pick-up systems are used for providing refill prescriptions to patients, the offer to counsel may be provided within the information provided by the kiosk to the patient during the processing phase prior to release of the medication to the patient. The elements of counseling shall include matters which the pharmacist deems significant in the exercise of his/her professional judgment and is consistent with applicable state laws.

AUTHORITY: sections [338.010.1 and 338.015.2, RSMo Supp. 1990,] 338.140 [Supp. 1989] and 338.280, RSMo [1986] 2000. Original rule filed May 1, 1992, effective Feb. 26, 1993. Amended: Filed March 4, 1993, effective Oct. 10, 1993. Amended: Filed Aug. 21, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

[Title 4-DEPARTMENT OF ECONOMIC DEVELOPMENT] [Division 220-State Board of Pharmacy] Title 20-DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2220-State Board of Pharmacy Chapter 2-General Rules

PROPOSED AMENDMENT

[4 CSR 220-2.450] 20 CSR 2220-2.450 Fingerprint Requirements. The board is proposing to add subsection (1)(G), delete section (2), renumber remaining sections, and amend the newly renumbered section (4).

PURPOSE: This amendment requires owners of drug distributors to provide criminal history background information to the board.

(1) Applicants for licensure or registration that must provide fingerprints to the Board of Pharmacy shall include:

(E) Drug distributor license manager-in-charge (unless currently licensed as a pharmacist in the state of Missouri); *[and]*

(F) Pharmacy technician/./; and

(G) Owners with a ten percent (10%) or more interest in a drug distributor entity (applying to non-publicly held companies only).

[(2) No application shall be considered complete without two (2) sets of fingerprints and the required fingerprinting fee.]

[(3)] (2) Information collected under this background review will be held as confidential in accordance with state and federal laws governing the dissemination of criminal history information.

[(4)] (3) Any application which is found to contain incomplete, inaccurate or false statements shall be deemed null and void. Any license or registration issued under such circumstances shall be considered a license or registration issued under the pretense of fraud, deception or misrepresentation and the board may file a complaint with the Administrative Hearing Commission to revoke or discipline the license or registration.

[(5)] (4) The board may, in the course of an investigation of a licensee, require that [two (2) sets of] fingerprints be submitted for a background check as provided for in this rule.

AUTHORITY: sections [338.185 and] 338.280 [RSMo 1994] and [338.013,] 338.140 [and 338.350], RSMo [Supp. 1997] **2000**. Original rule filed Jan. 6, 1997, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Amended: Filed Aug. 21, 2006.

PUBLIC COST: This proposed amendment will cost state agencies and political subdivisions approximately three hundred forty-five dollars and sixty-seven cents (\$345.67) annually for the life of the rule with a continuous annual increase of twenty-two dollars and twentyone cents (\$22.21). It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE COST: This proposed amendment will cost private entities approximately five thousand ninety-five dollars (\$5,095) for the life of rule with a continuous annual increase of five hundred nine dollars and fifty cents (\$509.50). It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

PUBLIC ENTITY FISCAL NOTE

I. RULE NUMBER

Title 4 -Department of Economic Development

Division 220 - Missouri Board of Pharmacy

Chapter 2 - General Rules

Proposed Amendment - 4 CSR 220-2.450 Fingerprinting Requirements

Prepared June 20, 2006 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Annual Cost	
	of Q	Compliance
Missouri Board of Pharmacy		\$345.67
Total Annual Cost of Compliance for the Life of the Rule with a Continous Annual Increase of \$22.21		

III. WORKSHEET

FIRST YEAR OF IMPLEMENTATION OF THE RULE

The board is unable to specifically determine the number of applicants that this rule amendment will impact; however, an estimate of approximately 50 non-publicly held drug distributor applications to be received per year.

STAFF	ANNUAL	SALARY TO	HOURLY	COST PER	COST PER	TOTAL COST
	SALARY	INCLUDE FRINGE BENEFIT	SALARY	MINUTE	APPLICATION	
Licensure Technician I	\$23,376	\$34,805	\$16.73	\$0.28	\$2.79	\$139.44
Executive Director	\$69,144	\$102,949	\$49.49	\$0.82	\$4.12	\$206.23
				Total pers	onal service costs	\$345.67

The figures below represent the personal service costs:

IV. ASSUMPTIONS

- 1. Based on FY03-FY06 actuals, the board estimates approximately 50 applications will be will received annually.
- 2. Employee's salaries were calculated using their annual salary multiplied by 48.89% for fringe benefits and then were divided by 2080 hours per year to determine the hourly salary. The hourly salary was then divided by 60 minutes to determine the cost per minute. The cost per minute was then multiplied by the amount of time individual staff spent on the processing of applications. The total cost was based on the cost per application multiplied by the estimated number of applications.
- 3. The board anticipates the staff will perform the following duties:

Licensure Technician I - Review and process drug distributor licensure application; and issue and mail license (10 minutes)

Executive Director - Review and approval of application. (5 minutes per application)

4. The total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

NOTE: The public fiscal note for this rule only reflects the cost for this particular process. However, private entity fees are set at an amount to cover the total actual cost incurred by the board, which includes personal service, expense and equipment and transfers.

PRIVATE ENTITY FISCAL NOTE

I. RULE NUMBER

Title 4 -Department of Economic Development

Division 220 - Missouri Board of Pharmacy

Chapter 2 - General Rules

Proposed Amendment - 4 CSR 220-2.450 Fingerprinting Requirements

Prepared June 20, 2006 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Estimate the number of entities	Classification by type of the	Estimated annual cost of compliance
by class which would likely be	business entities which would	with the amendment by affected
affected by the adoption of	likely be affected:	entities:
the proposed amendment:		
100	Licensees	\$5,095.00
	(Identix Fingerprinting Fee @ \$50.95)	
	Estimated Annual Cost for the Life	\$5,095.00
	of the Rule with a Continuous	
	Annual Increase of \$509.50	

III. WORKSHEET

See table above.

IV. ASSUMPTION

- 1. For the purpose of this fiscal note, the board estimates approximately 50 non-publicly held drug distributor applications will received per year and an average of two (2) owners per application twill incur an Identix fingerprinting fee of \$50.95. The board anticipates a continuous growth rate of 10%.
- 2. The fees estimated above are paid directly Identix. Applicants are required to schedule an appointment with Identix to be fingerprinted. Due to the varying locations of the Identix office and the location of the application, costs were not calculated in this fiscal note for travel expenses.
- 3. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

[Title 4-DEPARTMENT OF ECONOMIC DEVELOPMENT] [Division 220-State Board of Pharmacy] Title 20-DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2220-State Board of Pharmacy Chapter 2-General Rules

PROPOSED AMENDMENT

[4 CSR 220-2.900] 20 CSR 2220-2.900 Automated Dispensing and Storage Systems. The board is proposing to amend sections (1) and (2).

PURPOSE: This amendment provides guidelines for automated refill patient self-service devices.

(1) Automated dispensing and storage systems (hereafter referred to as automated system or system) are hereby defined to include, but are not limited to, mechanical systems that perform operations or activities, relative to the storage, packaging or dispensing of medications, and which collect, control, and maintain all transaction information. Such systems may be used in pharmacies and where a pharmacy permit exists, for maintaining patient care unit medication inventories or for a patient profile dispensing system, provided the utilization of such devices is under the supervision of a pharmacist. A pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist. In order to supervise the system within an ambulatory care setting, the pharmacist must maintain constant visual and auditory communication with the site and full control of the automated system must be maintained by the pharmacist and shall not be delegated to any other person or entity. Supervision of an automated refill patient self-service device requires that a pharmacist employed by the pharmacy by which the device is owned and operated be available at all times during operating hours of the pharmacy or telephonically after hours to fulfill any patient counseling as required by law.

(E) Automated systems shall maintain adequate security systems and procedures to prevent unauthorized access or use and shall at all times maintain compliance with all state and federal drug laws including all controlled substance requirements and patient confidentiality laws.

1. Any remote automated system that stocks controlled substances must maintain a perpetual inventory from each site.

2. Automated systems in ambulatory care settings must be located in an area that will provide adequate space for private consultations to occur and must only be installed within the same area utilized by the prescriber for the provision of clinical services.

3. Automated refill patient self-service devices must be physically attached to the pharmacy so that access to areas used to restock the device are only accessible through the pharmacy physical plant by pharmacy personnel.

(J) Drugs that are repackaged for use in automated systems at remote locations must comply with [4 CSR 220-2.130] 20 CSR 2220-2.130 Drug Repackaging requirements. Automated refill patient self-service devices must comply with all labeling and dispensing laws governing the provision of medication refills to patients. Products that are considered temperature sensitive or products that require further manipulation in order to be ready for use by a patient shall not be provided through patient self-service devices, unless the device has the capability to provide storage conditions in compliance with Federal Drug Administration (FDA) requirements.

(K) If an automated system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers must occur at the pharmacy where the original inventory is maintained unless provided by a *[Federal Drug Administration (FDA)]* **FDA** approved repackager and who is licensed as a drug distributor. The prepackaged cartridges or containers may be sent to the automated system **at remote locations** to be loaded into the machine by registered technicians under the supervision of a pharmacist or by a pharmacist provided that—

1. A pharmacist has verified the container has been properly filled and labeled;

2. The individual containers are transported to the automated system in a secure, tamper-evident container; and

3. The automated system utilizes technologies to ensure that the containers are accurately loaded in the automated system.

(L) Any pharmacy that maintains an automated system for remote dispensing to ambulatory patients must maintain a video camera and audio system to provide for effective communication between pharmacy personnel and consumers. It must be a system that will allow for the appropriate exchange of oral as well as written communications to facilitate patient counseling as provided in [4 CSR 220-2.190] 20 CSR 2220-2.190 and other matters involved in the correct transaction or provision of drugs.

1. Video monitors used for the proper identification and communication with persons receiving prescription drugs shall be a minimum of twelve inches (12") wide and provided at both the pharmacy and remote location for direct visual contact between pharmacist and patient.

2. Both the video monitor and the audio system must be in good working order or operations utilizing the automated system shall cease until appropriate corrections or repairs are made to the system(s).

3. Backlighting or other factors that may inhibit video or audio performance must be taken into account when using such systems to identify recipients of prescription drugs. Positive identification of recipients must be made before any drug is delivered.

(2) Each automated system shall maintain a manual of policies and procedures that, at a minimum, shall include the following:

(A) System operations that include specific and measurable accountability for safety, security, accuracy, patient confidentiality, access, data retention and retrieval, downtime procedures, emergency *[or]* first dose **or refill patient self-service** procedures, inspection of systems by pharmacy personnel, installation requirements, maintenance, medication security, quality assurance, inventory levels and control, staff education and training and system set-up and malfunction.

(B) Documentation by the automated system **at remote locations** for on-site patient administration and remote dispensing of medications that includes specific identification of patients, medications used along with dates and times the system is utilized.

AUTHORITY: sections 338.210 and 338.220, RSMo Supp. [2002] 2005 and 338.140 and 338.280, RSMo 2000. Original rule filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed Feb. 18, 2003, effective Sept. 30, 2003. Amended: Filed Aug. 21, 2006.

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

PRIVATE COST: This proposed amendment will cost private entities approximately seven hundred fifty thousand dollars (\$750,000) for the life of the rule with a continuous annual increase of thirty thousand dollars (\$30,000). It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee. NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

PRIVATE ENTITY FISCAL NOTE

I. RULE NUMBER

Title 4 -Department of Economic Development

Division 220 - Missouri Board of Pharmacy

Chapter 2 - General Rules

Proposed Amendment - 4 CSR 220-2.900 Automated Dispensing and Storage Systems

Prepared June 20, 2006 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Annual Costs

Estimate the number of entities by class which would likely be affected by the adoption of the proposed amendment:	Classification by type of the business entities which would likely be affected:	Estimated annual cost of compliance with the amendment by affected entities:
50	Licensees (Automated Dispensing Machine @ \$15,000)	\$750,000
	Annual Cost During the First Year of nation of the Rule with a Continuous Annual Increase of \$30,000	\$750,000

III. WORKSHEET

See table above.

IV. ASSUMPTION

- Automated dispensing systems are available for purchase by the pharmacy, but the decision is up to the pharmacy permit holder to determine whether the pharmacy will use this method for dispensing. The board cannot accurately determine how many of the approximate 1,257 pharmacies will elect to purchase this new type of system for their pharmacy setting at a cost of approximately \$15,000 per unit. However, for the purpose of this fiscal note, the board estimates that approximately 4% of the pharmacies (approx. 50) will purchase and utilize such a system in the first year. Thereafter, the board estimates that approximately 2 pharmacies will annually purchase the system.
- 2. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

[Title 4-DEPARTMENT OF ECONOMIC DEVELOPMENT] [Division 220-State Board of Pharmacy] Title 20-DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2220-State Board of Pharmacy Chapter 5-Drug Distributor

PROPOSED AMENDMENT

[4 CSR 220-5.020] 20 CSR 2220-5.020 Drug Distributor Licensing Requirements. The board is proposing to amend subsection (4)(F) and add section (9).

PURPOSE: This amendment requires drug distributor managers-incharge to provide the board with employment history and requires out-of-state drug distributors to designate a registered agent in Missouri for service of process purposes.

(4) Drug distributor license applications and renewal applications shall be completed and submitted to the Board of Pharmacy along with the appropriate fees before any license is issued or renewed. Information required on the application shall include:

(F) The name of the manager in charge who meets the requirements as set forth in [4 CSR 220-5.030(2) and completes the] 20 CSR 2220-5.030(2); a complete notarized manager-in-charge affidavit of the license application [and has it notarized]; and a history of employment/occupations and offices held during the past seven (7) years; and

(9) Each licensed corporate wholesale distributor located outside of this state that distributes drugs in this state shall designate a registered agent in this state for service of process. Any licensed corporate wholesale distributor that does not designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal process in any action or proceeding against any licensed corporate wholesale distributor growing out of or arising from such distribution. Service of process shall be accomplished as authorized by law.

AUTHORITY: sections 338.330, 338.333, 338.335, 338.337, 338.340 and 338.350, RSMo 2000. Original rule filed Feb. 4, 1991, effective June 10, 1991. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 21, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

[Title 4-DEPARTMENT OF ECONOMIC DEVELOPMENT] [Division 220-State Board of Pharmacy] Title 20-DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2220-State Board of Pharmacy Chapter 5-Drug Distributor

PROPOSED AMENDMENT

[4 CSR 220-5.030] 20 CSR 2220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors. The board is amending subsections (2)(A), (2)(E), (3)(M) and (3)(O).

PURPOSE: This amendment adds language which requires a drug distributor manager-in-charge to be present and involved in the daily operation of the facility; requires procedures for record keeping, investigating and reporting counterfeit or suspected counterfeit drugs/devices to the board and other federal/state agencies; and prohibits issuance of a drug distributor license to a location that is a residence.

(2) No drug distributor license will be issued unless the facility is under the direct supervision of a manager-in-charge.

(A) The board shall consider the same factors in reviewing the qualifications of someone who is appointed as a manager-in-charge as those outlined in [4 CSR 220-5.020] 20 CSR 2220-5.020(8)(A)1.

(E) Drug distributor operations must be conducted at all times under the supervision of a properly designated manager-in-charge. **The manager-in-charge must be actively involved and aware of the actual daily operations of the drug distributor operation. The manager-in-charge must be physically present at the drug distributor operation during normal business hours, except for time periods when absent due to illness, scheduled vacation or other authorized absence; and be aware of, and knowledgeable about, all polices and procedures pertaining to the operations of the drug distributor operation.** When the person who is managerin-charge resigns or is terminated from the position, the holder of the license shall immediately notify the board office of the resignation or **termination of the manager-in-charge and by notarized affidavit give** the name of the new manager-in-charge.

(3) Minimum standards of practice for drug distributors shall include the following:

(M) Wholesale drug and pharmacy 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 for correcting all errors and inaccuracies in inventories. Drug distributors shall include in their written policies and procedures the following:

1. A procedure where the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

2. A procedure to be followed for handling recalls and withdrawals of prescription drugs. This procedure shall be adequate to deal with recalls and withdrawals due to any—

A. Action initiated at the request of the FDA or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

B. Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

C. Action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

3. A procedure to ensure that drug distributors prepare for, protect against and handle any crisis that affects the security or operation of any facility in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency; [and]

4. A procedure for reporting counterfeit or suspected counterfeit drugs or devices or counterfeiting or suspected counterfeiting activities to the board;

5. A procedure for the mandatory reporting to the board and any other appropriate federal or state agency of all shortages of prescription drugs and devices where it is known or suspected that diversion or theft is occurring;

6. A procedure for investigating discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband in the inventory and reporting such discrepancies within three (3) business days to the board and any other appropriate federal or state agency shall be maintained by each drug distributor;

7. A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) and device(s) to the board within the three (3) business days; and

[4.]8. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for three (3) years after disposition of the outdated drugs;

(O) No drug distributor license shall be issued to any location, regardless of zoning, **that is a residence or** that shares an address and/or physical space with a business not related to the distribution of prescription drugs or drug-related devices, or not licensed and regulated by the state of Missouri.

AUTHORITY: sections 338.333, 338.343 and 338.350, RSMo 2000. Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Amended: Filed Aug. 21, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

[Title 4-DEPARTMENT OF ECONOMIC DEVELOPMENT] [Division 232-Missouri State Committee of Interpreters] Title 20-DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION Division 2232-Missouri State Committee of Interpreters Chapter 2-Licensure Requirements

PROPOSED RULE

[4 CSR 232-2.040] 20 CSR 2232-2.040 Certifications Recognized by the Board

PURPOSE: This rule allows applicants with certain national certifications to become licensed in Missouri.

(1) In addition to the certificates specified in section 209.322, RSMo, the following licenses and certifications are recognized as qualifying credentials for an initial license, renewal license or temporary license:

(A) Certification issued by the National Association of the Deaf (NAD) and the Registry of Interpreters for the Deaf, Inc. (RID), doing business as NAD-RID National Interpreter Certification, c/o RID, Inc., 333 Commerce Street, Alexandria, VA 22314, as follows:

- 1. National Interpreter Certification (NIC);
- 2. NIC Advanced; and
- 3. NIC Master.

AUTHORITY: section 209.328.2(3), RSMo 2000. Emergency rule filed Aug. 22, 2006, effective Sept. 1, 2006, expires Feb. 27, 2007. Original rule filed Aug. 22, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support or in opposition to this proposed rule with the Missouri State Committee of Interpreters, Pamela Groose, Executive Director, PO Box 1335, Jefferson City, MO 65102, by facsimile to (573) 526-3489, or by email at Interpreters@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Title 9—DEPARTMENT OF MENTAL HEALTH Division 10—Director, Department of Mental Health Chapter 7—Core Rules for Psychiatric and Substance Abuse Programs

PROPOSED AMENDMENT

9 CSR 10-7.140 Definitions. The director is amending subsection (2)(RR).

PURPOSE: The purpose of this amendment is to modify the definition of qualified substance abuse professional to require certification or registration by the Missouri Substance Abuse Counselors' Certification Board, Inc. for all substance abuse professionals that do not meet the definition of qualified mental health professional.

(2) Unless the context clearly indicates otherwise, the following terms shall mean:

(RR) Qualified substance abuse professional, a person who demonstrates substantial knowledge and skill regarding substance abuse by being either—

[1. A counselor, psychologist, social worker or physician licensed in Missouri who has at least one (1) year of full-time experience in the treatment or rehabilitation of substance abuse;

2. A graduate of an accredited college or university with a master's degree in social work, counseling, psychology, psychiatric nursing or closely related field who has at least two (2) years of full-time experience in the treatment or rehabilitation of substance abuse;

3. A graduate of an accredited college or university with a bachelor's degree in social work, counseling, psychology or closely related field who has at least three (3) years of full-time experience in the treatment or rehabilitation of substance abuse; or

4. An alcohol, drug or substance abuse counselor certified by the Missouri Substance Abuse Counselors Certification Board, Inc;] **1.** A physician or qualified mental health professional licensed in Missouri with at least one (1) year of full-time experience in treatment of persons with substance use disorders; or

2. A person certified or registered by the Missouri Substance Abuse Counselors' Certification Board, Inc.;

AUTHORITY: sections 630.050 and 630.055, RSMo 2000. Original rule filed Feb. 28, 2001, effective Oct. 30, 2001. Amended: Filed April 15, 2002, effective Nov. 30, 2002. Amended: Filed Aug. 31, 2006.

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

PRIVATE COST: This proposed amendment will cost private entities seventy-seven thousand five hundred dollars (\$77,500) in the aggregate for initial registration in the first year. This proposed amendment will cost private entities two hundred eight thousand seven hundred dollars (\$208,700) in the aggregate for renewal and continuing education in the second year. This proposed amendment will cost private entities one hundred sixty-one thousand two hundred dollars (\$161,200) in the aggregate annually for biennial renewal and continuing education in the third year and future years.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment by writing to Terry Morris, Division of Alcohol and Drug Abuse, PO Box 687, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Fiscal Note Private Entity Cost

I. Rule Number and Name: 9 CSR 10-7.140 Definitions

Type of Rulemaking: Proposed Amendment

II. **SUMMARY OF FISCAL IMPACT.** Present a summary of the fiscal impact. If the proposed rulemaking will affect more than one category of business, use one row for each category. In the first row, fill in the estimated number of business in the first category. In the second column, fill in the type of business in the category. In the third column, fill in the aggregate cost (over the life of the rule) to all businesses in this category.

Estimate of the number of entities by class which would likely be affected by the adopting of the proposed rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
All	Qualified Substance Abuse Counselors (QSAC)	\$77,500 (initial registration year one)
All	Qualified Substance Abuse Counselors (QSAC)	\$208,700 (first year renewal year two)
All	Qualified Substance Abuse Counselors (QSAC)	\$161,200 (on-going annual cost year three and future years)

III. WORKSHEET. (Present more detailed fiscal information.)

Year one (Fiscal Year 2007) this rule will require approximately 500 substance abuse counselors to become certified or registered at a cost of \$155 to either the individual counselor or provider. (500 * \$155 = total cost \$77,500.)

Year two (Fiscal Year 2008) this rule will require approximately 500 substance abuse counselors to renew their certification or registration at a cost of \$190 to either the individual counselor or provider. This renewal will expire April 30, 2008. $(500 * $190 = \cos t of $95,000)$ Subsequent renewals will be for two year periods. In addition in order to renew, each counselor will be required to have 30 hours of continuing education units (c.e.u.). The estimated cost for each hour of c.e.u. is \$7.58. $(500 * 30 * $7.58 = \cos t of $113,700)$ Total cost year 2 (\$95,000 + \$113,700 = total cost \$208,700). Year three (Fiscal Year 2009) and beyond for the life of this rule will require renewals for two year periods, costs will be calculated on an estimated annual basis. For each 2 year renewal each counselor will be required to have 60 units of c.e.u. over the two year period. Annualized cost estimate for c.e.u. (\$7.58 * 30 * 500 = \$113,700). Total estimated annualized cost year for 3 and beyond (\$47,500 + \$113,700 = total cost \$113,700 = total cost \$113,700 = total cost \$113,700 = total cost \$100 / 2) = \$47,500. Annualized cost year for 3 and beyond (\$47,500 + \$113,700 = total cost \$113,700 = total cost \$113,700 = total cost \$113,700 = total cost \$100 / 2) = \$47,500. Annualized cost year for 3 and beyond (\$47,500 + \$113,700 = total cost \$113,700 = total cost \$161,200).

The amendment will require current qualified substance abuse professionals not licensed as a physician, mental health professional or certified by the Missouri Substance Abuse Counselors' Certification Board to have their education and experience approved by the Missouri Substance Abuse Counselors' Certification Board. Those individuals approved by the Missouri Substance Abuse Counselors' Certification Board will be designated as registered substance abuse professionals and meeting the Division's criteria for qualified substance abuse professional. The Division reimburses only qualified substance abuse professionals to perform certain key service functions.

IV. ASSUMPTIONS AND METHODOLOGY. (Present assumptions, references and methods of acquiring information that underlie the conclusions in the fiscal note. Examples of information that might be included here are the sources of information presented in the fiscal note, why those sources were chosen and eventualities that might cause the fiscal impact to be different from your estimate.)

The Department of Mental Health estimates that 500 QSAC will be required to certify or register with the Missouri Substance Abuse Counselors' Certification Board. The QSAC will also be required to renew the certification or registration every other year. The estimated annualized cost of renewal is (190*.5*500 =) \$47,500.

The average cost of c.e.u. was calculated by taking the cost of the ADA Spring Seminar (\$125) and dividing it by the number of c.e.u. that can be earned (16.5). \$125/16.5 = \$7.58. The estimated annualized cost of c.e.u. is (\$7.58*30*500 =) \$113,700.

Total annualized cost \$47,500 + \$113,700 = \$161,200.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 5—Conduct of Gaming

PROPOSED AMENDMENT

11 CSR 45-5.180 Tournament Chips and Tournaments. The commission is amending section (3).

PURPOSE: This rule is being amended to clarify entry fees and allowed adjustments to adjusted gross receipts.

(3) As used in this rule, entry fees shall be defined as the total amount paid by a person or on a person's behalf for participation in a tournament. [a]A tournament is a contest offered and sponsored by a Class A licensee in which patrons may be assessed an entry fee or be required to meet some other criteria to compete against one another in a gambling game or series of gambling games in which winning patrons receive[d] a portion or all of the entry fees, if any, which may be increased with cash or non-cash prizes from the Class A licensee. Class A licensees may conduct tournaments provided:

(F) Entry fees shall be subject to the adjusted gross receipts tax pursuant to section 313.822, RSMo. Entry fees shall be considered as buy-in except when paid with chips, tokens, or a ticket[;]. At least eighty percent (80%) of all entry fees must be returned to tournament participants as winnings;

(G) Cash and non-cash [W]/winnings paid in a [free] tournament shall [not] be deductible from adjusted gross revenue, but any such deduction shall not exceed the total entry fees received for the tournament and non-cash winnings shall be deductible only to the dollar value thereof actually invoiced to and paid by the licensee; and

AUTHORITY: sections 313.004, 313.805, 313.807 and 313.817, RSMo 2000. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Amended: Filed Nov. 10, 1997, effective June 30, 1998. Amended: Filed May 6, 1999, effective Dec. 30, 1999. Amended: Filed July 9, 2004, effective Jan. 30, 2005. Amended: Filed June 30, 2005, effective Jan. 30, 2006. Amended: Filed Aug. 30, 2006.

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

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

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for 10:00 a.m. on November 7, 2006, in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 5—Conduct of Gaming

PROPOSED AMENDMENT

11 CSR 45-5.190 Minimum Standards for Electronic Gaming Devices. The commission is amending subsection (2)(I) and adding section (4).

PURPOSE: This rule is being amended to require pay glass and its corresponding artwork for mechanical displays for game theme variations be submitted for approval and to require adherence to requirements set forth in minimum internal control standards.

(2) Electronic gaming devices shall-

(I) Clearly and accurately display applicable rules of play and the award that will be paid to the player when the player obtains a specific win, including mystery awards. The displays shall clearly indicate whether awards are designated in denominational units, currency, credits or some other unit. All paytable information must be able to be accessed by a player prior to the player committing to a wager. Pay glass and its corresponding artwork for mechanical displays must be submitted to an independent testing laboratory designated by the commission for review and approval prior to implementation within the state;

(4) In addition to the requirements of this rule, all licensees shall comply with Chapter E of the Minimum Internal Control Standards as authorized by 11 CSR 45-9.030.

AUTHORITY: sections 313.004, 313.800 and 313.805, RSMo 2000. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Amended: Filed June 25, 1996, effective Feb. 28, 1997. Amended: Filed May 13, 1998, effective Oct. 30, 1998. Amended: Filed March 31, 2005, effective Oct. 30, 2005. Amended: Filed Aug. 30, 2006.

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

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

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for 10:00 a.m. on November 7, 2006, in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 5—Conduct of Gaming

PROPOSED AMENDMENT

11 CSR 45-5.200 Progressive Slot Machines. The commission is amending subsection (5)(C).

PURPOSE: This amendment allows required logs to be maintained electronically.

(5) The operation of wide-area progressive slot machines is allowed subject to compliance with all other requirements of this rule, in addition to the following conditions:

(C) The licensee authorized to provide a wide-area system must keep a hard **or electronic** copy log of all events for a period of at least sixty (60) days;

AUTHORITY: sections 313.004, 313.800 and 313.805, RSMo 2000. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 30, 2006.

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

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

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for 10:00 a.m. on November 7, 2006, in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 11—Taxation Regulations

PROPOSED AMENDMENT

11 CSR 45-11.040 Return—Gaming Tax. The commission is amending sections (1)–(4), adding section (2) and renumbering the remaining sections.

PURPOSE: This rule establishes the procedure for tax returns for gaming tax. This rule is being amended to codify filing practices for tax returns currently in use by the commission, including electronic filing of returns and the imposition of filing deadlines.

(1) The licensee shall [be responsible not only for the collection and payment of the amount of the gaming tax, but also shall make a] file a tax return [to] with the commission [on the dates prescribed by the commission showing the daily-1] gross receipts, 2] amount of winnings paid to wagerers, 3] resulting adjusted gross receipts and 4] amount of gaming tax, and other information as the commission may require;] for each gaming day the licensee holds a Class A license and shall remit to the commission any unpaid amount shown on the return.

(2) The tax return filed with the commission shall include the following:

(A) The electronic daily filing of a record of the—1) gross receipts, 2) amount of winnings paid to wagerers, 3) resulting adjusted gross receipts, 4) amount of gaming tax, 5) admission fee liability, and 6) other information as the commission may require; using a form and set of procedures required by the commission. This portion of the return shall be deemed timely filed if received by the commission not later than 12:00 p.m. Central Standard Time on the first day financial institutions are open for business after the close of the business day on which the gaming tax and admission fee liability accrued;

(B) The electronic weekly filing of supporting worksheets using automated forms and a set of procedures required by the commission. This portion of the return shall be deemed timely filed if received by the commission not later than 12:00 p.m. Central Standard Time on the Friday following each gaming week which, for the purposes of this section, means Wednesday of each week through the following Tuesday; and

(C) The weekly filing by electronic transmission or fax of signed Daily Tax Transmittal Reports for each gaming day in the gaming week. This portion of the return shall be deemed timely

filed if received by the commission not later than 12:00 p.m. Central Standard Time on the Friday following each gaming week.

[(2)](3) [The tax return filed with the commission shall be on a form supplied by the commission and shall be filed at the address shown on the return.] It is the duty of the licensee to obtain any computer hardware and software necessary to file a tax return electronically. It is also the duty of the licensee to obtain any required form from the commission and adhere to any required set of procedures when filing a return. [f]Failure to obtain the [form] required forms or adhere to the required procedures will not [be an] excuse the licensee [for failing to file the] from filing any required returns.

[(3)](4) [The commission in its discretion may require electronic filing upon the terms and conditions that the commission shall specify.] The time for filing any portion of a tax return may be extended by the commission upon the submission by the licensee of a written request for extension prior to the filing due date. The commission shall not extend the time for filing any portion of a tax return by more than seven (7) days and no request for extension shall be granted without the showing of good cause. In granting a request for extension, the commission shall provide the licensee with written approval of request for extension. Approval by the commission of a request for extension shall not extend the time for payment of any gaming tax or fee.

[(4)](5) Every licensee is required to file a tax return [on the prescribed basis] in accordance with the provisions of this section even [though] if no wagers were made or admission fees charged during the period covered by the return.

AUTHORITY: sections 313.004, 313.805, and 313.822, RSMo [1994] 2000. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Amended: Filed June 25, 1996, effective Feb. 28, 1997. Amended: Filed Aug. 30, 2006.

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

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate, due to the fact that all casinos in Missouri currently follow the practices prescribed by the rule.

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Department of Public Safety, Missouri Gaming Commission, Riverboat Gaming Division, PO Box 1847, 3417 Knipp Drive, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. Private entities who feel there is cost which exceeds five hundred dollars (\$500) associated with this rule, are requested to submit the cost (estimated or actual, if available) with the comments. Public hearing is scheduled for 10:00 a.m. on November 7, 2006, in the commission hearing room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 11—Taxation Regulations

PROPOSED RESCISSION

11 CSR 45-11.090 Determination of Timeliness and Extensions for Filing a Return. This rule contained the commission's timeliness and extension requirements for returns.

PURPOSE: This rule is being rescinded as the commission's timeliness and extension requirements for returns have been included in the provisions of 11 CSR 45-11.040.

AUTHORITY: sections 313.004, 313.805, 313.820, and 313.822, RSMo Supp. 1993. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Rescinded: Filed Aug. 30, 2006.

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

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

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed rescission with the Department of Public Safety, Missouri Gaming Commission, Riverboat Gaming Division, PO Box 1847, 3417 Knipp Drive, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. Private entities who feel there is cost which exceeds five hundred dollars (\$500) associated with this rule, are requested to submit the cost (estimated or actual, if available) with the comments. Public hearing is scheduled for 10:00 a.m. on November 7, 2006, in the commission hearing room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 11—Taxation Regulations

PROPOSED AMENDMENT

11 CSR 45-11.110 Refund—Claim for Refund. The commission is amending sections (1)–(7), adding section (5) and renumbering sections as needed.

PURPOSE: This rule establishes the procedure for tax returns for gaming tax. This rule is being amended to correct grammatical errors, eliminate Appendix A to the rule, and to streamline the tax return approval process.

(1) If a tax or fee, penalty or interest has been paid by a licensee that is in excess of the amount *[owned]* owed, the licensee may file a claim for refund or credit. No such claim for refund or credit shall be allowed unless duplicate copies of the claim are filed within three (3) years from the date of overpayment. *[No claim will be considered unless filed within that time.]* The three (3)*[-]* year period of limitation for the credit or refund begins with the date the licensee pays taxes to the commission on account of the adjusted gross receipts in question or with the date the licensee pays fees to the commission on account of the tickets of admission in question.

(2) Every claim for refund or credit must include the *[claim for Refund or Credit Form shown in Appendix A of this rule, which must be in writing under oath and must state the specific grounds upon which the claim is founded. Amended returns are required to be filed for all periods involved in the overpayment. The claim must also include a request for hearing as described in 11 CSR 45-13.030.]* following:

(A) Claim For Refund Or Credit Form provided by the commission, which must be in writing, signed by an authorized agent of the licensee, and state the specific grounds upon which the claim is founded; and

(B) Amended returns for all periods involved in the overpayment of the tax or fee, penalty or interest that has been paid by the licensee.

(4) A claim for credit or refund shall be approved only[-] after the commission has determined the claim to be valid and recorded its approval on the Claim For Refund Or Credit Form filed by the licensee. The commission may authorize the director, or the director's designated representative, to make the initial determination as to the validity of any claim for credit or refund filed with the commission and to approve or deny the claim; provided, however, that this section shall not limit any other authorization of the director. The authorization granted herein shall not include the authority to review findings of a hearing officer under the provisions of 11 CSR 45-13.

[(A) After a hearing process procedure is conducted in accordance with 11 CSR 45-13.060, provided that the hearing officer may, at his/her discretion, recommend a summary judgment without an actual hearing, and after a final commission order is entered in accordance with 11 CSR 45-13.070, granting such credit or refund; or

(B) After the director has determined, in his/her discretion, that there are no material facts in dispute regarding the validity of the refund or credit claim, and the director then, in his/her discretion, issues an order setting forth findings of fact, conclusions of law and an order granting the claim for refund or credit.]

(5) In cases where a claim for credit or refund is denied by the commission, the licensee may submit a request for a hearing, in accordance with 11 CSR 45-13, to review the commission's decision to deny the claim.

[(5)](6) In cases where a claim for credit is approved, the commission will issue a credit memorandum[, in the form shown in Appendix A of this rule, in] for the amount of the overpayment [along with the final order]. The credit may [then] be applied by the [person] licensee in satisfaction of subsequent tax or fee liability. A copy of the approved credit memorandum must be attached to the return to which it is being applied.

(A) A refund is made rather than a credit *[where]* when the approved credit cannot be taken as a credit on the next return filed with the commission. The *[R]* refund *[is]* shall be made with interest as determined by section 32.065, RSMo.

(B) Any approved credit of the gaming tax or admission fee shall be made without interest.

(C) Taxes or fees which are claimed to have been unconstitutionally imposed or collected are subject to the same requirements as other claims for refund or credit.

[(6)](7) All claims for credit or refund filed with the commission and any documents filed in support of such claims or introduced [through the] in a hearing [procedure] to contest [such claims] the denial of a claim shall be deemed by the commission to be open records.

[(7)](8) The [c]Claim [f]For [r]Refund [o]Or [c]Credit [f]Form[s] shall be made available on the commission's website at www.mgc.dps.mo.gov and may be requested by writing to the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102.

AUTHORITY: sections 313.004, 313.800, 313.805 and 313.822, RSMo [1994] 2000. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Amended: Filed Feb. 19, 1998, effective Aug. 30, 1998. Emergency amendment filed June 5, 2000, effective June 16, 2000, expired Feb. 22, 2001. Amended: Filed June 23, 2000, effective Jan. 30, 2001. Amended: Filed Aug. 30, 2006.

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

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars (\$500) in the aggregate, due to the fact that all casinos in Missouri currently follow the practices prescribed by the rule.

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Department of Public Safety, Missouri Gaming Commission, Riverboat Gaming Division, PO Box 1847, 3417 Knipp Drive, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. Private entities who feel there is cost which exceeds five hundred dollars (\$500) associated with this amendment, are requested to submit the cost (estimated or actual, if available) with the comments. Public hearing is scheduled for 10:00 a.m. on November 7, 2006, in the commission hearing room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 12—Liquor Control

PROPOSED AMENDMENT

11 CSR 45-12.020 Excursion Liquor License *and Premises* **Defined**. The commission is amending sections (1), (2) and (3).

PURPOSE: The amendment further defines the requirements for excursion liquor licenses.

(1) As used in this chapter, the following terms mean:

(A) "*[e]*Excursion liquor licensee," *[shall mean]* any Class A applicant or licensee who has been issued an excursion liquor licensee which authorizes the Class A applicant or licensee to serve, offer for sale or sell intoxicating liquor aboard any excursion gambling boat or facility immediately adjacent to and contiguous with the excursion gambling boat which is owned and operated by the Class A applicant or licensee*[.]*; and

(B) "Licensed premises," any and all property owned and operated by the Class A applicant or licensee immediately adjacent to and contiguous with its riverboat gaming operation as defined in 11 CSR 45-1.090. 11 CSR 45-12.091 to the contrary notwithstanding, hotel guest rooms are not considered to be on the licensed premises.

(2) An excursion liquor license shall be a license granted for a one (1)-year term by the commission for sale of intoxicating liquor by the drink at retail for consumption on the licensed premises, and the sale of intoxicating liquor in the original package at locations specifically indicated on the license for consumption off the licensed premises.

(3) The sale of any intoxicating liquor except malt liquor, in the original package, in any quantity less than fifty (50) milliliters shall be deemed sale by the drink, **and** once so made, the container and every case shall be emptied and its contents served as other intoxicating liquor served or sold by the drink.

AUTHORITY: sections 313.004, 313.805 and 313.840, RSMo [1994] 2000. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Emergency amendment filed June 14, 1994, effective June 24, 1994, expired Oct. 21, 1994. Emergency amendment filed Oct. 25, 1994, effective Nov. 4, 1994, expired March 3, 1995. Amended: Filed June 14, 1994, effective Jan. 29, 1995. Amended: Filed May 13, 1998, effective Oct. 30, 1998. Amended: Filed Aug. 30, 2006.

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

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

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for 10:00 a.m. on November 7, 2006, in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 12—Liquor Control

PROPOSED AMENDMENT

11 CSR 45-12.040 Applications. The commission is amending sections (1) and (2).

PURPOSE: This amendment further clarifies the requirements for excursion liquor licenses.

(1) Application for an excursion liquor license must be made on forms provided by the commission (see Appendix A, included here-in).

(2) The application shall describe with particularity the areas of the premises in which intoxicating liquors will be served, sold, and stored.

AUTHORITY: sections 313.004, 313.805 and 313.840, RSMo [1994] 2000. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. Amended: Filed May 13, 1998, effective Oct. 30, 1998. Amended: Filed Aug. 30, 2006.

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

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

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for 10:00 a.m. on November 7, 2006, in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 11—DEPARTMENT OF PUBLIC SAFETY Division 45—Missouri Gaming Commission Chapter 12—Liquor Control

PROPOSED AMENDMENT

11 CSR 45-12.090 Rules of Liquor Control. The commission is amending subsection (3)(A) and adding new sections (22), (23) and (24).

PURPOSE: This amendment further defines the requirements for reliance on identification cards, prohibits free intoxicating liquor on the gaming floor, permits the removal of unfinished bottles of wine, and permits charitable or religious organizations to provide or auction intoxicating liquor in nongaming areas under certain circumstances.

(3) Sale to Minors and Other Persons. An excursion liquor licensee shall not, through actions of his/her own or of an employee, sell, vend, give away its or otherwise supply any intoxicating liquor in any quantity whatsoever to any person under the age of twenty-one (21) years, to any person intoxicated or appearing to be in a state of intoxication, or to a habitual drunkard. A licensee shall not permit any person under the age of twenty-one (21) years, or any habitual drunkard to consume intoxicating liquor on the licensed premises.

(A) Any licensee who in good faith relies on a[n operator's or chauffeur's] valid and unexpired driver's or commercial driver's license issued under the provision of section 302.177, RSMo or under the laws of [the] any state [of Arkansas, Illinois, Oklahoma, Kansas or lowa] or territory or the United States to residents of those states or territories, or a valid and unexpired identification card as provided under section 302.181, RSMo, or under the laws of any state or territory of the United States to residents of those states or territories, or a valid and unexpired identification card issued by any uniformed service of the United States, or a valid and unexpired passport shall not be disciplined for a sale to a minor in violation of section (1).

(22) Complimentary Service of Intoxicating Liquor. An excursion liquor licensee shall not, through actions of his/her own or of an employee, supply any intoxicating liquor in any quantity whatsoever free of charge or as a complimentary to any person on the gaming floor of the premises.

(23) Unfinished bottles of wine may be carried out of a restaurant bar, when—It shall not be unlawful for the excursion liquor licensee or employee of a food and beverage outlet located in nongaming areas to allow patrons to carry out one (1) or more bottles of unfinished wine under the following conditions:

(A) The patron must have ordered a meal;

(B) The bottle or bottles of wine must have been at least partially consumed during the meal;

(C) The restaurant bar must provide a dated receipt for the unfinished bottle or bottles of wine; and

(D) The restaurant bar must securely reseal the bottle or bottles of wine and place them in one (1) or more one (1)-time-use, tamperproof, transparent bags and securely seal the bags. (24) Activities for certain organizations allowed, when— Excursion liquor licensees may, in nongaming areas of their licensed premises, permit charitable or religious organizations as defined in section 313.005, RSMo, or educational institutions, to hold:

(A) Events or activities for which admission is charged and beer, wine, brandy, or nonintoxicating beer which has been donated, delivered or caused to be delivered pursuant to the provisions of section 311.332, RSMo, is available without a separate charge. Such occurrences shall not constitute resale for the purposes of this rule; or

(B) Auctions of wine in the original package for fund-raising purposes pursuant to the provisions of section 311.332, RSMo; provided that all remaining beer, wine, brandy, and nonintoxicating beer so donated, delivered, or caused to be delivered to the charitable or religious organization or educational institution at the close of the event, activity or auction shall remain the property and responsibility of the charitable or religious organization or educational institution and shall not be converted to the benefit of the excursion liquor licensee.

AUTHORITY: sections 313.004 and 313.805, RSMo 2000 and 313.840, RSMo Supp. [2003] 2005. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 30, 2006.

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

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

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COM-MENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for 10:00 a.m. on November 7, 2006, in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.

Title 12—DEPARTMENT OF REVENUE Division 10—Director of Revenue Chapter 23—Motor Vehicle

PROPOSED RESCISSION

12 CSR 10-23.422 Issuance of Purple Heart License Plates. This rule clarified procedures for issuance of Purple Heart license plates.

PURPOSE: This rule is being rescinded as it has been determined that existing legislation authorizing the issuance of Purple Heart license plates does not require clarification through rule.

AUTHORITY: sections 301.144, RSMo Supp. 1990, and 301.451, RSMo Supp. 1991. Emergency rule filed Sept. 16, 1991, effective Sept. 26, 1991, expired Jan. 23, 1992. Original rule filed Sept. 16, 1991, effective Jan. 13, 1992. Rescinded: Filed Aug. 23, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rescission with the Missouri Department of Revenue, Legal Services Division, Governmental Affairs Bureau, PO Box 475, Jefferson City, MO 65105-0475. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of [Health Standards] Regulation and Licensure Chapter 82—General Licensure Requirements

PROPOSED AMENDMENT

19 CSR 30-82.010 General Licensure Requirements. The department is amending sections (1)-(8) and deleting the form which follows this rule in the *Code of State Regulations*.

PURPOSE: This amendment deletes the terms residential care facility I and II used in this rule and replaces those terms with residential care facility and assisted living facility, clarifies who may sign an application, clarifies and supplements requirements for disclosure of information, and incorporates the application form and other forms by reference.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Persons wishing to operate a skilled nursing facility, intermediate care facility, [residential care facility II] assisted living facility or residential care facility [1] shall [submit information to the division as set out in the application for license to operate a long-term care facility form, including all documents listed in that application.] complete form MO 580-2631 (9-05), Application for License to Operate a Long-Term Care Facility, incorporated by reference in this rule and available through the Department of Health and Senior Services' (department's) website at www.dhss.mo.gov, or by mail at: Department of Health and Senior Services Warehouse, Attention General Services Warehouse, PO Box 570, Jefferson City, MO 65102-0570, telephone: (573) 526-3861. This rule does not incorporate any subsequent amendments or additions. The completed application shall contain a statement that the information submitted is true and correct to the operator's knowledge and belief and shall be signed under oath or affirmation before a notary public by a person with the express authority to sign on behalf of the operator. The completed application form shall be submitted to Fee Receipts, Section for Long Term Care, Department of Health and Senior Services, PO Box 570, 930 Wildwood, Jefferson City, MO 65109. One application may be used to license multiple facilities if located [The applicant may use one (1) application form, if the operator wishes to license more than one (1) facility] on the same premises.

(A) The applicant *[,]* shall submit the following documents and information as listed in the application:

1. Financial information demonstrating that the applicant has the financial capacity to operate the facility;

2. A document disclosing the location, capacity and type of licensure and certification of any support buildings, wings or floors housing residents on the same or adjoining premises or plots of ground;

3. A document disclosing the name, address and type of license of all other long-term care facilities owned or operated by either the applicant or by the owner of the facility for which the application is being submitted;

4. A copy of any executed management contracts between the applicant and the manager of the facility;

5. A copy of any executed contract conveying the legal right to the facility premises, including, but not limited to, leases, subleases, rental agreements, contracts for deed and any amendments to those contracts;

6. A copy of any contract by which the facility's land, building, improvements, furnishings, fixtures or accounts receivable are pledged in whole or in part as security, if the value of the asset pledged is greater than five hundred dollars (\$500);

7. A nursing home surety bond or noncancelable escrow agreement, if the applicant holds or will hold facility residents' personal funds in trust;

8. A document disclosing the name, address, title and percentage of ownership of each affiliate of any general partnership, limited partnership, general business corporation, nonprofit corporation, limited liability company or governmental entity which owns or operates the facility or is an affiliate of an entity which owns or operates the facility *[; and]*. If an affiliate is a corporation, partnership, or LLC, a list of the affiliate's affiliates must also be submitted. As used in this rule, the word "affiliate" means:

A. With respect to a partnership, each partner thereof;

B. With respect to a limited partnership, the general partner and each limited partner with an interest of five percent (5%) or more in the limited partnership;

C. With respect to a corporation, each person who owns, holds, or has the power to vote five percent (5%) or more of any class of securities issued by the corporation, and each officer and director;

D. With respect to an LLC, the LLC managers and members with an interest of five percent (5%) or more;

9. If applicable, a document stating the name and nature of any additional businesses in operation on the facility premises and the document issued by the division giving its prior written approval for each business[.];

10. A list of all principals in the operation of the facility and their addresses and titles and, so that the department may verify the information disclosed pursuant to paragraphs (1)(A)11. and (1)(A)12. of this rule, the Social Security numbers or employer identification numbers of the operator and all principals in the operation of the facility. As used in this rule, "principal" means officer, director, owner, partner, key employee, or other person with primary management or supervisory responsibilities;

11. Disclosure concerning whether the operator or any principals in the operation of the facility are excluded from participation in the Title XVIII (Medicare) or Title XIX (Medicaid) program or any state or territory;

12. Disclosure concerning whether the operator or any principals in the operation of the facility have ever been convicted of a felony in any state or federal court concerning conduct involving either management of a long-term care facility or the provision or receipt of health care services; and

13. Emergency telephone, fax and email contact information for the facility administrator, director of nursing and the operator's corporate office.

(B) Every facility that provides specialized Alzheimer's or dementia care services, as defined in sections 198.500 to 198.515, RSMo [Supp. 1997], by means of an Alzheimer's special care unit or program shall submit to the [Division of Aging, as part of] department with the licensure application or renewal, the following: 1. [A form entitled "Alzheimer's Special Care Services Disclosure Form" shall be developed by the Division of Aging which provides information, if applicable, of] Form MO 580-2637, Alzheimer's Special Care Services Disclosure (2-03), incorporated by reference in this rule and available through the department's website: www.dhss.mo.gov, or by mail at: Department of Health and Senior Services Warehouse, Attention General Services Warehouse, PO Box 570, Jefferson City, MO 65102-0570, telephone: (573) 526-3861. This rule does not incorporate any subsequent amendments or additions. The form shall be completed showing how the care [is different] provided by the special care unit or program differs from care provided in the rest of the facility in the following areas:

A. The Alzheimer's special care unit's or program's written statement of its overall philosophy and mission which reflects the needs of residents afflicted with dementia;

B. The process and criteria for placement in, or transfer or discharge from, the unit or program;

C. The process used for assessment and establishment of the plan of care and its implementation, including the method by which the plan of care evolves and is responsive to changes in condition;

D. Staff training and continuing education practices;

E. The physical environment and design features appropriate to support the functioning of cognitively impaired adult residents;

F. The frequency and types of resident activities;

G. The involvement of families and the availability of family support programs;

H. The costs of care and any additional fees; and

I. Safety and security measures; and

2. [A document developed by and/or approved by the division] Form Guide to Selecting an Alzheimer's Special Care Unit (6/06) #455, incorporated by reference in this rule and available through the department's website: at www.dhss.mo.gov, or by mail at: Department of Health and Senior Services Warehouse, Attention General Services Warehouse, PO Box 570, Jefferson City, MO 65102-0570, telephone: (573) 526-3861 or a document of choice which contains, but is not limited to[, updated] all information on selecting an Alzheimer's special care unit or program that is contained in the Guide to Selecting an Alzheimer's Special Care Unit (12/03) #455. This rule does not incorporate any subsequent amendments or additions.

(C) If, after filing an application, the operator identifies an error or if any information changes the issuance of the license, the operator shall—

1. Submit the correction or additional information to the [division] department's Licensure and Certification Unit in a letter accompanied by a notarized statement that the information being submitted is true and correct to the best of the operator's knowledge and belief; or

2. Submit the correction or additional information to the [division by using [MO Form 886-2609, entitled: Corrections for LTC Facility License Application] department's Licensure and Certification Unit. Information shall be submitted using form MO 580-2623 (9-05), Corrections For Long Term Care Facility License Application, incorporated by reference in this rule and available through the Department of Health and Senior Services' (department's) website at www.dhss.mo.gov, or by mail at: Department of Health and Senior Services Warehouse, Attention General Services Warehouse, PO Box 570, Jefferson City, MO 65102-0570, telephone: (573) 526-3861. This rule does not incorporate any subsequent amendments or additions. The completed application form shall be signed by a person with express authority to sign on behalf of the operator and shall be submitted to Fee Receipts, Section for Long Term Care, Department of Health and Senior Services, PO Box 570, 930 Wildwood, Jefferson City, MO 65109.

(D) If, as a result of an application review, the *[division]* department requests a correction or additional information, the operator,

within ten (10) working days of receipt of the written request shall-

1. Submit the correction or additional information to the *[division]* department in a letter accompanied by a notarized statement that the information being submitted is true and correct to the best of the operator's knowledge and belief; or

2. Submit the correction or additional information [to the division by using MO Form 886-2609, entitled: Corrections for LTC Facility License Application] using form MO 580-2623 (9-05), Corrections For Long Term Care Facility License Application referenced in paragraph (1)(C)2. of this rule.

(E) A new facility shall submit an application for an original license not less than thirty (30) days before the anticipated opening date. The *[division]* department must approve the application before a licensure inspection is scheduled. Sixty (60) days after its receipt, the *[division]* department shall consider any application for an original license withdrawn if it is submitted without all the required information and documents. If intending to continue with licensure, the operator shall submit a new application and fee along with all necessary documents.

(H) The [division] department shall issue each license only for the premises and operator named in the application. This license shall cover the entire premises unless stipulated otherwise and shall not be transferable. If the licensed operator of a facility is replaced by another operator, the new operator shall apply for a new license before the effective date of the change. A change of operator shall include a change in form of business as well as a change of person. Upon receipt of the application and receipt of confirmation that the change of operator has taken place, the [division] department shall grant the new operator a temporary operating permit of sufficient duration to allow the [division] department time to evaluate the application, conduct any necessary inspection(s) to determine substantial compliance with the law and the rules, and to either issue or deny a license to the new operator. The new operator shall be subject to all the terms and conditions under which the previous operator's license or temporary operating permit was issued. This includes any existing statement of deficiencies, plans of correction and compliance with any additional requirements imposed by the [division] department as a result of any existing substantial noncompliance. The new operator, however, shall apply to the [division] department for renewal in his/her/its name for any exception to the rules that had been granted the previous operator under the provisions of section (3) of this rule.

(I) The operator shall accompany each application for a license to operate a long-term care facility (skilled nursing facility, intermediate care facility, assisted living facility residential care facility [// or residential care facility IJ) with a license fee of one hundred dollars (\$100) for those facilities which have a resident capacity of at least three (3) but less than twenty-five (25), three hundred dollars (\$300) for those facilities which have a resident capacity of twentyfive through one hundred (25–100), and six hundred dollars (\$600) for those facilities with a capacity of over one hundred (100+). The operator shall submit a separate fee for each facility's license application. This fee is nonrefundable unless the facility withdraws the application within ten (10) days of receipt by the [division] department. The [division] department will issue a license for a period of no more than two (2) years for the premises and operator named in the application. If the license is for less than two (2) years, the [division] department will prorate the fees accordingly.

(K) The *[division]* department shall issue a separate license for each level of care located on the same premises, whether applied for by one (1) application or more than one (1). If the operator uses one (1) application for two (2) or more levels of care on the same premises, the *[division]* department shall issue licenses with one (1) expiration date. If two (2) or more levels of care have existing licenses with different expiration dates and the operator elects to apply for licenses for the levels of care by submitting one (1) relicensure application, the expiration dates of the licenses issued shall be two (2) years subsequent to the expiration date of the license of the level of care expiring earliest following receipt of the application by the *[divi-sion]* department. Fees for unused portions of licenses resulting from the submission of one (1) application for two (2) or more levels of care are nonrefundable.

(L) After receiving a license application, the *[division]* department shall review the application, investigate the applicant and the statements sworn to in the application for license and conduct any necessary inspections. A license shall be issued if—

1. The *[division]* department has determined that the application is complete, and that all necessary documents have been filed with the application including an approved nursing home bond or noncancelable escrow agreement if personal funds of residents are held in trust;

2. The *[division]* department has determined that the statements in the application are true and correct;

3. The *[division]* department has determined that the facility and the operator are in substantial compliance with the provisions of sections 198.003–198.096, RSMo and the corresponding rules;

4. The *[division]* department has determined that the applicant has the financial capacity to operate the facility;

5. The *[division]* department has verified that the administrator of a residential care facility *[//]*, assisted living facility, intermediate care facility or skilled nursing facility is currently licensed by the Missouri Board of Nursing Home Administrators under the provisions of Chapter 344, RSMo;

6. The *[division]* department has received the fee required by subsection (1)(I) of this rule;

7. The applicant meets the definition of operator as defined [by 13 CSR 15-11.010(19)] in 19 CSR 30-83.010;

8. The applicant has received a Certificate of Need, if required, or has received a determination from the Certificate of Need Program that no certificate is required, has completed construction, and is in substantial compliance with the licensure rules and laws:

9. The *[division]* department has determined that neither the operator, owner or any principals in the operation of the facility have ever been convicted of an offense concerning the operation of a long-term care facility or other health care facility or, while acting in a management capacity, ever knowingly acted or knowingly failed to perform any duty which materially and adversely affected the health, safety, welfare or property of a resident;

10. The *[division]* department has determined that neither the operator, owner or any principals in the operation of the facility are excluded from participation in the Title XVIII (Medicare) or Title XIX (Medicaid) program or any state or territory;

11. The *[division]* department has determined that neither the operator, owner or any principals in the operation of the facility have ever been convicted of a felony in any state or federal court concerning conduct involving either management of a long-term care facility or the provision or receipt of health care services; and

12. The *[division]* department has determined that all fees due the state have been paid.

(M) If, during the period in which a license is in effect, a change occurs which causes the statements in the application to no longer be correct, including change of administrator, or if any document is executed which replaces, succeeds or amends any of the documents filed with the application, within ten (10) working days of the effective date of the change, the operator shall—

1. Submit a letter to the *[division]* department's Licensure and Certification Unit that contains a correction of the application with notification of the effective date of the change and a copy of any new documents. The operator must ensure the letter is accompanied by a notarized statement that the information being submitted is true and correct to the best of the operator's knowledge and belief; or

2. Submit to the [division] department a correction of the application and a copy of any new documentation and information by [using MO Form 886-2609; entitled: Corrections for LTC Facility License Application] submitting form Corrections for

Long Term Care Facility License Application referenced in paragraph (1)(C)2. of this rule.

(N) If from an analysis of financial information submitted with the application, or if from information obtained during the term of a license, the operator appears insolvent or a tendency toward insolvency, the *[division]* department shall have the right to request additional financial information from the operator. Within ten (10) working days after receiving a written request from the *[division]* department, the operator shall—

1. Submit to the *[division]* department the additional information requested in a letter accompanied by a notarized statement that the information being submitted is true and correct to the best of the operator's knowledge and belief; or

2. Submit the financial information to the *[division by using* MO Form 886-2609] department submitting form Corrections for Long Term Care Facility License Application referenced in paragraph (1)(C)2. of this rule.

(O) A license applicant's financial information, data and records submitted to the *[division]* department as required by this rule, including, but not limited to, copies of any Internal Revenue Service forms, shall be open for inspection and be released only—

1. To designated employees of the *[division]* department;

2. To the applicant furnishing this information or to his/her representative as designated in writing;

3. To the director of the [Department of Social Services] **department** or to his/her representative as designated in writing;

4. To the state auditor or his/her representative as designated in writing;

5. To appropriate committees of the general assembly or their representatives as designated in writing;

6. In any judicial or administrative proceeding brought under the Omnibus Nursing Home Act; or

7. When so ordered by a court of competent jurisdiction.

(P) To obtain a license for an additional level of care on the premises, the licensed operator shall submit a written request to the *[division]* department for the issuance of a license for the desired level of care. The request shall indicate the level of care, the number of beds desired, the name and address of the facility, the name and address of the operator, and shall include the notarized signature of the operator. The licensure fee shall accompany this request. Requests are subject to *[division]* department approval. The operator shall submit this request no less than sixty (60) days prior to the initiation date of the new level of care. The *[division]* department shall coordinate this license's expiration date with that of the original license and the *[division]* department shall prorate the license fee accordingly.

(Q) To request issuance of an amended license or temporary operating permit currently in effect, the operator shall—

1. Submit a written request to the *[division]* department containing the request for amendment, the date the operator would like the amendment to be effective, and the number of the license or temporary operating permit to be amended; *[and]*

2. Submit a fee for the issuance of the amended license or temporary operating permit as required by subsection (1)(R) of this rule[.]; and

3. An operator of an assisted living facility with a license or temporary operating permit that refers to 19 CSR 30-86.043 may request an amended license or temporary operating permit that refers to 19 CSR 30-86.047 and, if requested, 19 CSR 30-86.045. The operator shall submit a notarized letter requesting the change. The letter shall include the name of the facility, the requested change, and the date the change is requested to be effective. Effective April 1, 2007, the letter shall be accompanied by the fee indicated in paragraph (1)(R)2. of this rule. After receipt of the letter, the department will complete an inspection to determine whether the operator and facility are in compliance with 19 CSR 30-86.047, 19 CSR 30-86.045, if applicable, and other applicable laws and regulations. If the operator requests an amended license referring to 19 CSR 30-86.047 and, if requested, 19 CSR 30-86.045, as part of its relicensure application, no additional fee will be charged.

(R) If an operator initiates a request to amend a license or temporary operating permit currently in effect, the *[division]* department requires the following fees—

1. If the request is for an increase in bed capacity, the operator shall submit a fee with the request which is the greater of—

A. The amount that would have been required by subsection (1)(I) of this rule if the increase in bed capacity has been included in the application, less any amount actually paid under that subsection; or

B. Fifty dollars (\$50); and

2. If the request is for a decrease in resident capacity or any other change, the operator shall submit a fee of twenty-five dollars (\$25) with the request.

(S) The *[division]* department shall approve all requests for bed changes prior to issuance of an amended license or temporary operating permit. The effective date of the amended license or temporary operating permit shall be no earlier than the date the *[division]* department approved the request for bed change.

(T) If the *[division]* department issues a temporary operating permit, and then issues a regular license later, the licensing period shall include the period of operation under the temporary operating permit. The licensing period shall also include any period during which the department was enjoined or stayed from revoking or denying a license or rendering the temporary operating permit null and void.

(V) The operator shall not provide care in any area on the premises to any related person who requires protective oversight unless there has been a written request to the *[division]* department to consider any portion of the facility for private use and that indicates facility staff shall not be used at any time to care for the relative(s). Prior to the area being used in that manner, the operator shall submit the request for the *[division's]* department's approval. The *[division]* department, after investigation, shall approve or disapprove the request in writing within thirty (30) days and shall issue or reissue the license indicating clearly which portion of the premises is excluded from licensure or which specific relative(s) is/are not considered a resident(s).

(2) If a facility was licensed under Chapter 197 or 198, RSMo and was in operation before September 28, 1979, or if an application was on file or construction plans were approved prior to September 28, 1979, the facility shall comply with construction, fire safety and physical plant rules applicable to an existing or existing licensed facility provided there has been continuous operation of the facility under a license or temporary operating permit issued by the division. If, however, there was an interruption in the operation of the facility due to license denial, license revocation or voluntary closure, the facility may be relicensed utilizing the same fire safety, construction and physical plant rules that were applicable prior to the license denial, license revocation or voluntary closure; provided that the facility reapplies for a license within one (1) year of the date of the denial, revocation or voluntary closure. Regardless of licensure, application, or construction plan approval date, intermediate care facilities and skilled nursing facilities shall comply with the fire safety standards published in 19 CSR 30-85.022.

(A) If a facility changes from a skilled nursing or intermediate care facility to any other level, or if the facility changes from *[a residential care facility II]* an assisted living facility to a residential care facility *[I]*, the facility shall comply with construction, fire safety and physical plant rules applicable to an existing or existing licensed facility as defined in *[13 CSR 15-11.010(8)]* 19 CSR 30-83.010.

(B) If the facility changes from a residential care facility *[I]* to any other level or if *[a residential care facility II]* an assisted living facility changes to an intermediate care or skilled nursing facility, the

facility shall comply with construction, fire safety and physical plant rules applicable to a new or newly licensed facility as defined in [13 CSR 15-11.010(17)] **19 CSR 30-83.010**.

(C) The facility shall comply with the rules applicable to a new or newly licensed facility if an application for relicensure has not been filed with the *[Division of Aging]* department within one (1) year of the license denial, license revocation or voluntary closure. All such facilities seeking licensure as an assisted living facility shall also comply with the requirements of 19 CSR 30-86.047 and, if applicable, 19 CSR 30-86.045.

(3) If a licensed facility discontinues operation as evidenced by the fact that no residents are in care or at any time the *[division]* department is unable to freely gain entry into the facility to conduct an inspection, unless the facility operator has made special arrangements with the *[division]* department for temporary closure, the facility shall be considered closed. The *[division]* department shall notify the operator in writing requesting the voluntary surrender of the license. If the *[division]* department does not receive the license within thirty (30) days, it shall be void. Later, if operation is to resume, the operator shall file a new application and fee and the provisions of section (1) shall apply.

(4) The *[division]* department may grant exceptions for specified periods of time to any rule imposed by the *[division]* department if the *[division]* department has determined that the exception to the rule would not potentially jeopardize the health, safety or welfare of any residents of a long-term care facility.

(A) The owner or operator of the facility shall make requests for exceptions in writing to the director of the *[division]* department. These requests shall contain—

1. A copy of the latest Statement of Deficiencies which *[indi-cates]* shows a violation of the rule being cited, if the exception request is being made as a result of a deficiency issued during an inspection of the facility;

2. The section number and text of the rule being cited;

3. If applicable, specific reasons why compliance with the rule would impose an undue hardship on the operator, including an estimate of any additional cost that might be involved;

4. An explanation of any extenuating factors that may be relevant; and

5. A complete description of the individual characteristics of the facility or residents, or of any other factors that would safeguard the health, safety and welfare of the residents if the exception were granted.

(B) With the advice of the *[division's]* department's licensure inspection field staff, the *[division]* department will consider any requests that contain all the information required in subsection (4)(A). The *[division]* department shall notify the operator, in writing, of the decision on any request for an exception, stating the reason(s) for acceptance or denial, and, if granted, the length of time the exception is to be in effect and any additional corrective factors upon which acceptance may be conditioned.

(C) The [division] department shall only grant exceptions to licensure requirements set out in rules imposed by the [division] department and cannot grant exceptions to requirements established by state statute or federal regulations. Operators wishing to obtain waivers of regulations under Title XVIII or Title XIX of the Social Security Act shall follow procedures established by the [Health Care Financing Administration (HCFA)] Centers for Medicare and Medicaid (CMS).

(5) When the *[division]* department issues a notice of noncompliance to a facility pursuant to the Omnibus Nursing Home Act (section 198.026, RSMo), the *[division]* department, only after affording the facility operator a reasonable opportunity to remedy the situation, shall(A) Make every reasonable effort to provide residents of the facility or their *[responsible parties]* legally authorized representatives or designees, if any—

1. A written notice of the noncompliance;

2. A list of other licensed facilities appropriate to the resident's needs; and

3. A list of agencies that will assist the resident if he/she moves from the facility; and

(B) After providing the information required by subsection (5)(A) and allowing a time period for the residents of the facility to relocate if they wish, notify the Social Security Administration in writing that a notice of noncompliance has been issued to the facility, and the effective date of the notice. If the facility achieves substantial compliance with standards and rules later, the *[division]* department shall notify the Social Security Administration of the effective date of the facility's substantial compliance.

(6) A licensed facility shall comply with the provisions of Title VI of the Civil Rights Act 1964, as amended; Section 504 of the Rehabilitation Act of 1973; Title IX of the Education Amendment of 1972; the Age Discrimination Act of 1975; the Omnibus Budget and Reconciliation Act of 1982; the Americans with Disabilities Act of 1990; and the Keyes Amendment to the Social Security Act. No person shall be denied admission to, be denied benefits of, or be subjected to discrimination under any program, activity or service provided by the facility based on his/her race, color, national origin, sex, religion, age or disability, including Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS). Every licensed facility shall complete and sign [an] form MO 580-2622 (9-05), Assurance of Compliance [(MO Form 886-3131)], incorporated by reference in this rule and available through the department's website at www.dhss.mo.gov or by telephone at (573) 526-8505 and file [it with the Division of Aging. The facility shall submit the signed assurance form with the application for license or with the first application for relicensure submitted after December 31, 1998.] the form with the application for licensure or relicensure. This rule does not incorporate any subsequent amendments or additions.

(7) The *[division's central office in Jefferson City]* department shall make available to interested individuals without charge a single copy of—

(8) Every skilled nursing facility, intermediate care facility, [and] residential care facility and assisted living facility issued a license or temporary operating permit by the [division] department shall submit the required certificate of need quarterly surveys to the [division] department on or before the fifteenth day of the first month following the previous Social Security quarter. (For example, for the Social Security quarter ending December 31, the due date is by January 15; for the Social Security quarter ending March 31, the due date is by April 15; for the Social Security quarter ending June 30, the due date is by July 15; and for the Social Security quarter ending September 30, the due date is by October 15). The information shall be submitted on the ICF/SNF Certificate of Need Quarterly Survey form or the RCF/ALF Certificate of Need Quarterly Survey form [(MO Form 886-900)] obtained from the Missouri Certificate of Need Program, PO Box 570, Jefferson City, MO 65102.

AUTHORITY: Executive Order 77-9 of the Governor filed Jan. 31, 1979, effective Sept. 28, 1979, [Chapter 198, sections 207.020, 208.152, 251.070 and 536.023, RSMo 1994 and Supp. 1997,] sections 198.018, 198.076, 198.079 and 198.515, RSMo 2000, 198.022, RSMo Supp. 2005 and 198.005 and 198.073, RSMo (CCS HCS SCS SB 616, 93rd General Assembly, Second Regular Session (2006)) This rule was originally filed as 13 CSR 15-10.010. Emergency rule filed Aug. 13, 1979, effective Oct. 1, 1979, expired Jan. 25, 1980. Original rule filed *Aug. 13, 1979, effective Dec. 13, 1979. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 23, 2006.*

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with David S. Durbin, Director of the Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of [Senior Services and] Regulation and Licensure Chapter 83—Definition of Terms

PROPOSED AMENDMENT

19 CSR 30-83.010 Definition of Terms. The department is adding sections (3), (8), (10), (11), (13), (18), (21), (22), (23), (24), (25), (28), (43), (48) and (49), amending sections (1), (4), (10), (12), (14), (15) and (19) and renumbering sections (2) through (34).

PURPOSE: This amendment deletes the terms residential care facility I and II and replaces those terms with residential care facility and assisted living facility; defines the levels of care and adds definitions of "activities of daily living," "assisted living facility," "community based assessment," "convenience," "dementia," "discipline," "facility," "home-like," "individualized service plan," "instrumental activities of daily living," "intermediate care facility," "keeping residents in place," "long-term care services," "residential care facility," "skilled nursing facility" and "social model of care," and amended the terms "chemical restraint," "existing or existing licensed facility," "fire-resistant construction," "level I medication aide," "longterm care facility" and "new or newly licensed facility" in order to comply with CCS HCS SCS SB 616, 93rd General Assembly, Second Regular Session (2006).

(1) Activities of daily living (ADL)—Shall mean one (1) or more of the following:

- (A) Eating;
- (B) Dressing;
- (C) Bathing;
- (D) Toileting;
- (E) Transferring; and
- (F) Walking.

[(1)](2) Administrator—Shall mean an individual person who is in general administrative charge of a facility.

(3) Assisted living facility (ALF)—Shall mean any premises, other than a residential care facility, intermediate care facility, or skilled nursing care facility, that is utilized by its owner, operator, or manager to provide twenty-four (24) hour services and protective oversight to three (3) or more residents who are provided with shelter, board, and who may need and are provided with the following:

(A) Assistance with any activities of daily living and any instrumental activities of daily living; (B) Storage, distribution or administration of medications; and (C) Supervision of health care under the direction of a licensed physician, provided that such services are consistent with a social

(D) The term "assisted living facility" does not include a facility where all of the residents are related within the fourth degree

of consanguinity or affinity to the owner, operator, or manager of the facility.

[(2)] (4) Automated dispensing system—Shall mean a mechanical system that performs functions that may include, but are not limited to, storing, packaging or dispensing medications, and that collects, controls and maintains all transaction information.

[(3)] (5) Certified-medication technician—Shall mean a nursing assistant who has completed a course in medication administration approved by the Department of Health and Senior Services.

[(4)] (6) Chemical restraint—Shall mean [any medication that is used for discipline or convenience and not required to treat medical symptoms. For the purposes of this definition, discipline means any action taken by the facility for the purpose of punishing or penalizing residents and convenience means any action taken by the facility to control a resident's behavior or maintain a resident with a lesser amount of effort by the facility and not in the resident's best interest.] a psychopharmacologic medication that is used for discipline or convenience and not required to treat medical symptoms.

[(5)] (7) Communicable disease—Any illness, disease or condition reportable to the Missouri Department of Health and Senior Services as required by 19 CSR 20-20.010 and 19 CSR 20-20.020 is considered, for the context of these rules, a communicable disease.

(8) Community based assessment—Shall mean documented basic information and analysis provided by appropriately trained and qualified individuals describing an individual's abilities and needs in activities of daily living, instrumental activities of daily living, vision/hearing, nutrition, social participation and support, and cognitive functioning using an assessment tool approved by the Department of Health and Senior Services (the department), that is designed for community based services and that is not the nursing home minimum data set. The assessment tool may be one developed by the department or one used by a facility which has been approved by the department.

[(6)] (9) Control of medication—Shall mean assuming responsibility by the facility for all facets of control of medication including, but not limited to, acquisition, storage, security and administration.

(10) Convenience—Shall mean any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest.

(11) Dementia—Shall mean a general term for the loss of thinking, remembering, and reasoning so severe that it interferes with an individual's daily functioning, and may cause symptoms that include changes in personality, mood, and behavior.

[(7)] (12) Designee—Shall mean an individual who has been designated in writing by a resident to handle matters and receive reports related to his/her personal possessions and property.

(13) Discipline—Shall mean any action taken by the facility for the purpose of punishing or penalizing residents.

[(8)] (14) Emergency medical procedure—Shall mean those written policies and procedures which describe the types and degrees of acci-

dents and injuries, how they will be treated, by whom, in which instances the resident's physician will be notified and how quickly.

[(9)] (15) Emergency medication supply—Shall mean a limited number of dosage units of prescription medications that may be administered to a resident in an emergency situation or for initial doses of a necessary medication when a pharmacy cannot provide a prescription for a resident within a reasonable time based on the resident's clinical needs at the time.

[(10)] (16) Existing or existing licensed facility—Shall mean a longterm care facility which was licensed and in operation or one whose plans were approved prior to June 10, 1981 for a skilled or intermediate care facility or prior to November 13, 1980 for residential care facilities [/] and [//] assisted living facilities except as otherwise indicated in 19 CSR 30-86.012, 19 CSR 30-86.022 and 19 CSR 30-86.032.

[(11)] (17) Exit—Shall mean a door leading to the outside or through a horizontal exit in a fire wall to a fire-safe area in the building.

(18) Facility—Shall mean any residential care facility, assisted living facility, intermediate care facility or skilled nursing facility licensed by the department.

[(12)] (19) Fire-resistant construction—For intermediate care facilities and skilled nursing facilities, fire-resistant construction shall mean that a facility meets the specifications for Type II (222) or Type II (111) construction as given in the *National Fire Protection Association Code 220. [The definition of f]*Fire-resistant construction for residential care facilities [*I*] and [*II*] assisted living facilities is [given in 19 CSR 30-86.022(2)(B)] defined in 19 CSR 30-86.022.

[(13]] (20) Hazardous area—Shall mean furnace rooms other than electric forced air furnaces, laundries, kitchens, maintenance shops and storage rooms of over one hundred (100) square feet and any areas which contain combustible materials which will be either easily ignited, burn with an intense flame or result in the production of dense smoke and fumes.

(21) Home-like—means a self-contained long-term care setting that integrates the psychosocial, organizational and environmental qualities that are associated with being at home. Home-like may include, but is not limited, to the following:

(A) A living room and common use areas for social interactions and activities;

(B) Kitchen and family style eating area for use by the residents;

(C) Laundry area for use by residents;

(D) A toilet room that contains a toilet, lavatory and bathing unit in each resident's room;

(E) Resident room preferences for residents who wish to share a room, and for residents who wish to have private bedrooms;

(F) Outdoor area for outdoor activities and recreation; and

(G) A place where residents can give and receive affection, explore their interests, exercise control over their environment, engage in interactions with others and have privacy, security, familiarity and a sense of belonging.

(22) Individualized service plan—Shall mean the planning document prepared by an assisted living facility which outlines a resident's needs and preferences, services to be provided, and the outcomes expected for the resident.

(23) Instrumental activities of daily living (IADL)—Shall mean one (1) or more of the following activities:

(A) Preparing meals;

- (B) Shopping for personal items;
- (C) Medication management;
- (D) Managing money;
- (E) Using the telephone;
- (F) Housework; and
- (G) Transportation ability.

(24) Intermediate care facility—Shall mean any premises, other than a residential care facility, assisted living facility, or skilled nursing facility, which is utilized by its owner, operator, or manager to provide twenty-four (24) hour accommodation, board, personal care, and basic health and nursing care services under the daily supervision of a licensed nurse and under the direction of a licensed physician to three (3) or more residents dependent for care and supervision and who are not related within the fourth degree of consanguinity or affinity to the owner, operator or manager of the facility.

(25) Keeping residents in place—Shall mean maintaining residents in place during a fire in lieu of evacuation where a building's occupants are not capable of evacuation or where evacuation has a low likelihood of success.

[(14)] (26) Level I medication aide—Shall mean an individual who has completed a course approved by the [Department of Health and Senior Services] department in medication administration in a residential care [type] facility or assisted living facility.

[(15)] (27) Long-term care facility—Shall mean a facility that is licensed either solely or in combination as a skilled nursing facility, an intermediate care facility, a residential care facility [//] or [a residential care facility 1] assisted living facility.

(28) Long-term care services—Shall mean the assistance and support that a resident receives in a residential care facility, assisted living facility, intermediate care facility and skilled nursing care facility, to meet the resident's individual need for nursing care, protective oversight, monitoring, medication management, social interactions, cooking, housekeeping, laundry and recreational activities.

[(16)] (29) Major fraction thereof—Shall mean anything over fifty percent (50%) of the number of occupied beds.

[(17]] (30) Major remodeling—Shall mean any remodeling of a long-term care facility which involves the addition of resident-use rooms, which affects fire safety or the structure of the building.

[(18)] (31) Multistory building—Shall mean any building with more than one (1) floor entirely above the grade. A floor that is partially below grade will be counted as the first story to determine sprinkler requirements only if it contains resident sleeping rooms.

[(19)] (32) New or newly licensed facility—Shall mean a long-term care facility whose plans are approved or which is licensed after June 10, 1981 for a skilled nursing or intermediate care facility or after November 13, 1980 for residential care facility [/] or [//] assisted living facility except as otherwise indicated in 19 CSR 30-86.012, 19 CSR 30-86.022 and 19 CSR 30-86.032.

[(20)] (33) Nursing personnel—Shall include any employee, including a nurse's aide or an orderly, who provides or assists in the provision of direct resident health care services.

[(21)] (34) Operator—Shall mean any person licensed or required to be licensed under the provisions of sections 198.003–198.096, RSMo, in order to establish, conduct or maintain a facility. The term

person required to be licensed shall mean any person having the following, as determined by the *[division]* department:

(A) Ultimate responsibility for making and implementing decisions regarding the operation of facility;

(B) Ultimate financial control of the operation of a facility; and

(C) Legal right to possession of the premises on which a facility is located.

[(22)] (35) Person—Shall mean any individual, or any entity, including, but not limited to, a corporation, partnership, association, nonprofit organization, fraternal organization, church or political subdivision of the state of Missouri.

[(23)] (36) Physical restraint—Shall mean any manual method or physical or mechanical device, material or equipment attached to or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body. Physical restraints include, but are not limited to leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions and lap trays the resident cannot remove easily. Physical restraints also include facility practices that meet the definition of a restraint, such as the following:

(A) Using side rails that keep a resident from voluntarily getting out of bed;

(B) Tucking in or using Velcro to hold a sheet, fabric or clothing tightly so that a resident's movement is restricted;

(C) Using devices in conjunction with a chair, such as trays, tables, bars or belts, that the resident cannot remove easily, that prevent the resident from rising;

(D) Placing the resident in a chair that prevents a resident from rising; and

(E) Placing a chair or bed so close to a wall that the wall prevents the resident from rising out of the chair or voluntarily getting out of bed.

[(24)] (37) Physician—Shall mean an individual licensed to practice medicine in the state of Missouri under Chapter 334, RSMo.

[(25)] (38) Premises—Shall mean any structure $[/[s_i]]$ that are in close proximity one to the other and which are located on a single piece of property.

[(26)] (39) Protective oversight—Shall mean an awareness twentyfour (24) hours a day of the location of a resident, the ability to intervene on behalf of the resident, supervision of nutrition, medication, or actual provisions of care and the responsibility for the welfare of the resident, except where the resident is on voluntary leave.

[(27)] (40) Qualified dietitian—Shall mean an individual who is registered by the American Dietetic Association or who is eligible for registration.

[(28)] (41) Qualified therapist—Shall mean an individual who is either registered or is eligible for registration by the national accrediting association for that therapy or, if applicable, is licensed by the state of Missouri for the practice of the profession in which s/he is engaged.

[(29)] (42) Qualified therapy assistant—Shall mean an individual who would be qualified as an occupational therapy or physical [therapy] therapist assistant as outlined in [CFR 405.1101] 42 CFR 484.4.

(43) Residential care facility (RCF)—Shall mean any premises, other than an assisted living facility, intermediate care facility, or skilled nursing facility, which is utilized by its owner, operator or manager to provide twenty-four (24) hour care to three (3) or more residents, who are not related within the fourth degree of consanguinity or affinity to the owner, operator, or manager of the facility and who need or are provided with shelter, board, and with protective oversight, which may include storage and distribution or administration of medications and care during shortterm illness or recuperation, except that, for purposes of eligible residents of facilities formerly licensed as residential care facilities II receiving supplemental welfare assistance payments, any residential care facility that was licensed as a residential care facility II on or before August 27, 2006 that continues to meet the licensure standards for a residential care facility II in effect on August 27, 2006 shall be considered a residential care facility II for purposes of its eligible residents receiving the cash grant payment amount allocated immediately prior to August 28, 2006 for residents of a residential care facility II pursuant to section 208.030, RSMo.

[(30)] (44) Responsible party—Shall mean an individual who has been designated in writing by the resident to handle matters and receive reports related to his/her general condition.

[(31)] (45) Self-administration of medication—Shall mean the act of actually taking or applying medication to oneself.

[(32)] (46) Self-control of medication—Shall mean assuming immediate responsibility by a resident for the storage and administration of medication for oneself while the facility retains ultimate control of medication.

[(33)] (47) Skilled nursing care—Shall mean services furnished pursuant to physicians' orders which require the skills of licensed nurses and which are provided directly by or under the on-site supervision of these personnel. Examples of skilled nursing care may include, but are not limited to: administration of levine tube or gastrostomy tube feedings; nasopharyngeal and tracheotomy aspiration; insertion of medicated or sterile irrigation solutions and replacement of catheters; administration of parenteral fluids; inhalation therapy treatments; administration of other treatments requiring aseptic technique; and administration of injectable medication other than insulin.

(48) Skilled nursing facility—Shall mean any premises, other than a residential care facility, assisted living facility or an intermediate care facility, which is utilized by its owner, operator or manager to provide for twenty-four (24) hour accommodation, board and skilled nursing care and treatment services to at least three (3) residents who are not related within the fourth degree of consanguinity or affinity to the owner, operator or manager of the facility. Skilled nursing care and treatment services are those services commonly performed by or under the supervision of a registered professional nurse for individuals requiring twentyfour (24) hours a day care by licensed nursing personnel including acts of observation, care and counsel of the aged, ill, injured or infirm, the administration of medications and treatments as prescribed by a licensed physician or dentist, and other nursing functions requiring substantial specialized judgment and skill.

(49) Social model of care—means long-term care services based on the abilities, desires, and functional needs of the individual delivered in a setting that is more home-like than institutional, that promote the dignity, individuality, privacy, independence and autonomy of the individual, that respects residents' differences and promotes residents' choices.

[(34)] (50) Voluntary leave—Shall mean an off-premise leave initiated by: a) a resident that has not been declared mentally incompetent or incapacitated by a court; or b) a legal guardian of a resident that has been declared mentally incompetent or incapacitated by a court. AUTHORITY: sections 198.006, RSMo Supp. [2003] 2005 and 198.009, RSMo 2000, and 198.005 and 198.073, RSMo (CCS HCS SCS SB 616, 93rd General Assembly, Second Regular Session (2006)). Emergency rule filed Sept. 7, 1979, effective Sept. 28, 1979, expired Jan. 24, 1980. This rule originally filed as 13 CSR 15-11.010. Original rule filed Sept. 7, 1979, effective Jan. 12, 1980. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 23, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with David S. Durbin, Director of the Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of [Health Standards] Regulation and Licensure Chapter 84—Training Program for Nursing Assistants

PROPOSED AMENDMENT

19 CSR 30-84.030 Level I Medication Aide. The department is amending sections (1), (6), (8), (9), (10), (11), (13), (14) and (15).

PURPOSE: This amendment deletes the terms residential care facility I and II used in this rule and replaces those terms with residential care facility and assisted living facility (ALF) for facilities licensed by the Department of Health and Senior Services pursuant to 198.005 and 198.073, RSMo (CCS HCS SCS SB 616, 93rd General Assembly, Second Regular Session (2006)), updates the educational material approved for the course, updates student qualifications relating to the Employee Disqualification List and criminal history, clarifies the training agencies that are eligible to apply for approval for a Level I Medication Aide Training Program and changes the name of the agency throughout the rule due to the transfer of the Division of Aging from the Department of Social Services to the Department of Health and Senior Services effective August 28, 2001.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) The *[purpose of the I]*Level I Medication Aide Training Program shall be **administered by the Department of Health and Senior Services (the department) in order** to prepare individuals for employment as level I medication aides in residential care facilities (RCFs) *[I and II]* and assisted living facilities (ALFs). The program shall be designed to teach skills in medication administration of nonparenteral medications in order to qualify students to perform this procedure only in RCFs *[I and II]* and ALFs in Missouri.

(6) The course developed by the Missouri Department of Elementary and Secondary Education and the [Division of Aging] Department of Health and Senior Services as outlined in the manual entitled Level I Medication Aide [(IE 64-1)] (50-6064-S and 50-6064-I) 2001 edition, produced by the Instructional Materials Laboratory, University of Missouri-Columbia, incorporated by reference in this rule and available through the Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570, shall be considered the approved course curriculum. This rule does not incorporate any subsequent amendments or additions to the materials incorporated by reference. Students and instructors each shall have a copy of this manual.

(8) Student Qualifications.

(A) Any individual employable [in] by an RCF [l or ll] or ALF to be involved in direct resident care shall be eligible to enroll as a student in [this] the course [or to challenge the final examination]. Employable shall mean an individual who is at least eighteen (18) years of age; not listed on the [Missouri Division of Aging] department's Employee Disqualification List (EDL) [or any other state's disqualification list;] and has not [been found guilty of, pled guilty to,] been convicted of, or entered a plea of guilty or nolo contendere to a crime in this state or any other state, which if committed in Missouri would be a class A or B felony [under] violation of Chapters 565, 566, and 569, RSMo[; a class D felony under], any violation of section 568.020, RSMo [1994] or any violation of section 198.070.3, RSMo [1994], unless a good cause waiver has been granted by the department pursuant to the provisions of 19 CSR 30-82.060.

(9) Those persons wanting to challenge the final examination shall submit a request in writing to the *[Missouri Division of Aging]* department's Section for Long Term Care director enclosing applicable documentation. If approved to challenge the examination, a letter so stating will be sent from the division to present to an approved instructor so that arrangements can be made for testing.

(10) Instructor Qualifications.

(A) An instructor shall be currently licensed to practice as either a registered nurse or practical nurse in Missouri or shall hold a current temporary permit from the Missouri State Board of Nursing. The licensee shall not be subject to current disciplinary action such as censure, probation, suspension or revocation. If the individual is a licensed practical nurse, the following additional requirements shall be met:

[1. Shall not be waived; and]

[2.] 1. Shall be a graduate of an accredited program which has pharmacology in the curriculum.

2. This additional requirement shall not be waived.

(B) In order to be qualified as an instructor, the individual shall have had one (1) year's experience working in a long-term care (LTC) facility licensed by the *[Division of Aging]* department or the Department of Mental Health within the past five (5) years; or shall be currently employed in an LTC facility licensed by the *[Division of Aging]* department or the Department of Mental Health and shall have been employed by that facility for at least six (6) months; or shall be an instructor in a Health Occupations Education program; and shall have attended a "Train the Trainer" workshop to implement the *[//Level I Medication Aide Program conducted by a Missouri registered nurse presenter approved by the [Missouri Division of Aging]* department.

(11) Sponsoring Agencies.

(A) The [level | Medication Aide Training Program may be sponsored by] following entities are eligible to apply to the department to be an approved training agency: an area vocational-technical school, a comprehensive high school, a community [junior] college, [a college or university approved by the Department of Elementary and Secondary Education, a currently licensed] an approved four (4) year institution of higher learning or an RCF [/ or // or an LTC association] or ALF licensed by the department.

(13) Records and Certification.

(A) Records.

1. The sponsoring agency shall maintain records of all individuals who have been enrolled in the *[/]*Level I Medication Aide Program and shall submit to the LTC association which approved the course all test booklets, a copy of the score sheets and a complete class roster.

2. A copy of the final record shall be provided to any individual enrolled in the course.

3. A final record may be released only with written permission from the student in accordance with the provisions of the Privacy Act (PL 90-247).

(B) Certification.

1. The LTC association which approved the course shall award a *///*Level I medication aide certificate to any individual successfully completing the course upon receiving the required final records and test booklets from the sponsoring agency.

2. The LTC association which approved the course shall submit to the *[Missouri Division of Aging]* department the names of all individuals receiving certificates.

(14) The [division] department shall maintain a list of LTC associations approved to handle the [/]Level I Medication Aide Training Program. In order for an LTC association to be approved by the [division] department the association shall enter into an agreement of cooperation with the [division] department which shall be renewable annually and shall effectively carry out the following responsibilities:

(D) Award certificates to individuals who successfully complete the course, provide the *[Division of Aging]* department with the names of those receiving certificates; and

(15) Maintaining Certification.

(A) If the *[division]* department, upon completion of an investigation, finds that the Level I *[M]*medication *[A]*aide has stolen or diverted drugs from a resident or facility or has had his/her name added to the employee disqualification list, the division shall delete such person's name from the *[division's]* department's Level I Medication Aide listing. Such deletion shall render the *[M]*medication *[A]*aide's certificate invalid.

AUTHORITY: sections 198.076, RSMo [1994] 2000 and 198.005 and 198.073, RSMo (CCS HCS SCS SB 616, 93rd General Assembly, Second Regular Session (2006). This rule originally filed as 13 CSR 15-13.030. Original rule filed May 14, 1985, effective Sept. 1, 1985. Amended: Filed Oct. 16, 1985, effective Jan. 12, 1986. Amended: Filed May 26, 1998, effective Jan. 30, 1999. Moved to 19 CSR 30-84.030, effective Aug. 28, 2001. Amended: Filed Aug. 23, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with David S. Durbin, Director of the Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of [Health Standards] Regulation and Licensure Chapter 84—Training Program for Nursing Assistants

PROPOSED AMENDMENT

19 CSR 30-84.040 Insulin Administration Training Program. The department is amending sections (1), (4), (6) and (9).

PURPOSE: This amendment deletes the terms residential care facility I and II used in this rule and replaces those terms with residential care facility and assisted living facility (ALF) for facilities licensed by the Department of Health and Senior Services pursuant to sections 198.005 and 198.073, RSMo (CCS HCS SCS SB 616, 93rd General Assembly, Second Regular Session (2006)), clarifies that all aspects of the training course as set forth in the rule must be met for an Insulin Administration Training Program to be approved, updates the educational material approved for the course, and changes the name of the agency throughout the rule due to the transfer of the Division of Aging from the Department of Social Services to the Department of Health and Senior Services effective August 28, 2001.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) The *[purpose of the]* Insulin Administration Training Program shall be administered by the Department of Health and Senior Services (the department) in order to prepare medication technicians in a skilled nursing facility (SNF) or intermediate care facility (ICF), or medication aides in a residential care facility (RCF) *[/] or I/]* or an assisted living facility (ALF) to administer insulin. The program shall be designed to present information on diabetes as it relates to symptoms and implications of proper or improper treatment, and to teach skills in insulin administration in order to qualify students to perform this procedure in long-term care (LTC) facilities in Missouri. All aspects of the Insulin Administration Training course included in this rule shall be met in order for the program to be approved.

(4) The manual entitled *Insulin Administration* (50-6080-S and 50-6080-I), *[1990]* **2001 edition**, produced by the Instructional Materials Laboratory, University of Missouri-Columbia, which is incorporated by reference in this rule, and available through the Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570, shall be considered the approved course curriculum. This rule does not incorporate any subsequent amendments or additions to the materials incorporated by reference. Students and instructors shall each have a copy of the manual.

(6) Student Qualifications.

(A) Any level I medication aide working in an RCF or ALF who is recommended in writing for training by an administrator/manager or nurse with whom s/he has worked shall be eligible to enroll as a student in this course.

(9) Records.

(D) The *[Division of Aging]* department shall maintain a list of approved certifying agencies to handle issuance of certificates for the Insulin Administration Program. In order for an agency to be

approved by the [Division of Aging] department to be a certifying agency, it shall enter into an agreement of cooperation with the [Division of Aging] department which shall be renewable annually and the agency shall effectively carry out the following responsibilities:

1. Review all documents submitted by the instructor to assure that the instructor is qualified in accordance with section (7);

2. Assure that all program requirements have been met as set forth in these rules or as stipulated in the agreement with the *[Division of Aging]* department;

3. Issue certificates to individuals who successfully complete the course;

4. Provide the *[Division of Aging]* department with the names of those receiving certificates on at least a monthly basis; and

5. Maintain accurate and complete records for a period of at least two (2) years.

AUTHORITY: sections 198.009 [RSMo Supp. 1997] and 198.076, RSMo [1994] 2000 and 198.005 and 198.073, RSMo (CCS HCS SCS SB 616, 93rd General Assembly, Second Regular Session (2006)). This rule originally filed 13 CSR 15-13.040. Original rule filed Oct. 15, 1990, effective March 14, 1991. Amended: Filed May 26, 1998, effective Nov. 30, 1998. Moved to 19 CSR 30-84.040, effective Aug. 28, 2001. Amended: Filed Aug. 23, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with David S. Durbin, Director of the Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Regulation and Licensure Chapter 86—Residential Care Facilities [/ and ||] and Assisted Living Facilities

PROPOSED AMENDMENT

19 CSR **30-86.012** Construction Standards for [New and Existing Residential Care Facilities II] Assisted Living Facilities and [New/y Licensed] Residential Care Facilities [/]. The department is adding new sections (1) and (27), amending sections (5), (8), (9), (11), (13), (15), (17), (24), and (25), and renumbering the sections throughout.

PURPOSE: This amendment deletes the terms residential care facility I and II used in this rule and replaces the term "residential care facility I with "residential care facility." This rule also replaces the term "residential care facility II" with "assisted living facility." Additional changes clarify the construction standards applicable to assisted living facilities formerly licensed as residential care facilities II that were built or had plans approved before or after certain dates and adds construction requirements for a home-like environment.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

Editor's Note: All rules relating to long-term care facilities licensed by the [Division of Senior Services and Regulations] department are followed by a Roman Numeral which refers to the class (either class I, II or III) of standard as designated in section 198.085.1, RSMo 2000.

(1) These standards apply to assisted living facilities and residential care facilities as indicated in the rule.

[(1)] (2) A facility shall submit a copy of plans of proposed new construction, additions to or major remodeling of an existing facility to the Section for Long Term Care of the Department of Health and Senior Services (hereinafter—the department). If the facility is to be licensed for more than nine (9) residents, a registered architect or registered professional engineer shall prepare the plans and specifications for new construction or additions to an existing facility in conformance with Chapter 327, RSMo. III

[(2)] (3) Construction of facilities shall begin only after the plans and specifications have received the written approval of the department. Facilities shall then be built in conformance with the approved plans and specifications. The facility shall notify the department when construction begins. If construction of the project is not started within one (1) year after the date of approval of the plans and specifications and completed within a period of three (3) years, the facility shall resubmit plans to the department for its approval and shall amend them, if necessary, to comply with the then current rules before construction work is started or continued. III

[(3)] (4) If the facility employs more than fifteen (15) people, it shall conform with section 504 of the Rehabilitation Act of 1973. Any facility that houses handicapped residents shall have the first floor rooms and living areas designed to be accessible to these residents. III

[(4)] (5) Facilities shall not house residents on a level where the outside grade line is more than three feet (3') above the floor level on the window side of the room. II

[(5)] (6) Residential care facilities [/ and //] and facilities whose plans were approved or which were initially licensed as residential care facilities II after December 31, 1987, shall provide a minimum of seventy (70) square feet per resident in private and multiple occupancy bedrooms. This square footage calculation shall include the floor space used for closets and built-in furniture and equipment if these are for resident use and the closet space does not exceed five (5) square feet per resident. Private bedrooms in existing [residential care facilities //] assisted living facilities and multiple occupancy bedrooms in residential care facilities II between November 13, 1980 and December 31, 1987, shall have a minimum of sixty (60) square feet of floor space per resident. II

[(6)] (7) Ceilings in bedrooms shall be a minimum of seven feet (7') in height or if a room with sloping ceiling is used, only the area where the ceiling height is at least seven feet (7') can be used to meet the required minimum square footage per resident. II

[(7)] (8) Facilities shall provide bedrooms with at least one (1) functional outside window with screen. Window size shall be not less than one-twentieth (1/20) or five percent (5%) of the required floor area. II

[(8)] (9) Facilities shall provide resident rooms with a full nonlouvered door that swings into the room. *[Residential care facilities II]* Facilities formerly licensed as residential care facilities II and existing prior to November 13, 1980, are exempt from this requirement. II

[(9)] (10) Facilities shall permit no more than four (4) beds per bedroom, regardless of the room size. [Residential care facilities II] Facilities formerly licensed as residential care facilities II and existing prior to November 13, 1980, are exempt from this requirement. II

[(10)] (11) One (1) tub or shower bath shall be provided for each twenty (20) residents or major fraction of twenty (20). Facilities exceeding twenty (20) residents shall have separate bathing facilities for each sex. II

[(11)] (12) One (1) toilet and lavatory shall be provided for each six (6) residents or major fraction of six (6). [Existing residential care facilities II] Facilities formerly licensed as residential care facilities II and in operation or whose plans were approved prior to November 13, 1980 are required to provide one (1) toilet for each ten (10) beds or major fraction of ten (10) and one (1) lavatory for every fifteen (15) residents or major fraction of fifteen (15). II

[(12)] (13) Separate toilet rooms shall be provided for each sex if common rooms with multi-stalls and stools are provided. II

[(13)] (14) Bath and toilet facilities shall be conveniently located so that residents can reach them without passing through the kitchen, another bedroom or auxiliary service areas. [Existing residential care facilities II] Facilities formerly licensed as residential care facilities II and in operation or whose plans were approved prior to November 13, 1980 are exempt from this requirement. II

[(14)] (15) Bath and toilet facilities shall be ventilated. III

[(15)] (16) Residential care facilities [1 and 11] and facilities formerly licensed as residential care facilities II whose plans were approved or which were initially licensed as residential care facilities II after December 31, 1987, shall have a community living and dining area separate from resident bedrooms with at least twenty-five (25) square feet per resident. The community living and dining area may be combined with footage required for another long-term care facility when the facility is on the same premises as another licensed facility. [Residential care facilities II] Facilities licensed as residential care facilities II prior to November 13, 1980, must have a living room area but they are exempt from minimum size requirements. Residential care facilities [I and II] and facilities licensed as residential care facilities II between November 13, 1980 and December 31, 1987, shall have a community living area with twenty (20) square feet per resident for the first twenty (20) residents and an additional fifteen (15) square feet per resident over a census of twenty (20). II

[(16)] (17) Facilities shall provide the following in the dietary area: a kitchen, dishwashing, refrigeration, and garbage disposal facilities. The facility shall arrange the kitchen and equipment to efficiently and sanitarily enable the storage, preparation, cooking and serving of food and drink to residents. II

[(17)] (18) Residential care facilities *[l and II]* and assisted living facilities shall provide a designated attendant's working area which includes: a storage space for records; locked storage space for medications; a handwashing sink with hot and cold running water, a soap dispenser and paper towels; and a telephone conveniently located to the area. Facilities licensed for twelve (12) or fewer residents are exempt from a separate working area. III

[(18)] (19) Facilities shall have a laundry area in a separate room for storing, sorting, washing, drying and distributing linen and personal clothing. Laundry facilities of a licensed long-term care facility located on the same premises may be used. Facilities licensed for twelve (12) or fewer residents will be exempt from having a separate room for laundry but the laundry room shall be separate from the kitchen and shall not be located in a room used by residents. III

[(19)] (20) All newly licensed facilities shall be of sturdy construction with permanent foundations. III

[(20)] (21) In buildings built prior to September 28, 1979, corridors shall have a minimum width of thirty-six inches (36"). First-floor resident room doors shall be a minimum of thirty-two inches (32") wide. Resident room doors of these buildings on the second floor and above shall be a minimum of thirty inches (30") wide. II/III

[(21)] (22) In newly licensed buildings constructed on or after September 28, 1979, all resident room doors shall be a minimum of thirty-two inches (32") wide on all floors. Corridors shall be a minimum of forty-eight inches (48") wide and interior stairs shall be at least thirty-six inches (36") wide. II/III

[(22)] (23) Exit doors in newly licensed facilities shall be at least thirty-six inches (36") wide, at least seventy-two inches (72") high and shall swing outward. II/III

[(23)] (24) When the facility accepts deaf residents, residential care facilities [/] with an asleep night attendant shall have appropriate assistive devices to enable each deaf person to negotiate a path to safety, including, but not limited to, visual or tactile alarm systems. II/III

[(24)] (25) [All r]Residential care facilities [1 and 11] and facilities formerly licensed as residential care facilities II whose plans were initially approved between December 31, 1987 and December 31, 1998, shall have at least one (1) hydraulic or electric motor-driven elevator if there are more than twenty (20) residents with bedrooms above the first floor. The elevator installations(s) shall comply with all local and state codes, [American Standards Association Specification (ASAS)] American Society for Mechanical Engineers (ASME) A17.1, Safety Code for Elevators, Dumbwaiters, and Escalators, and the National Fire Protection Association's applicable codes. All facilities with plans approved on or after January 1, 1999, shall comply with all local and state codes, [ASAS] ASME A17.1, 1993 Safety Code for Elevators and Escalators, and the 1996 National Electrical Code. [which,] These references are incorporated by reference in this rule and available at: American Society for Mechanical Engineers, Three Park Avenue, New York, NY 10016-5990; and The American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036. This rule does not incorporate any additional amendments or additions. II

[(25)] (26) [All r]Residential care facilities [I and II] and facilities whose plans were approved or which were initially licensed as residential care facilities II after December 31, 1987, shall provide an air-conditioning system, or individual room air-conditioning units, capable of maintaining resident-use areas at eighty-five degrees Fahrenheit (85°F) (29.4°C) at the summer design temperature. II

(27) A facility that is built or has plans approved on or after August 28, 2006, shall be more home-like than institutional with respect to construction and physical plant standards. Any facility licensed as a residential care facility II prior to August 28, 2006, shall qualify as being more home-like than institutional with respect to construction and physical plant standards. II AUTHORITY: sections 198.076, RSMo 2000 and 198.005 and 198.073, RSMo (CCS HCS SCS SB616, 93rd General Assembly, Second Regular Session (2006)). This rule originally filed as 13 CSR 15-15.012. Original rule filed July 13, 1983, effective Oct. 13, 1983. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 23, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with David S. Durbin, Director of the Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Regulation and Licensure Chapter 86—Residential Care Facilities [/ and ||] and Assisted Living Facilities

PROPOSED AMENDMENT

19 CSR 30-86.022 Fire Safety Standards for *[New and Existing]* **Residential Care Facilities** *[I and II] and Assisted Living Facilities.* The department is amending sections (1), (2), (4), (5), (6), (8), (9) and (10), and adding sections (15) and (16).

PURPOSE: This amendment deletes the terms residential care facility I and II used in this rule and replaces the term "residential care facility I" with "residential care facility." This rule also replaces the term "residential care facility II" with "assisted living facility" and clarifies the definition of "area of refuge."

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

PUBLISHER'S NOTE: All rules relating to long-term care facilities licensed by the [Division of Aging] department are followed by a Roman Numeral notation which refers to the class (either class I, II or III) of standard as designated in section 198.085.1, RSMo. Supp. 1999.

(1) Definitions. For the purpose of this rule, the following definition shall apply:

(A) Area of refuge—A space located in **or immediately adjacent to** a path of travel leading to *[a public way]* **an exit** that is protected from the effects of fire, either by means of separation from other spaces in the same building or *[by virtue of]* **its** location, *[thereby]* permitting a delay in *[egress travel from any leve]]* **evacuation**. An area of refuge *[has a temporary use during egress. It generally serves as a staging area that provides relative safety to its occupants while potential emergencies are assessed, decisions are made, and mitigating activities are begun. Taking refuge within such an area is, thus, a stage*

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of the total egress process; a stage between egress from the immediately threatened area and egress to a public way] may be temporarily used as a staging area that provides some relative safety to its occupants while potential emergencies are assessed, decisions are made, and evacuation has begun.

(2) General Requirements:

(A) All National Fire Protection Association (NFPA) codes and standards cited in this rule: NFPA 10, Standard for Portable Fire Extinguishers, 1994 edition; NFPA 13R, Installation of Sprinkler Systems, 1996 edition; NFPA 13, Installation of Sprinkler Systems, 1976 edition; NFPA 13 or NFPA 13R, Standard for the Installation of Sprinkler Systems in Residential Occupancies Up to and Including Four Stories in Height, 1999 edition; NFPA 13 or NFPA 13D, Standard for the Installation of Sprinkler Systems, 1999 edition; NFPA 13D, Standard for the Installation of Sprinkler Systems in One- and Two-Family Dwellings and Manufactured Homes, 1994 edition; NFPA 96, Ventilation Control and Fire Protection of Commercial Cooking Operations, 1994 edition; NFPA 101, The Life Safety Code, 2000 edition; NFPA 72, National Fire Alarm Code, 1996 edition; NFPA 72A, Local Protective Signaling Systems. 1975 edition; NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems, 1998 edition; and NFPA 253, Standard Method of Test for Critical Radiant Flux of Floor Covering Systems Using a Radiant Heat Energy Source, 2000 edition with regard to the minimum fire safety standards for residential care facilities // and /// and assisted living facilities are incorporated by reference in this rule and available for purchase from the National Fire Protection Agency, 1 Batterymarch Park, Quincy, MA 02269-9101; www.nfpa.org; by telephone at (617) 770-3000 or 1-800-344-3555. This rule does not incorporate any subsequent amendments or additions to the materials listed above.

(G) When the facility accepts residents who are deaf, residential care facilities *[I]* with an asleep night attendant shall have appropriate assistive devices to enable each deaf person to negotiate a path to safety, including, but not limited to, visual or tactile alarm systems. I/II

(4) Range Hood Extinguishing Systems.

(A) In facilities *[licensed]* formerly licensed as residential care facilities II on or after July 11, 1980, and residential care facilities formerly licensed as residential care facilities I on or before July 11, 1980, or in any facility with fewer than twenty-one (21) beds, the kitchen shall provide either:

1. An approved automatic range hood extinguishing system properly installed and maintained in accordance with the 1994 NFPA 96, *Standard on Ventilation Control and Fire Protection of Commercial Cooking Operations*; or

2. A portable fire extinguisher of at least ten (10) pounds, or the equivalent, in the kitchen area in accordance with the 1994 NFPA 10. II/III

(D) The range hood and its extinguishing system shall be inspected and certified at least twice annually in accordance with the 1994 edition of NFPA 96. II/III

(5) Fire Drills.

(A) All facilities shall develop a written plan for fire drills or other emergencies, and evacuation, and shall request consultation and assistance annually from a local fire unit. Such plan shall include, if consistent with the direction of the local fire unit and as appropriate for the fire or emergency, a phased response ranging from relocation of residents within the facility, to relocation to an area of refuge, to total evacuation. II/III

(6) Exits, Stairways and Fire Escapes.

(C) In residential care facilities and facilities formerly licensed as residential care facilities II, *[F]* floors housing residents who require the use of a walker, wheelchair or other assistive devices or aids, or who are blind, must have two (2) accessible exits to grade or such residents must be housed near accessible exits as specified in 19 CSR 30-86.042[/(32)](33) for residential care facilities and 19 CSR 30-86.043(31) for facilities formerly licensed as residential care facilities II. Unless otherwise prohibited by 19 CSR 30-86.045 or 19 CSR 30-86.047, [F]facilities equipped with a complete sprinkler system, in accordance with the 1996 edition of NFPA 13 or NFPA 13R with sprinklered attics, and smoke partitions, as defined by subsection (9)(I) of this rule, may house such residents on floors that do not have accessible exits to grade if each required exit is equipped with an area of refuge as defined and described in subsections (1)(A) and (6)(D) of this rule.. I/II

(8) Fire Alarm Systems.

(B) All residential care facilities *[/]* licensed for more than twenty (20) residents shall be equipped with a complete fire alarm system in accordance with the applicable edition of NFPA 72. I/II

(C) [All residential care facilities II] Facilities that are required to comply with the requirements of 19 CSR 30-86.043 shall be equipped with a complete fire alarm system in accordance with the applicable edition of NFPA 72. I/II

(D) All residential care facilities **and assisted living facilities** with more than one (1) structure on the premises housing residents shall be equipped with a complete fire alarm system in accordance with the applicable edition of NFPA 72. I/II

(F) Residential care facilities [/] licensed for twenty (20) or fewer residents shall be equipped with a complete automatic fire alarm system or individual home-type detectors. The individual home-type detectors shall be UL-approved battery-powered detectors which sense smoke and automatically sound an alarm which can be heard throughout the facility. If individual home-type detectors are being used, there shall be one (1) detector per resident-use room, in corridors and stairwells and in any hazardous area other than the kitchen where either a smoke or heat detector may be used. I/II

(G) The fire alarm system shall be an electrically supervised system with standby emergency power installed and maintained in accordance with the 1996 NFPA 72. Those facilities that are required to comply with the requirements of 19 CSR 30-86.042 and 19 CSR 30-86.043, with plans approved prior to October 1, 2000, shall comply with the provision of the 1975 edition of NFPA 72A, *Local Protective Signaling Systems.* [Those facilities with plans approved on or after October 1, 2000, shall comply with the 1996 edition of NFPA 72.] I/II

(H) [As] At a minimum, the fire alarm system shall consist of a manual pull station at or near each attendant's station and each required exit, smoke detectors located no more than thirty feet (30') apart in the corridors or passageways with no point in the corridor or passageway more than fifteen feet (15') from a detector and no point in the building more than thirty feet (30') from a detector. In residential care facilities formerly licensed as residential care facilities I and existing prior to November 13, 1980, and those facilities that are required to comply with the requirements of 19 CSR 30-86.043, smoke detectors located every fifty feet (50') will be acceptable. The smoke detectors will not be required in facilities licensed prior to November 13, 1980, if a complete heat detector system, interconnected to the fire alarm system, is provided in every space throughout the facility. It must include audible signal(s) which can be heard throughout the building and a main panel that interconnects all alarm-activating devices and audible signals. I/II

(N) Refer to section (16) of this rule for additional fire alarm standards for those assisted living facilities which provide services to residents with a physical, cognitive, or other impairment that prevents the individual from safely evacuating the facility with minimal assistance.

(9) Protection from Hazards.

(A) In *[residential care]* facilities *[l and II]* and assisted living facilities licensed on or after November 13, 1980, for more than

twelve (12) residents, hazardous areas shall be separated by construction of at least a one (1)-hour fire-resistant rating. In facilities equipped with a complete automatic fire alarm system, not individual residential-type detectors, the one (1)-hour fire separation is required only for furnace or boiler rooms. Hazardous areas equipped with a complete sprinkler system are not required to have this one (1)-hour fire separation. Doors to hazardous areas shall be self-closing and shall be kept closed unless an electromagnetic holdopen device is used which is interconnected with the fire alarm system. **Residential care facilities formerly licensed as residential care facilities I and existing prior to November 13, 1980, and facilities formerly licensed as residential care II facilities and existing prior to November 13, 1980, shall be exempt from this requirement. II**

(E) In *[residential care facilities II]* assisted living facilities that are required to comply with the requirements of 19 CSR 30-86.043 and were formerly licensed as residential care facilities II on or after November 13, 1980, each floor shall be separated by construction of at least a one (1)-hour fire resistant rating. Buildings equipped with a complete sprinkler system may have a nonrated smoke separation barrier between floors. Doors between floors must be a minimum of one and three-fourths inches (1 3/4") thick and be solid core wood doors or metal doors with an equivalent fire rating. II

(F) In *[residential care]* facilities *[I and II licensed prior to November 13, 1980, and multi-storied residential care facilities I]* licensed on or after November 13, 1980, there shall be a smoke separation barrier between the floors of resident-use areas and any floor below the resident-use area. This shall consist of a solid core wood door or metal door with an equivalent fire rating at the top or the bottom of the stairs. There shall not be a transom above the door that would permit the passage of smoke. II

(I) In facilities whose plans [are] were approved or which [are] were initially licensed after December 31, 1987, for more than twenty (20) residents, each floor used for resident bedrooms shall be divided into at least two (2) smoke sections by one (1)-hour rated smoke stop partitions. No smoke section shall exceed one hundred fifty feet (150') in length. If, however, neither the length nor width of a floor exceeds seventy-five feet (75'), no smoke stop partitions are required unless the facility is required to comply with the requirements of 19 CSR 30-86.045 or 19 CSR 30-86.047. Openings in smoke stop partitions shall be protected by solid core doors equipped with closers and magnetic hold-open devices. Any duct passing through this smoke wall shall be equipped with automatic resetting smoke dampers that are activated by the fire alarm systems. Smoke dampers are not required where both smoke sections are protected by Quick Response Sprinklers. Smoke partitions shall extend from outside wall-to-outside wall and from floor-to-floor or floor-to-roof deck. II

(J) Facilities whose plans *[are]* were approved or which *[are]* were initially licensed after December 31, 1987, for more than twenty (20) residents and which are unsprinklered shall have one (1)-hour rated corridor walls with one and three-quarters inch (1 3/4") solid core wood doors or metal doors with an equivalent fire rating. II

(L) Refer to section (16) of this rule for additional standards for those assisted living facilities which provide services to residents with a physical, cognitive, or other impairment that prevents the individual from safely evacuating the facility with minimal assistance.

(10) Sprinkler Systems.

(A) [All residential care facilities II that are not of fire-resistant construction which house any residents above the second floor shall be provided throughout with] In facilities that are required to comply with the requirements of 19 CSR 30-86.043, an automatic sprinkler system shall be installed and maintained according to the applicable edition of the NFPA 13, *Standard* for the Installation of Sprinkler Systems, if residents reside above the second floor and the facility is not of fire resistant construction. I/II (B) Residential care facilities [I] that are not of fire-resistant construction and which house residents above the third floor shall be provided throughout with an automatic sprinkler system installed and maintained according to the applicable edition of the NFPA 13 or NFPA 13D, *Standard for the Installation of Sprinkler Systems in One- and Two-Story Dwellings and Manufactured Homes*. I/II

(D) All *[residential care]* facilities *[] and []]* initially licensed or with plans approved on or after October 1, 2000, shall have complete sprinkler systems installed and maintained in accordance with the 1996 edition of NFPA 13 or NFPA 13R, except that multilevel assisted living facilities that are required to comply with the requirements in 19 CSR 30-86.045 and multilevel assisted living facilities built after August 28, 2006, shall provide a complete sprinkler system in accordance with the 1996 edition of NFPA 13. Multilevel assisted living facilities with major renovations after August 27, 2006, shall provide a complete sprinkler system in accordance with the 1996 edition of NFPA 13 in the portion of the facility where the major renovation occurred. In areas where public water supplies are not available, a private water supply meeting the requirements of the 1994 edition of NFPA 13D, Standard for the Installation of Sprinkler Systems in One- and Two-Family Dwellings and Manufactured Homes, will be acceptable for all facilities except multilevel assisted living facilities that are required to comply with the requirements of 19 CSR 30-86.045 or 19 CSR 30-86.047. I/II

(G) Refer to section (16) of this rule for additional sprinkler system standards for those assisted living facilities which provide services to residents with a physical, cognitive, or other impairment that prevents the individual from safely evacuating the facility with minimal assistance.

(15) Standards for Designated Separated Areas.

(A) When a resident resides among the entire general population of the facility, the facility shall take necessary measures to provide such residents with the opportunity to explore the facility and, if appropriate, its grounds. When a resident resides within a designated, separated area that is secured by limited access, the facility shall take necessary measures to provide such residents with the opportunity to explore the separated area and, if appropriate, its grounds. If enclosed or fenced courtyards are provided, residents shall have reasonable access to such courtyards. Enclosed or fenced courtyards that are accessible through a required exit door shall be large enough to provide an area of refuge for fire safety at least thirty feet (30') from the building. Enclosed or fenced courtyards that are accessible through a door other than a required exit shall have no size requirements. II

(B) The facility shall provide freedom of movement for the residents to common areas and to their personal spaces. The facility shall not lock residents out of or inside their rooms. I/II

(C) The facility may allow resident room doors to be locked providing the residents request to lock their doors. Any lock on a resident room door shall not require the use of a key, tool, special knowledge or effort to lock or unlock the door from inside the resident's room. Only one (1) lock shall be permitted on each door. The facility shall ensure that facility staff have the means or mechanisms necessary to open resident room doors in case of an emergency. I/II

(D) Every facility shall use a personal electronic monitoring device for any resident whose physician recommends the use of such device. II

(E) The facility may provide a designated, separated area where residents, who are mentally incapable of negotiating a pathway to safety, reside and receive services and which is secured by limited access if the following conditions are met:

1. Dining rooms, living rooms, activity rooms, and other such common areas shall be provided within the designated, separated area. The total area for common areas within the designated, separated area shall be equal to at least forty (40) square feet per resident; II/III

2. Doors separating the designated, separated area from the

remainder of the facility or building shall not be equipped with locks that require a key to open; I/II

3. If locking devices are used on exit doors egressing the facility or on doors accessing the designated, separated area, delayed egress magnetic locks shall be used. These delayed egress devices shall comply with the following:

A. The lock must unlock when the fire alarm is activated;

B. The lock must unlock when the power fails;

C. The lock must unlock within thirty (30) seconds after the release device has been pushed for at least three (3) seconds, and an alarm must sound adjacent to the door;

D. The lock must be manually reset and cannot automatically reset; and

E. A sign shall be posted on the door that reads: PUSH UNTIL ALARM SOUNDS, DOOR CAN BE OPENED IN 30 SECONDS. I/II

4. The delayed egress magnetic locks may also be released by a key pad located adjacent to the door for routine use by staff. I/II

(16) Additional fire safety standards for assisted living facilities which provide services to residents with a physical, cognitive, or other impairment that prevents the individual from safely evacuating the facility with minimal assistance. All such facilities must comply with the following requirements:

(A) The facility shall be equipped with a complete electrically supervised fire alarm system in accordance with the provisions of subsection 13-3.4 of the 1997 *Life Safety Code for Existing Health Care Occupancy*, incorporated herein by reference and available from the National Fire Protection Agency, 1 Batterymarch Park, Quincy, MA 02269-9101. This rule does not incorporate any subsequent amendments or additions to these materials. At a minimum the system shall include smoke detectors located no more than thirty feet (30') apart in corridors with no point in the corridor located more than fifteen feet (15') from a smoke detector. The fire alarm system shall be equipped to automatically transmit an alarm to the fire department; I/II

(B) Each floor used for resident bedrooms shall be divided into at least two (2) smoke sections by one (1)-hour rated smoke stop partitions. No smoke section shall exceed one hundred fifty feet (150') in length. At a minimum, openings in smoke stop partitions shall be protected by one and three-fourths inches (1 3/4")thick solid core wood doors or labeled, fire rated doors with an equivalent or greater fire rating. The doors shall be equipped with closures and if held open, shall be equipped with magnetic hold-open devices that automatically release upon activation of the fire alarm system. Any duct passing through this smoke wall shall be equipped with automatic resetting smoke dampers that are activated by the fire alarm system. Smoke dampers are not required where both smoke sections are protected throughout the entire section by quick response sprinklers on an NFPA 13 system. Smoke partitions shall extend from outside wall-to-outside wall and from floor-to floor or floor-to-roof deck; II and

(C) In addition to the requirements at subsections (4)(A)1. and 2. of this rule, all facilities shall be equipped with a complete automatic sprinkler system installed and maintained in accordance with the following:

1. The 1996 edition of the National Fire Protection Association (NFPA) 13, *Standard for the Installation of Sprinkler Systems* (1996 edition of NFPA 13); or

2. The 1996 edition of NFPA 13R, Sprinkler Systems in Residential Occupancies Up To and Including Four Stories in Height (1996 edition of NFPA 13R), which are incorporated herein by reference and available from the National Fire Protection Agency, 1 Batterymarch Park, Quincy, MA 02269-9101. This rule does not incorporate any subsequent amendments or additions to these materials; and

3. Single story facilities must comply with either NFPA 13 or

NFPA 13R;

4. Multistory facilities must comply with NPFA 13. I/II

AUTHORITY: sections 198.076, RSMo 2000 and 198.005 and 198.073, RSMo (CCS HCS SCS SB616, 93rd General Assembly, Second Regular Session (2006)). This rule originally filed as 13 CSR 15-15.022. Original rule filed July 13, 1983, effective Oct. 13, 1983. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 23, 2006.

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

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

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with David S. Durbin, Director, Division of Regulation and Licensure, Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Regulation and Licensure Chapter 86—Residential Care Facilities [/ and ||] and Assisted Living Facilities

PROPOSED AMENDMENT

19 CSR 30-86.032 Physical Plant Requirements for [New and Existing] **Residential Care Facilities** [*I and II*] and Assisted Living Facilities. The department is amending sections (1), (3), (7), (10), (11), (13), (18) and (33) and adding a new section (35).

PURPOSE: This amendment deletes the term "residential care facility I" used in this rule and replaces the term with "residential care facility" and deletes the term "residential care facility II" used in this rule and replaces the term "residential care facility II" with "assisted living facility." The amendment deletes the definition of "respite care," adds the definition of "home-like" and requirements for a wireless call system. This amendment clarifies the requirements for non-licensed and licensed adult daycare programs, handrails and grab bars affixed in toilets and bathing areas, wood-burning stoves and electrical appliance approval standards and that facilities shall be more home-like than institutional with respect to construction and physical plant standards.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

Editor's Note: All rules relating to long-term care facilities licensed by the [Division of Senior Services and Regulation] department are followed by a Roman Numeral notation which refers to the class (either class I, II or III) of standard as designated in section 198.085.1, RSMo 2000. (1) Definitions. For the purpose of this rule, the following definitions shall apply:

[(A) Non-licensed adult day care program shall mean a group program designated to provide care and supervision to meet the needs of four (4) or fewer impaired adults for periods of less than twenty-four (24) hours but more than two (2) hours per day in a long-term care facility.

(B) Respite care shall mean short-term care and health services to an impaired individual who is at least seventeen (17) years of age and who receives care or supervision that is normally provided in home by his or her family or other caregiver.]

[(C)] (A) Adult day health care program shall mean a program operated by a provider certified to provide Medicaid-reimbursed adult day health care services to Medicaid-eligible participants in accordance with 19 CSR 70-92.010[.];

[(D)] (B) Associated adult day health care program shall mean an adult day health care program, which is connected physically with a licensed long-term care facility but has separate designated space for an adult day health care program which is above the licensed space requirement for the long-term care residents. An associated adult day health care program may share, in part, staff, equipment, utilities, dietary and security with the connected long-term care facility. Recipients of adult day health care program may participate with the residents of the long-term care facility for some activities and programs[.];

(C) Home-like—means a self-contained long-term care setting that integrates the psychosocial, organizational and environmental qualities that are associated with being at home. Home-like may include, but is not limited to the following:

1. A living room and common use areas for social interactions and activities;

2. Kitchen and family style eating area for use by the residents;

3. Laundry area for use by residents;

4. A toilet room that contains a toilet, lavatory and bathing unit in each resident's room;

5. Resident room preferences for residents who wish to share a room, and for residents who wish to have private bed-rooms;

6. Outdoor area for outdoor activities and recreation; and

7. A place where residents can give and receive affection, explore their interests, exercise control over their environment, engage in interactions with others and have privacy, security, familiarity and a sense of belonging; and

(D) Non-licensed adult day care program shall mean a group program designated to provide care and supervision to meet the needs of four (4) or fewer impaired adults for periods of less than twenty-four (24) hours but more than two (2) hours per day in a long-term care facility.

(3) Only activities necessary to the administration of the facility shall be contained in any building used as a long-term care facility except as follows:

(B) Adult day care may be provided for four (4) or fewer participants without prior written approval of the department if the long-term care facility meets the following stipulations:

1. The operation of the adult day care business shall not interfere with the care and delivery of services to the long-term care residents;

2. The facility shall only accept participants in the adult day care program appropriate to the level of care of the facility and whose needs can be met;

3. The facility shall not change the physical layout of the facility without prior written approval of the department;

4. The facility shall provide a private area for adult day care residents to nap or rest;

5. Adult day care participants shall not be included in the cen-

sus, and [the licensed capacity of the long-term care facility shall not be exceeded] the number of adult day care participants shall not be more than four (4) above the licensed capacity of the facility; and

6. The adult day care participants, while on-site, are to be included in the determination of staffing patterns for the long-term care facility;

(C) An associated adult day health care program may be operated without prior written approval if the provider of the adult day health care services is certified in accordance with 19 CSR 70-92.010. **II/III**

[(D) Respite care may be provided without prior written approval if the facility meets the following stipulations:

1. The operation of the respite care business shall not interfere with the care and delivery of services to the longterm care residents;

 The facility shall only accept individuals in the respite care program appropriate to the level of care of the facility and whose needs can be met;

3. The facility shall not change the physical layout of the facility without prior written approval of the department;

4. The facility shall admit the respite care resident into a long-term care resident room;

5. Respite care residents shall be included in the census, and the licensed capacity of the long-term care facility shall not be exceeded; and

6. The respite care residents shall be included in the determination of staffing patterns for the long-term care facility. II/III]

(7) Newly licensed facilities shall have handrails and grab bars affixed in all toilet and bathing areas. Existing licensed facilities shall have handrails and grab bars available in at least one (1) bath and toilet area. The foregoing requirements are applicable to residential care facilities. All assisted living facilities shall have handrails and grab bars affixed in all toilet and bathing areas. II

(10) In newly licensed facilities or if a new heating system is installed in an existing licensed facility, the heating of the building shall be restricted to steam, hot water, permanently installed electric heating devices or a warm air system employing central heating, plants with installation such as to safeguard the inherent fire hazard, or approved installation of outside wall heaters which bear the approved label of the American Gas Association or National Board of Fire Underwriters. The foregoing requirements are applicable to residential care facilities. In assisted living facilities, the heating of the building shall be restricted to steam, hot water, permanently installed electric heating devices or a warm air system employing central heating plants with installation such as to safeguard the inherent fire hazard, or approved installation of outside wall heaters which bear the approved label of the American Gas Association or National Board of Fire Underwriters. [All] For all facilities, oil or gas heating appliances shall be properly vented to the outside[.] and [7]the use of portable heaters of any kind is prohibited. If approved wall heaters are used, adequate guards shall be provided to safeguard residents. I/II

(11) Wood-burning stoves shall not be installed in newly licensed facilities or in existing licensed facilities that did not previously have a wood-burning stove. If wood-burning stoves are used in an existing licensed facility, or wood-burning furnaces or fireplaces are used, flues or chimneys shall be maintained in good condition and kept free of accumulation of combustible materials. The foregoing requirements are applicable to residential care facilities. Wood-burning stoves shall not be installed in assisted living facilities. II

(13) In facilities that are constructed or have plans approved after July 1, 2005, electrical wiring shall be installed and maintained in

accordance with the requirements of the *National Electrical Code*, 1999 edition, National Fire Protection Association, Inc. [One Batterymarch Park, Quincy, Massachusetts 02269], incorporated by reference in this rule and available by mail at One Batterymarch Park, Quincy, MA 02269, and local codes. This rule does not incorporate any subsequent amendments or additions to the materials incorporated by reference. Facilities built between [July 1, 2005 and] September 28, 1979 and July 1, 2005 shall be maintained in accordance with the requirements of the National Electrical Code, which was in effect at the time of the original plan approval and local codes. This rule does not incorporate ay subsequent amendments or additions. In facilities built prior to September 28, 1979, electrical wiring shall be maintained in good repair and shall not present a safety hazard. All facilities shall have wiring inspected every two (2) years by a qualified electrician. II/III

(18) If extension cords are used, they must be Underwriters' Laboratory (UL)-approved or shall comply with other recognized electrical appliance approval standards and sized to carry the current required for the appliance used. Only one (1) appliance shall be connected to one (1) extension cord and only two (2) appliances may be served by one (1) duplex receptacle. If extension cords are used, they shall not be placed under rugs, through doorways or located where they are subject to physical damage. II/III

(33) All *[new and existing residential care facilities II]* assisted living facilities and all residential care facilities/// whose plans are approved or which are initially licensed for more than twelve (12) residents after December 31, 1987 shall be equipped with a call system consisting of an electrical intercommunication system, a wireless pager system, buzzer system or hand bells. An acceptable mechanism for calling attendants shall be located in each toilet room and resident bedroom. Call systems for facilities whose plans are approved or which are initially licensed after December 31, 1987 shall be audible in the attendant's work area. II/III

(35) A facility that is built or has plans approved on or after August 28, 2006, shall be more home-like than institutional with respect to construction and physical plant standards. Any facility licensed as a residential care facility II prior to August 28, 2006, shall qualify as being more home-like than institutional with respect to construction and physical plant standards. II

AUTHORITY: sections 198.076, RSMo 2000 and 198.005 and 198.073, (CCS HCS SCS SB616, 93rd General Assembly, Second Regular Session (2006)). This rule originally filed as 13 CSR 15-15.032. Original rule filed July 13, 1983, effective Oct. 13, 1983. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 23, 2006.

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

PRIVATE COST: This proposed amendment will cost facilities formerly licensed as residential care facilities II a total one-time cost in the aggregate of six thousand one hundred sixty-one dollars (\$6,161).

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with David S. Durbin, Director, Senior Services, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register.** No public hearing is scheduled.

FISCAL NOTE PRIVATE COST

I. RULE NUMBER

	19 CSR 30-86.032 Physical Plant Requirements for Residential Care Facilities and Assisted Living Facilities
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of	Classification by types of	Estimate in the aggregate as
entities by class which would	the business entities which	to the cost of compliance
· ·	would likely be affected:	with the rule by the affected
		entities:
37	Facilities formerly Licensed	Total One-Time Cost in the
	as Residential Care Facility	Aggregate \$6,161*
	II	
	entities by class which would likely be affected by the adoption of the proposed rule:	entities by class which would likely be affected by the adoption of the proposed rule:the business entities which would likely be affected:37Facilities formerly Licensed as Residential Care Facility U

III. and IV. WORKSHEET AND ASSUMPTIONS

Beginning February, 1980, regulations have required residential care facility IIs to install handrails in all toilet areas and grab bars in all bathing areas. According to DHSS licensure records, 53 residential care facility IIs were existence prior to February, 1980. Based on comments received from the long term care industry DHSS estimates 70% of the 53 total existing residential care facility IIs in existence prior to February, 1980, will choose to comply with Assisted Living Facility standards ($53 \times .70 = 37$). All costs are based on this percentage (37 facilities).

Handrails and Grab Bars – This proposed rule requires assisted living facilities to have handrails affixed in all toilet areas and grab bars affixed in all bathing areas. According to a national home improvement store, the cost of a handrail is \$13.58 and the cost of a grab bar is \$10.96. According to a local contractor, cost for contract labor to install handrails and grab bars is \$30 per hour. DHSS estimates two hours of contract labor per facility to install handrails and grab bars. Current requirements for new facilities (facilities licensed after February, 1980) require facilities to have a toilet area for every 6 licensed beds and a bathing area for every ten licensed beds. Current requirements for existing facilities (facilities licensed prior to February, 1980) require only one toilet area to have a hand rail and only one bathing area to have a grab bar. Based on current requirements for new facilities, DHSS estimates each assisted living facility will need to install six additional grab bars (15,515 bed capacity in residential care facility IIs / 365 total facilities) / (6 number of licensed beds requiring a toilet area) -(1) bathing area currently required for existing facilities) and three additional handrails (15,515 bed capacity in residential care facility IIs / 365 total facilities) / (10 number of licensed beds requiring a bathing area) -(1 bathing area currently required for existing facilities). DHSS estimates the total one time cost to assisted living facilities in the aggregate to be $6.161 (65.76 \cot \theta \sin \theta \sin \theta + 40.74 \cot \theta \sin \theta) \times (37$ facilities) + (\$60 cost of two contract labor hours x 37 facilities).

* At an August 7,2006 public meeting, various members of the long term care industry verbally reported various estimated costs for specific requirements, but did not elaborate how they reached these conclusions.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 30—Division of Regulation and Licensure Chapter 86—Residential Care Facilities [/ and ||] and Assisted Living Facilities

PROPOSED AMENDMENT

19 CSR 30-86.042 Administrative, Personnel and Resident Care Requirements for New and Existing Residential Care Facilities *[/ and II]*. The department is adding new sections (1), (11), (12), (18), (19), (20), (22), (33), (34), (37), (41), (43), (47), (48), (49), (52), (53), (54), (55), (56), (58), and (59); amending sections (2), (3), (4), (7), (8), (9), (10), (11), (13), (17), (19), (24), (26), (28), (29), (32), (37), (46), (47), (48), (50), (51), (55), (59), (60), and (61); deleting sections (1), (6), (12), (18), (25), (30), (34), (38), (40), (41), (42), (43), (44), (45), (49), (52), (53), (54), (56), and (57), and renumbering and reordering sections throughout.

PURPOSE: This amendment changes the name of the agency throughout the rule due to the transfer of the Division of Aging from the Department of Social Services to the Department of Health and Senior Services; deletes all references to residential care facilities I and II, replaces the term "residential care facility I" with "residential care facility," defines the terms "department," "outbreak" and significant change; adds, updates or clarifies requirements for criminal background check and Employee Disqualification List; medication standards; administration and personnel requirements, adult day care, new employee orientation, requirements for meeting the needs of residents having psychosocial difficulties, behavior management difficulties, including disruptive or assaultive behaviors; requirements for protective oversight when residents are on voluntary leave from the facility and the statutorily mandated orientation training requirements for Alzheimer's disease and related dementias.

Editor's Note: All rules relating to long-term care facilities licensed by the [Division of Aging] department are followed by a Roman Numeral notation which refers to the class (either class I, II or III) of standard as designated in section 198.085.1, RSMo 1986.

[(1) For a residential care facility II, a person shall be designated to be administrator who is currently licensed as a nursing home administrator under Chapter 344, RSMo. II]

(1) Definitions. For the purpose of this rule, the following definitions shall apply:

(A) Department-Department of Health and Senior Services; and

(B) Outbreak—an occurrence in a community or region of an illness(es) similar in nature, clearly in excess of normal expectancy and derived from a common or a propagated source.

(2) For a residential care facility [*I*], a person shall be designated as administrator/manager who is either currently licensed as a nursing home administrator or is at least twenty-one (21) years of age, has never been convicted of an offense involving the operation of a long-term care or similar facility and who attends at least one (1) continuing education workshop within each calendar year given by or approved by the [Division of Aging] department. When used in this chapter of rules, the term manager shall mean that person who is designated by the operator to be in general administrative charge of a residential care facility [*I*]. It shall be considered synonymous to "administrator" as defined in section 198.006, RSMo and the terms administrator and manager may be used interchangeably. II/III

(3) [By January 1, 1991, t] The administrator/manager of a residential care facility [/ or //] shall have successfully completed the state approved Level I Medication Aide course unless [s/he] he or **she** is a physician, pharmacist, licensed nurse or a certified medication technician, or if the facility is operating in conjunction with a skilled nursing facility or intermediate care facility on the same premises, or, for *[a residential care facility II]* an assisted living facility, if the facility employs on a full-time basis, a licensed nurse who is available seven (7) days per week. II/III

(4) The operator shall be responsible to assure compliance with all applicable laws and regulations. The administrator/manager shall be fully authorized and empowered to make decisions regarding the operation of the facility and shall be held responsible for the actions of all employees. The administrator/manager's responsibilities shall include oversight of residents to assure that they receive *[appropriate]* care **appropriate to their needs**. II/III

[(6) For a residential care facility II, the administrator cannot be listed or function in more than one (1) facility at the same time unless s/he serves no more than four (4) facilities which are within a thirty (30)-mile radius and licensed to serve in total no more than one hundred (100) residents. However, one (1) administrator may serve as the administrator of more than one (1) licensed facility if all facilities are on the same premises. II/III]

[(7)] (6) The administrator/manager shall designate, in writing, a staff [person] member in charge in [his/her] the administrator/manager's absence. [For a residential care facility II, if the administrator is absent for more than thirty (30) consecutive days, during which time s/he is not readily accessible for consultation by telephone with the person in charge, or if the administrator is absent from the facility for more than sixty (60) working days during the course of a calendar year, the person designated to be in charge shall be a licensed nursing home administrator.] II/III

[(8)] (7) The facility shall not care for more residents than the number for which the facility is licensed. If the facility operates a nonlicensed adult day care program within the licensed facility, the day care participants shall be counted in the staffing determination during the hours the day care participants are in the facility. II/III

[(9)] (8) The facility's current license shall be posted in a conspicuous place and notices provided to the facility by the [Division of Aging] department granting exception(s) to regulatory requirements shall be posted alongside of the facility's license. III

[(10)] (9) All personnel responsible for resident care shall have access to the legal name of each resident, name and telephone number of resident's physician [and next of kin or, responsible party], resident's designee or legally authorized representative in the event of emergency. II/III

[(11)] (10) All persons who have any contact with the residents in the facility shall not knowingly act or omit any duty in a manner which would materially and adversely affect the health, safety, welfare or property of residents. No person who is listed on the Employee Disqualification List (EDL) maintained by the [division] department as required by section 198.070, RSMo shall work or volunteer in the facility in any capacity whether or not employed by the operator. For the purpose of this rule, a volunteer is an unpaid individual formally recognized by the facility as providing a direct care service to residents. The facility is required to check the EDL for individuals who volunteer to perform a service for which the facility might otherwise have to hire an employee. The facility is not required to check the EDL for an individuals or groups such as scout groups, bingo or sing-along leaders. The facility is not required to check the EDL for an individual such as a priest,

minister or rabbi visiting a resident who is a member of the individual's congregation. However, if the minister, priest or rabbi serves as a volunteer facility chaplain, the facility is required to check the EDL since the individual would have potential contact with all residents. I/II

[(12)] (11) [Effective August 28, 1997, each facility shall, not later than two (2) working days of the date an applicant for a position to have contact with residents is hired, request a criminal background check, as provided in sections 43.530, 43.540 and 610.120, RSMo. Each facility must maintain in its record documents verifying that the background checks were requested and the nature of the response received for each such request. The facility must ensure that any applicant who discloses prior to the check of his/her criminal records that he/she has been convicted of, plead guilty or nolo contendere to, or has been found guilty of any A or B felony violation of Chapter 565, 566, or 569, RSMo, or any violation of subsection 3 of section 198.070, RSMo, or of section 568.020, RSMo, will not be allowed to work in contact with patients or residents until and unless a check of the applicant's criminal record shows that no such conviction occurred. II/III] Prior to allowing any person who has been hired in a full-time, part-time or temporary position to have contact with any residents the facility shall, or in the case of temporary employees hired through or contracted for an employment agency, the employment agency shall prior to sending a temporary employee to a provider:

(A) Request a criminal background check for the person, as provided in section 43.540, RSMo. Each facility must maintain in its record documents verification that the background checks were requested and the nature of the response received for each such request. II

1. The facility must ensure that any applicant or person hired or retained who discloses prior to the receipt of the criminal background check that he or she has been convicted of, pled guilty or pled *nolo contendere* to in this state or any other state or has been found guilty of a crime, which if committed in Missouri would be a class A or B felony violation of Chapter 565, 566, or 569, RSMo or any violation of subsection 198.070.3, RSMo or of section 568.020, RSMo, will not have contact with residents. I/II

2. Upon receipt of the criminal background check, the facility must ensure that if the criminal background check indicates that the person hired or retained by the facility has been convicted of, pled guilty or pled *nolo contendere* to in this state or any other state or has been found guilty of a crime, which if committed in Missouri would be a class A or B felony violation of Chapter 565, 566, or 569, RSMo or any violation of subsection 198.070.3, RSMo or of section 568.020, RSMo, the person will not have contact with residents unless the facility obtains verification from the department that a good cause waiver has been granted and maintains a copy of the verification in the individual's personnel file; I/II

(B) Make an inquiry to the department, whether the person is listed on the Employee Disqualification List as provided in section 660.315, RSMo. The inquiry may be made via Internet at www.dhss.mo.gov/EDL/; II/III

(C) If the person has registered with the department's Family Care Safety Registry (FCSR), the facility may utilize the Registry in order to meet the requirements of subsections 11(A) and (11) (B) of this rule. The FCSR is available via Internet at www.dhss.mo.gov/EDL/; and II/III

(D) For persons for whom the facility has contracted for professional services (i.e., plumbing or air conditioning repair) that will have contact with any resident, the facility must require a criminal background check or ensure that the individual is accompanied by a facility staff person while in the facility. I/II (12) A facility shall not employ as an agent or employee who has access to controlled substances any person who has been found guilty or entered a plea of guilty or *nolo contendere* in a criminal prosecution under the laws of any state or of the United States for any offense related to controlled substances. II

(A) A facility may apply in writing to the department for a waiver of this section for a specific employee.

(B) The department may issue a written waiver to a facility upon determination that a waiver would be consistent with the public health and safety. In making this determination, the department shall consider the duties of the employee, the circumstances surrounding the conviction, the length of time since the conviction was entered, whether a waiver has been granted by the department's Bureau of Narcotics and Dangerous Drugs pursuant to 19 CSR 30-1.034 when the facility is registered with that agency, whether a waiver has been granted by the federal Drug Enforcement Administration (DEA) pursuant to 21 CFR 1301.76 when the facility is also registered with that agency, the security measures taken by the facility to prevent the theft and diversion of controlled substances, and any other factors consistent with public health and safety. II/III

(13) The facility must develop and implement written policies and procedures which require that persons hired for any position which is to have contact with any patient or resident have been informed of their responsibility to disclose their prior criminal history to the facility as required by section 660.317.5, RSMo. The facility must also develop and implement policies and procedures which ensure that the facility does not knowingly hire, after August 28, 1997, any person who has or may have contact with a patient or resident, who has been convicted of, plead guilty or *nolo contendere* to, in this state or any other state, or has been found guilty of any **class** A or B felony violation of Chapter 565, 566 or 569, RSMo, or any violation of subsection 3 of section 198.070, RSMo, or of section 568.020, RSMo. II/III

(17) The administrator/manager shall be responsible [for monitoring the health of the employees] for preventing an employee known to be diagnosed with communicable disease from exposing residents to such disease. The facility's policies and procedures must comply with the department's regulations pertaining to communicable diseases, specifically 19 CSR 20-20.010 through 19 CSR 20-20.100. II /III

(18) [Prior to or on the first day that a new employee works in the facility s/he shall receive orientation of at least one (1) hour appropriate to his/her job function. This shall include, at a minimum, job responsibilities, how to handle emergency situations, the importance of infection control and handwashing, confidentiality of resident information, preservation of resident dignity, how to report abuse/neglect to the Division of Aging (1-800-392-0210), information regarding the Employee Disqualification List and, instruction regarding the rights of residents and protection of property. II/III] The facility shall screen residents and staff for tuberculosis as required for long-term care facilities by 19 CSR 20-20.100. II

(19) Prior to or on the first day that a new employee works in the facility he or she shall receive orientation of at least one (1) hour appropriate to his or her job function. This shall include at least the following:

(A) Job responsibilities;

(B) Emergency response procedures;

(C) Infection control and handwashing procedures and requirements;

(D) Confidentiality of resident information;

(E) Preservation of resident dignity;

(F) Information regarding what constitutes abuse/neglect and how to report abuse/neglect to the department (1-800-392-0210);

(G) Information regarding the Employee Disqualification List;(H) Instruction regarding the rights of residents and protection

of property; and (I) Instruction regarding working with residents with mental illness. II/III

(20) In addition to the orientation training required in section (19) of this rule any facility that provides care to any resident having Alzheimer's disease or related dementia shall provide orientation training regarding mentally confused residents such as those with Alzheimer's disease and related dementias as follows:

(A) For employees providing direct care to such persons, the orientation training shall include at least three (3) hours of training including at a minimum an overview of mentally confused residents such as those having Alzheimer's disease and related dementias, communicating with persons with dementia, behavior management, promoting independence in activities of daily living, and understanding and dealing with family issues; and II/III

(B) For other employees who do not provide direct care for, but may have daily contact with, such persons, the orientation training shall include at least one (1) hour of training including at a minimum an overview of mentally confused residents such as those having dementias as well as communicating with persons with dementia. II/III

[(19)] (21) The administrator/manager shall maintain on the premises an individual personnel record on each facility employee [of the facility], which shall include the following:

(A) [t]The employee's name and address;

(B) Social Security number;

(C) [d]Date of birth;

(D) *[d]*Date of employment;

(E) Documentation of experience and education including for positions requiring licensure or certification, documentation [of specialized training on medication and/or insulin administration, or both] evidencing competency for the position held, which includes copies of current licenses, transcripts when applicable, or for those individuals requiring certification, such as level I medication aides (LIMA), certified nurse aides, certified medication technicians (CMT) and insulin administration aides; printing the Web Registry search results page available at www.dhss.mo.gov/cnaregistry shall meet the requirements of the employer's check regarding valid certification;

(F) [r/References, if available;

(G) [t]/The results of background checks required by section 660.317, RSMo; and a copy of any good cause waiver granted by the department, if applicable;

(**H**) *[p]***P**osition in the facility;

(I) *[w]*Written statement signed by a licensed physician or physician's designee indicating the person can work in a long-term care facility and indicating any limitations;

(J) Documentation of the employee's tuberculin screening status;

(K) [record that] Documentation of what the employee was instructed on [residents' rights, facility's policies, job duties and any other] during orientation training; and

(L) [r/Reason for termination[. Personnel records shall be maintained for at least one (1) year following termination of employment.] if the employee was terminated due to abuse or neglect of a resident, residents' rights issues or resident injury. III

(22) Personnel records shall be maintained for at least two (2) years following termination of employment. III

[(20)] (23) There shall be written documentation maintained in the facility showing actual hours worked by each employee. III

[(21)] (24) No one individual shall be on duty with responsibility for oversight of residents longer than eighteen (18) hours per day except

in a residential care facility /// licensed for twelve (12) or fewer residents. I/II

[(22)] (25) Employees who are counted in meeting the minimum staffing ratio and employees who provide direct care to the residents shall be at least sixteen (16) years of age. III

[(23)] (26) One (1) employee at least eighteen (18) years of age shall be on duty at all times. I/II

[(24)] (27) Staffing for Residential Care Facility [/].

(A) The facility shall have an adequate number and type of personnel on duty at all times for the proper care of residents and upkeep of the facility. At a minimum, one (1) employee shall be on duty for every forty (40) residents *[or fraction of forty (40)]* to provide protective oversight to residents and for fire safety. I/II

Staff	Residents
1	1-40
2	41-80
3	81-120
4	121-160

(B) The required staff person shall be in the facility awake, dressed and prepared to assist residents in case of emergency, except that in a facility licensed for twelve (12) or fewer residents, this person may be asleep during the night hours. In a facility licensed for twenty (20) or fewer residents, the required staff person may be asleep if there is a sprinkler system or if there is a complete automatic fire detection system. I/II

(C) In a facility of more than one hundred (100) residents, the *[administration]* administrator/manager shall not be counted when determining the personnel required. II

(D) If the facility is opened in conjunction with and is immediately adjacent to and contiguous to another licensed long-term care facility and if—

1. The resident bedrooms of the residential care facility *[I]* are on the same floor or on the ground floor immediately below that of the other licensed facility;

2. There is an approved call system in each resident's bedroom and bathroom or a patient-controlled system connected to a nursing station of the other licensed facility;

3. There is a complete fire alarm system in the residential care facility *[I]* connected to the complete fire alarm system in the other licensed facility;

4. The staffing of the other licensed facility is greater than their minimum requirements; and

5. Periodic visits to the residential care facility [*I*] are made by a staff person to determine the welfare of the residents in the residential care facility; then, for a facility serving twenty (20) or fewer residents, there need not be an attendant on duty during the day and evening shifts and the attendant may be asleep during the night shift; or if the facility is on the same floor as the other licensed facility, there need not be an attendant at night. If there are more than twenty (20) residents, there shall be at least one (1) staff person awake and dressed at all times for every forty (40) residents or fraction of forty (40). I/II

(E) Those facilities which have only an asleep attendant during the night-time period and those facilities which have only the minimum staff required by subsection [(24)](27)(D) during the night-time period shall not accept residents who are blind, use assistive devices, such as walkers or wheelchairs, or who need care greater than can be provided with the staffing pattern in those facilities. Those residents who were living in a residential care facility/// prior to July 11, 1980, may remain in that facility with an asleep attendant even though they may be blind, deaf or use assistive devices provided they can demonstrate the ability to reach safety unassisted or with assistive devices. II

[(25) Staffing for Residential Care Facility. II

(A) The facility shall have an adequate number and type of personnel for the proper care of residents and upkeep of the

facility. At a minimum, the staffing pattern for fire safety and care of residents shall be one (1) staff person for every fifteen (15) residents or major fraction of fifteen (15) during the day shift, one (1) person for every twenty (20) residents or major fraction of twenty (20) during the evening shift and one (1) person for every twenty-five (25) residents or major fraction of twenty-five (25) during the night shift. I/II

Time	Personnel	Residents
7 a.m. to 3 p.m. (Day)*	1	3–15
3 p.m. to 9 p.m. (Evening)*	1	3–20
9 p.m. to 7 a.m. (Night)*	1	3–25

*If the shift hours vary from those indicated, the hours of the shifts shall show on the work schedules of the facility [and shall not be less than six (6) hours]. III

(B) The required staff shall be in the facility awake, dressed and prepared to assist residents in case of emergency. I/II

(C) In a facility of more than one hundred (100) residents, the administrator shall not be counted when determining the personnel required. II

(D) If a residential care facility II is operated in conjunction with and is immediately adjacent to and contiguous to another licensed long-term care facility and if the resident bedrooms of the residential care facility II are on the same floor as at least a portion of a licensed intermediate care or skilled nursing facility; there is an approved call system in each resident's bedroom and bathroom or a patient-controlled call system; and there is a complete fire alarm system in the facility tied into the complete fire alarm system in the other licensed facility, then the following minimum staffing for oversight and care of residents, for upkeep of the facility and for fire safety shall be one (1) staff person for every eighteen (18) residents or major fraction of residents during the day shift, one (1) person for every twenty-five (25) residents or major fraction or residents during the evening shift and one (1) person for every thirty (30) residents or major fraction of residents during the night shift. I/II

Time	Personnel	Residents
7 a.m. to 3 p.m.		
(Day) *	1	3–18
3 p.m. to 9 p.m.	4	0.05
(Evening)*	1	3–25
9 p.m. to 7 a.m. (Night)*	1	3-30
(ivigiti)	1	5-50

*If the shift hours vary from those indicated, the hours of the shifts shall show on the work schedules of the facility and shall not be less than six (6) hours. III

(E) There shall be a licensed nurse employed by the facility to work at least eight (8) hours per week at the facility for every thirty (30) residents or additional major fraction of thirty (30). The nurse's duties shall include, but shall not be limited to, review of residents' charts, medications and special diets or other orders, review of each resident's adjustment to the facility and observation of each individual resident's general physical and mental condition. The nurse shall inform the administrator/manager of any problems noted and these shall be brought to the attention of the resident's physician. II/III]

[(26)] (28) All residents shall be physically and mentally capable of negotiating a normal path to safety unassisted or with the use of assistive devices within five (5) minutes of being alerted of the need to evacuate. I/II

[(27)] (29) Residents suffering from short periods of incapacity due to illness, injury or recuperation from surgery may be allowed to remain or be readmitted from a hospital if the period of incapacity does not exceed forty-five (45) days and written approval of a physician is obtained for the resident to remain in or be readmitted to the facility. II/III

[(28)] (30) The facility shall not admit or continue to care for residents whose needs cannot be met. If necessary services cannot be obtained in or by the facility, the resident shall be promptly referred to appropriate outside resources or [transferred to a] discharged from the facility [providing the appropriate level of care]. I/II

[(29)] (31) In the event a resident is transferred from the facility, staff shall forward a report of the resident's current medical status, [shall accompany him/her.] physician's orders/prescriptions, and if applicable, a copy of the resident's advanced directives/living will to the facility to which the resident is being transferred. If the resident is transferring to a private residence, facility staff shall provide the reports to the resident or his or her designee or legally authorized representative. II/III

[(30)] (32) Residents admitted to a facility on referral by the Department of Mental Health shall have an individual treatment plan or individual habilitation plan on file prepared by the Department of Mental Health updated annually. *[///]* II

[(31) Residents under sixteen (16) years of age shall not be admitted. []]

[(32)] (33) Placement of residents in the building shall be determined by their abilities. Those residents who require the use of a walker or who are blind shall be housed on a floor which has direct exits at grade, a ramp or no more than two (2) steps to grade with a handrail **unless an area of refuge as defined in 19 CSR 30-86.022 is provided**. Those residents who use a wheelchair shall be able to demonstrate the ability to transfer to and from the wheelchair unassisted. They shall be housed near an exit and there shall be a direct exit at grade, or a ramp or an area of refuge as defined in 19 CSR **30-86.022**. II

(34) Requirements for facilities which admit or retain residents with mental illness or mental retardation diagnosis and residents with assaultive or disruptive behaviors:

(A) Each resident who exhibits mental and psychosocial adjustment difficulty(ies) shall receive appropriate treatment and services to address the resident's needs and behaviors; I/II

(B) If specialized rehabilitative services for mental illness or mental retardation are required to enable a resident to reach and maintain the highest practicable level of physical, mental and psychosocial functioning, the facility must ensure the required services are provided; and II

(C) The facility shall maintain in the resident's record the most recent progress notes and personal plan developed and provided by the Department of Mental Health or designated administrative agent for each resident whose care is funded by the Department of Mental Health or designated administrative agent. III

(35) The use of interventions to manage disruptive or assaultive resident behaviors shall be employed with sufficient safeguards to ensure the safety, welfare and rights of the resident and shall be in accordance with the therapeutic goals for the resident. I/II

(36) Residents under sixteen (16) years of age shall not be admitted. III

[(33)] (37) Residents admitted or readmitted to the facility shall have an admission physical examination by a licensed physician. Documentation should be obtained prior to admission but shall be on file not later than ten (10) days after admission and shall contain information regarding the resident's current medical status and any special orders or procedures which should be followed. If the resident is admitted directly from a hospital or another long-term care facility and is accompanied on admission by a report which reflects his/her current medical status, an admission physical will not be required. II/III

[(34) If at any time a resident or prospective resident is diagnosed with a communicable disease, the Division of Aging shall be notified within seven (7) days and if the facility can meet the resident's needs the resident may be admitted or does not need to be transferred. Appropriate infection control procedures shall be followed if the resident remains in or is accepted by the facility. I/II]

(38) The facility shall follow appropriate infection control procedures. The administrator or his or her designee shall make a report to the local health authority or the department of the presence or suspected presence of any diseases or findings listed in 19 CSR 20-20.020, sections (1)–(3) according to the specified time frames as follows:

(A) Category I diseases or findings shall be reported to the local health authority or to the department within twenty-four (24) hours of first knowledge or suspicion by telephone, facsimile, or other rapid communication; I/II

(B) Category II diseases or findings shall be reported to the local health authority or the department within three (3) days of first knowledge or suspicion; I/II

(C) Category III The occurrence of an outbreak or epidemic of any illness, disease or condition which may be of public health concern, including any illness in a food handler that is potentially transmissible through food. This also includes public health threats such as clusters of unusual diseases or manifestations of illness and clusters of unexplained deaths. Such incidents shall be reported to the local authority or to the department by telephone, facsimile, or other rapid communication within twentyfour (24) hours of first knowledge or suspicion. I/II

[(35)] (39) Protective oversight shall be provided twenty-four (24) hours a day. For residents departing the premises on voluntary leave, the facility shall have, at a minimum, a procedure to inquire of the resident or resident's guardian of the resident's departure, of the resident's estimated length of absence from the facility, and of the resident's whereabouts while on voluntary leave. I/II

[(36)] (40) Residents shall receive proper care to meet their needs. Physician orders shall be followed. I/II

[(37)] (41) In case of behaviors which may potentially pose a threat of harm, serious illness, [accident] significant change in condition, injury or death, staff shall take appropriate action and shall [be taken and the person designated in the resident's record as the responsible party and, if applicable, the guardian shall be immediately notified.] promptly attempt to contact the individual listed in the resident's record as the legally authorized representative, designee or placement authority. The facility shall contact the attending physician or designee and notify the local coroner or medical examiner immediately upon the death of any resident of the facility prior to transferring the deceased resident to a funeral home. II/III

[(38)] (42) [Every resident shall be clean, dry and free of offensive body and mouth odor.] The facility shall encourage and assist each resident based on his or her individual preferences and needs, to be clean and free of body and mouth odor. [///]] II

[(39)] (43) Except in the case of emergency, the resident shall not be inhibited by chemical and/or physical restraints that would limit self-

care or ability to negotiate a path to safety unassisted or with assistive devices. I/II

[(40) A supply of clean linen shall be available in the facility and provided to residents to meet their daily needs. II/III

(41) Beds shall be made daily and linen changed at least weekly or more often if needed to maintain a clean, dry bed. *II/III*

(42) The resident's unit shall be thoroughly cleaned and disinfected following a resident's death, discharge or transfer. *II/III*

(43) Commodes and urinals, if used, shall be kept at the bedside of the residents. They shall not be left open and the container shall be emptied promptly and thoroughly cleaned after each use. In a residential care facility I, portable commodes and urinals may be used only during short periods of recuperation from illness or for night-time use. III

(44) Cuspidors shall be emptied and cleaned daily or disposable cartons shall be provided daily. []]

(44) If the resident brings unsealed medications to the facility, the medications shall not be used unless a pharmacist, physician or nurse examines, identifies and determines the contents to be suitable for use. The individual performing the identification shall document his or her review. II/III

[(45) Self-control of prescription medication by a resident may be allowed only if approved in writing by the resident's physician and allowed by facility policy. If a resident is not taking any prescription medication, the resident may be permitted to control the storage and use of nonprescription medication unless there is a physician's written order or facility policy to the contrary. If not permitted, all medications for that resident, including over-the-counter medications, shall be controlled by the administrator unless the physician specifies otherwise. II/III]

[(46)] (45) Self-control of prescription medication by a resident may be allowed only if approved in writing by the resident's physician and allowed by facility policy. A resident may be permitted to control the storage and use of nonprescription medication unless there is a physician's written order or facility policy to the contrary. Written approval for self-control of prescription medication shall be rewritten as needed but at least annually and after any period of hospitalization. II/III

[(47)] (46) All medication shall be *[safety]* safely stored at proper temperature and shall be kept in a secured location behind at least one (1) locked door or cabinet. Medication shall be accessible only to persons authorized to administer medications. II/III

(A) If access is controlled by the resident, a secured location shall mean in a locked container, a locked drawer in a bedside table or dresser or in a resident's private room if locked in *[his/her]* his or her absence, although this does not preclude access by a responsible employee of the facility. II/III

(B) Schedule II controlled substances shall be stored in locked compartments separate from non-controlled medications, except that single doses of Schedule II controlled substances may be controlled by a resident in compliance with the requirements for selfcontrol of medication of this rule. II/III

(C) Medication that is not in current use and is not destroyed shall be stored separately from medication that is in current use. $\rm II/III$

[(48)] (47) All prescription medications shall be supplied as individual prescriptions **except where an emergency medication supply is allowed**. All medications, including over-the-counter medications shall be packaged and labeled in accordance with applicable professional pharmacy standards[,] and state and federal drug laws [and regulations and the United States Pharmacopeia (USP)]. Labeling shall include accessory and cautionary instructions as well as the expiration date, when applicable, and the name of the medication as specified in the physician's order. Medication labels shall not be altered by facility staff and medications shall not be repackaged by facility staff except as allowed by section (48) of this rule. Over-the-counter medications for individual residents shall be labeled with at least the resident's name. II/III

(48) Controlled substances and other prescription and non-prescription medications for administration when a resident temporarily leaves a facility shall be provided as follows:

(A) Separate containers of medications for the leave period may be prepared by the pharmacy. The facility shall have a policy and procedure for families to provide adequate advance notice so that medications can be obtained from the pharmacy; II/III

(B) Prescription medication cards or other multiple-dose prescription containers currently in use in the facility may be provided by any authorized facility medication staff member if the containers are labeled by the pharmacy with complete pharmacy prescription labeling for use. Original manufacturer containers of non-prescription medications, along with instructions for administration, may be provided by any authorized facility medication staff member; II/III

(C) When medications are supplied by the pharmacy in customized patient medication packages that allow separation of individual dose containers, the required number of containers may be provided by any authorized facility medication staff member. The individual dose containers shall be placed in an outer container that is labeled with the name and address of the facility and the date; II/III

(D) When multiple doses of a medication are required and it is not reasonably possible to obtain prescription medication labeled by the pharmacy, and it is not appropriate to send a container of medication currently in use in the facility, up to a twenty-four (24)-hour supply of each prescription or non-prescription medication may be provided by a licensed nurse in United States Pharmacopeia (USP) approved containers labeled with the facility name and address, resident's name, medication name and strength, quantity, instructions for use, date, initials of individual providing, and other appropriate information; II/III

(E) When no more than a single dose of a medication is required, any authorized facility medication staff member may prepare the dose as for in-facility administration in a USP approved container labeled with the facility name and address, resident's name, medication name and strength, quantity, instructions for use, date, initials of person providing, and other appropriate information;

(F) The facility may have a policy that limits the quantity of medication sent with a resident without prior approval of the prescriber; II/III

(G) Returned containers shall be identified as having been sent with the resident, and shall not later be returned to the pharmacy for reuse; and II/III

(H) The facility shall maintain accurate records of medications provided to and returned by the resident. II/III

(49) Upon discharge or transfer of a resident, the facility shall release prescription medications, including controlled substances, held by the facility for the resident when the physician writes an order for each medication to be released. Medications shall be labeled by the pharmacy with current instructions for use. Prescription medication cards or other containers may be released if the containers are labeled by the pharmacy with complete pharmacy prescription labeling. II/III

[(49) Injections shall be administered only by a physician or licensed nurse, except that residents who require insulin, upon written order of their physician, may administer their own insulin or the insulin may be administered by a person trained to do so by a licensed nurse or physician and the resident's condition shall be monitored by his/her physician. After December 31, 1990, unless insulin is self-administered or it is administered only by a physician or licensed nurse, it shall be administered by a certified medication technician or a level I medication aide who has successfully completed the state-approved course for insulin administration, taught by an approved instructor and who was recommended for training by an administrator or nurse with whom s/he works. Anyone trained prior to December 31, 1990, who completed the state-approved insulin administration course taught by an approved instructor shall be considered qualified to administer insulin in a residential care facility I or II. Anyone trained prior to December 31, 1990, to administer insulin by a licensed nurse or physician not using the state-approved course may qualify by challenging the final examination of the insulin administration course. I/II]

(50) Injections shall be administered only by a physician or licensed nurse, except that insulin injections may be administered by a CMT or LIMA who has successfully completed the stateapproved course for insulin administration, taught by a department-approved instructor. A resident who requires insulin, may administer his or her own insulin if approved in writing by the resident's physician and trained to do so by a licensed nurse or physician. The facility is responsible to monitor the resident's condition and continued ability for self- administration. I/II

[(50)] (51) The administrator/manager shall develop and implement a safe and effective system of medication control and use, which assures that all residents' medications are administered [or distributed] by personnel at least eighteen (18) years of age, in accordance with physicians' instructions using acceptable nursing techniques. [Until January 1, 1991, those facilities administering medications shall utilize personnel trained in medication administration (a licensed nurse, certified medication technician or level I medication aide) and] The facility shall employ a licensed nurse eight (8) hours per week for every thirty (30) residents to monitor each resident's condition and medication. [Distribution] Administration of medication shall mean delivering to a resident [his/her] his or her prescription medication either in the original pharmacy container, or for internal medication, removing an individual dose from the pharmacy container and placing it in a small [cup] container or liquid medium for the resident to remove from the container and self-administer. External prescription medication may be applied by facility personnel if the resident is unable to do so and the resident's physician so authorizes. [After December 31, 1990, a/All [persons] individuals who administer [or distribute] medication shall be trained in medication administration and, if not a physician or a licensed nurse, shall be a certified medication technician or level I medication aide. I/II

[(51)] (52) Medication Orders.

(A) Physician's instructions, as evidenced by the prescription label or by signed order of a physician, shall be accurately followed. If the physician changes the order which is designated on a prescription label, there shall be on file in the resident's record a signed physician's order to that effect with the amended instructions for use or until the prescription label is changed by the pharmacy to reflect the new order. II/III

(B) Physician's written and signed orders are not required, but if it is the facility's or physician's policy to use the orders, they shall include: name of the medication, dosage, *[and]* frequency and route of administration and the orders shall be renewed at least every three (3) months. Computer generated signatures may be used if safeguards are in place to prevent their misuse. Computer identification codes shall be accessible to and used only by the individuals whose signatures they represent. Orders that include optional doses or include *pro re nata* (PRN) administration frequencies (C) [Verbal and t]Telephone and other verbal orders shall be [taken] received only [to] by a licensed nurse, medication technician, level I medication aide or pharmacist and shall be immediately reduced to writing and signed by that individual. If a telephone or other verbal order is given to a medication technician or level I medication aide, an initial dosage [of a new prescription] shall not be [initiated] administered until the order has been reviewed by telephone, facsimile or in person by a licensed nurse or pharmacist. II

(D) The review shall be documented by the **licensed** nurse's or pharmacist's signature within seven (7) days. III

(E) The physician shall sign all *[verbal and]* telephone **and other verbal** orders within seven (7) days. III

(F) [The administration or distribution of medication shall be recorded on a medication sheet or directly in the resident's record and, if recorded on a medication sheet, shall be made part of the resident's record. The administration or distribution shall be recorded by the same person who prepares the medication and who distributes or administers it.] Medication staff shall record administration of medication on a medication sheet or directly in the resident's record. If administration of medication is recorded on a medication sheet, the medication sheet shall be made part of the resident's medical record. The same individual who prepares and administers the medication shall record the administration. II/III

[(52) No stock supply of prescription medication may be kept in the facility except in a residential care facility II, except an emergency drug supply as recommended by a pharmacist or physician may be kept if approved by the Division of Aging. Storage and use of medications in the emergency drug supply shall assure accountability. II/III]

[(53) Stock supplies of nonprescription medication may be kept for pro re nata (PRN) use in both residential care facility Is or IIs as long as the particular medications are approved in writing by a consulting physician, a registered nurse or a pharmacist. II/III]

[(54) All controlled substances shall be handled according to state laws and regulations as given in and required by 19 CSR 30-1 and Chapter 195, RSMo. II/III]

(53) Influenza and pneumococcal polysaccharide immunizations may be administered per physician-approved facility policy after assessment for contraindications.

(A) The facility shall develop a policy that provides recommendations and assessment parameters for the administration of such immunizations. The policy shall be approved by the facility medical director for facilities having a medical director, or by each resident's attending physician for facilities that do not have a medical director, and shall include the requirements to:

1. Provide education regarding the potential benefits and side effects of the immunization to each resident or the resident's designee or legally authorized representative; II/III

2. Offer the immunization to the resident or the resident's designee or legally authorized representative when it is medically indicated or the resident has been immunized as recommended by the policy; II/III

3. Provide the opportunity to refuse the immunization; and II/III

4. Perform an assessment for contraindications. II/III

(B) The assessment for contraindications and documentation of the education and opportunity to refuse the immunization shall be dated and signed by the nurse performing the assessment and placed in the medical record.

(C) The facility shall with access screening and immunization through outside sources with the approval of each resident's physician, such as county or city health departments. II/III

(54) Stock supplies of nonprescription medication may be kept when specific medications are approved in writing by a consulting physician, a registered nurse or a pharmacist. II/III

(55) Records shall be maintained upon receipt and disposition of all controlled substances and shall be maintained separately from other records, for two (2) years.

(A) Inventories of controlled substances shall be reconciled as follows: II/III

1. Controlled Substance Schedule II medications shall be reconciled each shift; and II

2. Controlled Substance Schedule III–V medications shall be reconciled at least weekly and as needed to ensure accountability. II/III

(B) Inventories of controlled substances shall be reconciled by the following:

1. Two (2) medication personnel, one of whom is a licensed nurse; or

2. Two (2) medication personnel, one of whom is the administrator/manager when no nurse is available on staff; or

3. Two (2) medication personnel either medication technicians or level I medication aides when neither a licensed nurse nor the administrator/manager is available. II/III

(C) Receipt records shall include the date, source of supply, resident name and prescription number when applicable, medication name and strength, quantity and signature of the supplier and receiver. Administration records shall include the date, time, resident name, medication name, dose administered and the initials of the individual administering. The signature and initials of each medication staff documenting on the medication administration record must be signed in the signature area of the medication record. II/III

(D) When self-control of medication is approved a record shall be made of all controlled substances transferred to and administered from the resident's room. Inventory reconciliation shall include controlled substances transferred to the resident's room. I/II

(56) Documentation of the wasting of controlled substances at the time of administration shall include the reason for the waste and the signature of another medication staff member or the administrator who witnesses the waste. If no medication staff member or the administrator is available at the time of administration, the controlled substance shall be properly labeled, clearly identified as unusable, stored in a locked area, and destroyed as soon as a medication staff member or the administrator is available to witness the waste. When no medication staff member or the administrator is available and the controlled substance is contaminated by patient body fluids, the controlled substance shall be destroyed immediately and the circumstances documented. II/III

(57) At least every three (3) months in a residential care facility, a pharmacist or registered nurse shall review the controlled substance record keeping including reconciling the inventories of controlled substances. This shall be done at the time of the drug regimen review of each resident. All discrepancies in controlled substance records shall be reported to the administrator or manager for review and investigation. The theft or loss of controlled substances shall be reported as follows: II/III

(A) The facility shall notify the department's Section for Long Term Care (SLTC) and other appropriate authorities of any theft or significant loss of any controlled substance medication written as an individual prescription for a specific resident upon the discovery of the theft or loss. The facility shall consider at least the following factors in determining if a loss is significant:

1. The actual quantity lost in relation to the total quantity;

2. The specific controlled substance lost;

3. Whether the loss can be associated with access by specific individuals;

4. Whether there is a pattern of losses, and if the losses appear to be random or not;

5. Whether the controlled substance is a likely candidate for diversion; and

6. Local trends and other indicators of diversion potential; II/III

(B) If an insignificant amount of such controlled substance is lost during lawful activities, which includes but are not limited to receiving, record keeping, access auditing, administration, destruction and returning to the pharmacy, a description of the occurrence shall be documented in writing and maintained with the facility's controlled substance records. The documentation shall include the reason for determining that the loss was insignificant; and II/III

(C) When the facility is registered with the Bureau of Narcotics and Dangerous Drugs (BNDD), the facility shall report to or document for the BNDD any loss of any stock supply controlled substance in compliance with 19 CSR 30-1.034. II/III

[(55)] (58) A pharmacist or registered nurse shall review the [drug regime] medication regimen of each resident. This shall be done at least [every other month in a residential care facility II and] every three (3) months in a residential care facility [/]. The review shall be performed in the facility and shall include, but shall not be limited to, indication for use, dose, possible [drug] medication interactions and medication/food interactions, contraindications, adverse reactions and a review of the medication system utilized by the facility. Irregularities and concerns shall be reported in writing to the resident's physician and to the administrator/manager. If after thirty (30) days, there is no action taken by a resident's physician and significant concerns continue regarding a resident's or residents' medication order(s), the administrator/manager shall contact or recontact the physician to determine if [s/he] he or she received the information and if there are any new instructions. II/III

[(56) Medication controlled by the facility shall be disposed of either by destroying, returning to the pharmacy or sending with residents on discharge. The following shall be destroyed within the facility within ninety (90) days: discontinued medication not returnable to the pharmacy, all discontinued controlled substances, outdated or deteriorated medication, medication of expired residents not returnable to the pharmacy, and medications not sent with the resident on discharge. II/III]

[(57) Disposition of medication controlled by the facility shall be recorded listing the resident's name, the date and the name, strength and quantity of the drug and the signature(s) of the person(s) involved. Medication destruction shall involve two (2) persons one (1) of whom shall be a pharmacist, a nurse or a state inspector. III]

(59) All medication errors and adverse reactions shall be promptly documented and reported to the administrator/manager and the resident's physician. If the pharmacy made a dispensing error, it shall also be reported to the issuing pharmacy. II/III

(60) Medications that are not in current use shall be disposed of as follows:

(A) Single doses of contaminated, refused, or otherwise unusable non-controlled substance medications may be destroyed by any authorized medication staff member at the time of administration. Single doses of unusable controlled substance medications shall be destroyed according to section (56) of this rule;

(B) Discontinued medications may be retained up to one hundred twenty (120) days prior to other disposition if there is reason to believe, based on clinical assessment of the resident, that the medication might be reordered;

(C) Medications may be released to the resident or family upon discharge according to section (48) of this rule;

(D) After a resident has expired, medications, except for controlled substances, may be released to the resident's legal representative upon written request of the legal representative that includes the name of the medication and the reason for the request;

(E) Medications may be returned to the pharmacy that dispensed the medications pursuant to 4 CSR 220-3.040 or returned pursuant to the Prescription Drug Repository Program, 19 CSR 20-50.020;

(F) All other medications, including all controlled substances and all expired or otherwise unusable medications, shall be destroyed within thirty (30) days as follows: II/III

1. Medications shall be destroyed within the facility by a pharmacist and a licensed nurse or by two (2) licensed nurses or when two (2) licensed nurses are not available on staff by two (2) individuals who have authority to administer medications, one (1) of whom shall be a licensed nurse or a pharmacist; and II/III

2. A record of medication destroyed shall be maintained and shall include the resident's name, date, medication name and strength, quantity, prescription number, and signatures of the individuals destroying the medications; and II/III

(G) A record of medication released or returned to the pharmacy shall be maintained and shall include the resident's name, date, medication name and strength, quantity, prescription number, and signatures of the individuals releasing and receiving the medications. III

[(58)] (61) Residents shall be encouraged to be active and to participate in activities. In a residential care facility licensed for more than twelve (12) residents, a method for informing the residents in advance of what activities are available, where they will be held and at what times they will be held shall be developed, maintained and used. II/III

[(59)] (62) The facility shall maintain [A] a record [shall be maintained] in the facility for each resident, which shall include the following:

(A) Admission information including the resident's name; admission date; confidentiality number; previous address; birth date; sex; marital status; Social Security number; Medicare and Medicaid numbers (if applicable); name, address and telephone number of the resident's physician and alternate; diagnosis, name, address and telephone number of the resident's *[next of kin, legal guardian,]* legally authorized representative or designee *[or person]* to be notified in case of emergency; and preferred dentist, pharmacist and funeral director; III *[and]*

(B) [A resident's record, including a] A review monthly or more frequently, if indicated, of the resident's general condition and needs; a monthly review of medication consumption of any resident controlling [his/her] his or her own medication, noting if prescription medications are being used in appropriate quantities; a daily record of [distribution or] administration of medication; [any physician's orders;] a logging of the [drug regime] medication regimen review process; a monthly weight; a record of each referral of a resident for services from an outside service; and a record of any [patient] resident incidents including behaviors that pose or have posed a threat of harm to self or others and accidents that potentially could result in injury or did result in injuries involving the resident[.]; and III

(C) Any Physician's Orders. All orders shall be signed and dated except as allowed by section (51) of this rule. III

[(60)] (63) A record of the daily resident census [as well as records regarding discharge, transfer or death of residents] shall be [kept] retained in the facility. III

[(61)] (64) Resident records shall be maintained by the operator for at least five (5) years after [the] a resident leaves the facility or after the resident reaches the age of twenty-one (21), whichever is longer and must include reason for discharge or transfer from the facility and cause of death, if applicable. III

AUTHORITY: sections 198.005 and 198.006, RSMo [Supp. 2003] (CCS HCS SCS SB 616, 93rd General Assembly, Second Regular Session (2006)) and 198.076, RSMo 2000. This rule originally filed as 13 CSR 15-15.042. Original rule filed July 13, 1983, effective Oct. 13, 1983. For intervening history, please consult the Code of State Regulations. Amended: Filed Aug. 23, 2006.

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

PRIVATE COST: This proposed amendment will cost facilities formerly licensed as residential care facilities I, an annual cost in the aggregate of four hundred forty-one thousand sixty-two dollars (\$441,062) plus a total one (1)-time cost in the aggregate of seven thousand nine hundred seventy-nine dollars (\$7,979). In addition, this proposed amendment will cost facilities who have received residential care facility I certificate of need approval a total annual cost in the aggregate of seventeen thousand seventy-seven dollars (\$17,077) plus a total one (1)-time cost in the aggregate of six hundred eighteen dollars (\$618). There will be an unknown number of newly constructed residential care facilities with an indeterminate cost.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with David S. Durbin, Director, Division of Regulation and Licensure, Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.

FISCAL NOTE PRIVATE COST

I. RULE NUMBER

Rule Number and Name:	19 CSR 30-86.042 Administrative, Personnel and Resident Care Requirements for New and Existing
	Residential Care Facilities
Type of Rulemaking:	Proposed Amendment

II. SUMMARY OF FISCAL IMPACT

 SUMMARI OF FISCAL IMIT		
Estimate of the number of entities by class which would likely be affected by the adoption of the proposed amendment:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the proposed amendment, by the affected entities:
266	Facilities formerly Licensed as Residential Care Facility I	Total Yearly Cost in the Aggregate \$441,062** One-Time Cost in the Aggregate \$7,979
10 facilities who have received Residential Care Facility I CON approval plus an unknown number of new Residential Care Facilities that will be constructed	Newly Constructed Residential Care Facilities	Total Yearly Cost in the Aggregate \$17,077 for the 10 known plus an indeterminate amount for the unknown One-Time Cost in the Aggregate \$618 for the 10 known plus an indeterminate amount for the unknown

III. and IV. WORKSHEET AND ASSUMPTIONS

Staff Training – This proposed amendment requires residential care facilities that provide care to residents with Alzheimer's disease or related dementia to provide 3 hours of dementia specific training to staff providing the care. According to the Alzheimer's Association, the cost for such a class is approximately \$225. Because of staff turnover, DHSS estimates each residential care facility will need three training sessions per year. DHSS estimates the total yearly cost for residential care facilities in the aggregate to be \$179,550 (\$225 cost per training x 3 training sessions per year) x (266 facilities).

Examination of Medications – This proposed amendment requires an examination of unsealed medications brought to the facility by a resident to be examined, identified and determined to be suitable prior to use. This proposed amendment requires this examination, identification and determination to be made by a pharmacist, physician or nurse. DHSS estimates each facility will require the services of a nurse, pharmacist or physician one hour

per week. Based on the Office of Administration, Division of Personnel, Uniform Classification and Pay System (Revised October 1, 2005) the average annual market salary for a licenses practical nurse I is \$24,984. DHSS has added an additional amount for fringe benefits which is based on current fringe benefit rates for state employees.* DHSS estimates the total yearly cost for residential care facilities in the aggregate to be \$236,021 (\$24,982 x .4207 fringe rate) + (\$24,982) / (2080 hours in a work year) x (1 hour) x (52 weeks per year) x (266 facilities).

Locked Compartment for Controlled Substances – This proposed amendment requires residential care facilities to store schedule II controlled substances in a locked compartment separate from other medications. Based on inspections conducted by DHSS, DHSS estimates fifty percent of existing residential care facilities currently meet this proposed requirement, therefore approximately 133 residential care facilities would incur a cost. According to MMF Industries, a lock-down security box costs \$59.99. DHSS estimates the total yearly cost for residential care facilities in the aggregate to be \$7,979 (\$59.99 cost for locked compartment x 133 facilities).

Controlled Substance Reviews – This proposed amendment requires residential care facilities to contract with either a registered nurse or pharmacist to conduct controlled substance record reviews every three months. Based on Office of Administration, Division of Personnel, Uniform Classification and Pay System (Revised October 1, 2005) the average annual market salary for a registered nurse I is \$35,076. DHSS estimates it will take one hour to complete the reviews. DHSS estimates the total yearly cost for residential care facilities in the aggregate to be \$25,491 ($$35,076 \times .4207$ fringe rate) + (\$35,076) / (2080 hours in a work year) x (1 hour) x (4 times per year) x (266 facilities).

Information obtained from the Certificate of Need Program reveals 10 facilities who have CON approval for residential care facility I. In determining the cost in the aggregate for these 10 facilities, DHSS utilized it's estimate of the yearly cost of compliance for each existing facility which is \$1,658 (\$441,062 total yearly cost in the aggregate for existing facilities / 266 number of facilities choosing to comply with this proposed amendment) plus three percent adjustment for inflation. DHSS estimates the actual costs for the 10 facilities with current CON approval for residential care facility I to be \$17,077 (\$1,658 cost to each facility) x (10 number of facilities with current CON approval for Residential Care Facility) x (.03 inflation adjustment) + (\$16,580).

In addition, these facilities will incur a one-time cost of \$618 (\$59.99 cost for locked compartment x.03 inflation adjustment) + \$59.99 x (10 facilities).

*The state of Missouri fringe benefit rate for fiscal year 2007 is 42.07 percent which includes retirement contribution, medical insurance, basic life insurance, long-term disability and Missouri deferred compensation. This rate was used throughout the fiscal note. Facilities can use this formula revised with their own figures to determine the cost to their facility.

** At an August 7,2006 public meeting, various members of the long term care industry verbally reported various estimated costs for specific requirements, but did not elaborate how they reached these conclusions.