



Rules of Department of Health and Senior Services

Division 30—Division of Regulation and Licensure Chapter 1—Controlled Substances

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**Title 19—DEPARTMENT OF
HEALTH AND SENIOR SERVICES**
Division 30—Division of
Regulation and Licensure
Chapter 1—Controlled Substances

**19 CSR 30-1.002 Schedules of Controlled
Substances**

PURPOSE: Chapter 195, RSMo states in section 195.230, RSMo that the Department of Health shall prepare a list of all drugs falling within the purview of controlled substances. Upon preparation, a copy of the list shall be filed in the Office of the Secretary of State. It also requires, in section 195.017. II, RSMo, the Department of Health to revise and republish the schedules semiannually for two years from September 28, 1971, and annually after that.

(1) Schedules of Controlled Substances.

(A) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the Drug Enforcement Administration (DEA) Controlled Substances Code Number set forth opposite it.

1. Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

A. Acetyl-alpha-methylfentanyl (N-(1-(1-methyl-2-phenethyl)-4-piperidyl)-N-phenylacetamide)	9815
B. Acetylmethadol	9601
C. Allylprodine	9602
D. Alphacetylmethadol (except levo-alpha-cetylmethadol also known as levo-alpha-acetylmethadol levo-thadyl acetate or LAAM)	9603
E. Alphameprodine	9604
F. Alphamethadol	9605
G. Alpha-methylfentanyl (N-1-(alphamethyl-beta-phenyl) ethyl-4-piperidyl) propionanilide; 1-(1-methyl-2-phenylethyl)-4 ((N-propionanilido) piperidine)	9814
H. Alpha-methylthiofentanyl (N-(1-methyl-2-(2-thienyl) ethyl-4-piperidyl)-N-phenylpropanamide)	9832
I. Benzethidine	9606
J. Betacetylmethadol	9607

K. Beta-hydroxyfentanyl (N-(1-(2-hydroxy-2-phenethyl)-4-piperidyl)-N-phenylpropanamide)	9830
L. Beta-hydroxy-3-methylfentanyl (other name: N-(1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidyl)-N-phenylpropanamide)	9831
M. Betameprodine	9608
N. Betamethadol	9609
O. Betaprodine	9611
P. Clonitazene	9612
Q. Dextromoramide	9613
R. Diampromide	9615
S. Diethylthiambutene	9616
T. Difenoixin	9168
U. Dimenoxadol	9617
V. Dimepheptanol	9618
W. Dimethylthiambutene	9619
X. Dioxaphetyl butyrate	9621
Y. Dipipanone	9622
Z. Ethylmethylthiambutene	9623
AA. Etonitazene	9624
BB. Etoxadine	9625
CC. Furethidine	9626
DD. Hydroxypethidine	9627
EE. Ketobemidone	9628
FF. Levomoramide	9629
GG. Levophenaclymorphan	9631
HH. 3-Methylfentanyl (N-(3-methyl-1-(2-phenylethyl)-4-piperidyl)-N-phenylpropanamide), its optical and geometric isomers, salts and salts of isomers	9813
II. 3-Methylthiofentanyl (N-(3-methyl-1-(2-thienyl) ethyl-4-piperidyl)-N-phenylpropanamide)	9833
JJ. Morpheridine	9632
KK. MPPP (1-methyl-4-phenyl-4-propionoxypiperidine)	9661
LL. Noracetylmethadol	9633
MM. Norlevorphanol	9634
NN. Normethadone	9635
OO. Norpipanone	9636
PP. Para-fluorofentanyl (N-(4-fluorophenyl)-N-(1-(2-phenethyl)-4-piperidyl) propanamide)	9812
QQ. PEPAP (1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine)	9663
RR. Phenadoxone	9637
SS. Phenampromide	9638
TT. Phenomorphan	9647
UU. Phenoperidine	9641
VV. Piritramide	9642
WW. Proheptazine	9643
XX. Properidine	9644

YY. Propiram	9649
ZZ. Racemoramide	9645
AAA. Thiofentanyl (N-phenyl-N-(1-(2-thienyl)ethyl-4-piperidyl)-propanamide)	9835
BBB. Tilidine	9750
CCC. Trimeperidine	9646
2. Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:	
A. Acetorphine	9319
B. Acetyldihydrocodeine	9051
C. Benzylmorphine	9052
D. Codeine methylbromide	9070
E. Codeine-N-Oxide	9053
F. Cyprenorphine	9054
G. Desomorphine	9055
H. Dihydromorphine	9145
I. Drotebanol	9335
J. Etorphine (except hydrochloride salt)	9056
K. Heroin	9200
L. Hydromorphanol	9301
M. Methyldesorphine	9302
N. Methyl dihydromorphine	9304
O. Morphine methylbromide	9305
P. Morphine methylsulfonate	9306
Q. Morphine-N-Oxide	9307
R. Myrophine	9308
S. Nicocodeine	9309
T. Nicomorphine	9312
U. Normorphine	9313
V. Pholcodeine	9314
W. Thebacon	9315
3. Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation, which contains any quantity of the following hallucinogenic substances or which contains any of its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation (For purposes of paragraph (1)(A)3. of this rule only, the term isomer includes the optical, position and geometric isomers.):	
A. Alpha-ethyltryptamine	7249
Some trade or other names: etryptamine; Monase; alpha-ethyl-1H-indole-3-ethenamine; 3-(2-aminobutyl)indole; alpha-ET and AET;	
B. Benzylpiperazine or other name BZP	7493
C. 4-bromo-2,5-dimethoxyamphetamine	7391



Some trade or other names: 4-bromo-2, 5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA;

D. 4-bromo-2,5-dimethoxyphenethylamine 7392

E. 2,5-dimethoxyamphetamine 7396

Some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA;

F. 2,5-dimethoxy-4-ethylamphetamine 7399

Some trade or other names: DOET

G. 2,5-dimethoxy-4-(n)-propylthiophenethylamine

H. 4-methoxyamphetamine 7411

Some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA;

I. 5-methoxy-3,4-methylenedioxyamphetamine 7401

J. 4-methyl-2,5-dimethoxyamphetamine 7395

Some trade and other names: 4-methyl-2, 5-dimethoxy-a-methylphenethylamine; DOM; and STP;

K. 3,4-methylenedioxy amphetamine 7400

L. 3,4-methylenedioxymethamphetamine (MDMA) 7405

M. 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy) phenethylamine, N-ethyl MDA, MDE and MDEA) 7404

N. N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4-(methylenedioxy) phenethylamine and N-hydroxy MDA) 7402

O. 3,4,5-trimethoxy amphetamine 7390

P. Bufotenine 7433

Some trade and other names: 3-(b-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine;

Q. Diethyltryptamine 7434

Some trade and other names: N, N-Diethyltryptamine; DET;

R. Dimethyltryptamine 7435

Some trade or other names: DMT;

S. Ibogaine 7260

Some trade and other names: 7-Ethyl-6,6b,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; Tabernanthe iboga;

T. Lysergic acid diethylamide 7315

U. Marihuana 7360

Some trade or other names: marijuana;

V. Mescaline 7381

W. Parahexyl 7374

Some trade or other names: 3-Hexyl-1-Hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo(b,d)pyran; Synhexyl; X. Peyote 7415

Meaning all parts of the plant presently classified botanically as *Lophophora williamsii* Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or extracts;

Y. N-ethyl-3-piperidyl benzoate 7482

Z. N-methyl-3-piperidyl benzoate 7484

AA. Psilocybin 7437

BB. Psilocyn 7438

CC. Tetrahydrocannabinols 7370

Synthetic equivalents of the substances contained in the plant or in the resinous extracts of Cannabis, sp, synthetic substances, derivatives and their isomers, or both, with similar chemical structure and pharmacological activity such as the following:

(I) D 1 cis or trans tetrahydrocannabinol and their optical isomers;

(II) D 6 cis or trans tetrahydrocannabinol and their optical isomers; and

(III) D 3, 4 cis or trans tetrahydrocannabinol and its optical isomers (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.);

DD. Ethylamine analog of phencyclidine 7455

Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl)-ethylamine, cyclohexamine, PCE;

EE. Pyrrolidine analog of phencyclidine 7458

Some trade or other names: 1(1-phenylcyclohexyl)-pyrrolidine PCPy, PHP;

FF. Thiophene analog of phencyclidine 7470

Some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP;

GG. Trifluoromethylphenylpiperazine or other name TFMPP;

HH. 1-(1-(2-thienyl)cyclohexyl) pyrrolidine 7473

Some other names: TCPy.

4. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever

the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

A. Gamma-hydroxybutyric acid and other names GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutonic acid; sodium oxybate; sodium oxybutyrate;

B. Mecloqualone 2572

C. Methaqualone 2565

5. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

A. Aminorex 1585

Some trade or other names: aminoxaphen; 2-amino-5-phenyl-2-oxazoline; 4,5-dihydro-5-phenyl-2-oxazolamine;

B. Cathinone (Some trade or other names: 2-amino-1-phenyl-1-propanone, alphaamino-propiofenone, 2-aminopropiofenone and norephedrone) 1235

C. Fenethylamine 1503

D. Methcathinone 1585

Some trade or other names: 2-(methylamino)-propiofenone; alpha-(methylamino)propiofenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylamino-propiofenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and URI 432; its salts, optical isomers and salts of optical isomers;

E. (±)cis-4-methylaminorex ((±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) 1590

F. N-ethylamphetamine 1475

G. N,N-dimethylamphetamine 1480

(some other names: N,N-alpha-trimethylbenzeneethanamine; N,N-alpha-trimethylphenethylamine), its salts, optical isomers and salts of optical isomers.

6. A temporary listing of substances subject to emergency scheduling under federal law shall include any material, compound, mixture or preparation which contains any quantity of the following substances:

A. N-(1-benzyl-4-piperidyl)-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers 9818

B. N-(1-(2-thienyl) methyl-4-piperidyl)-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers 9834

(B) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical



name or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

1. Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, Schedule II shall include any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis opium and opiate; and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone and naltrexone and their respective salts, but including the following:

A. Raw opium	9600
B. Opium extracts	9610
C. Opium fluid	9620
D. Powdered opium	9639
E. Granulated opium	9640
F. Tincture of opium	9630
G. Codeine	9050
H. Ethylmorphine	9190
I. Etorphine hydrochloride	9059
J. Hydrocodone	9193
K. Hydromorphone	9150
L. Metopon	9260
M. Morphine	9300
N. Oxycodone	9143
O. Oxymorphone	9652
P. Thebaine	9333

Any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (1)(B)1. of this rule shall be included in Schedule II, except that these substances shall not include the isoquinoline alkaloids of opium; opium poppy and poppy straw; coca leaves 9040 and any salt, compound, derivative or preparation of coca leaves including cocaine 9041 and ecgonine 9180 and their salts, isomers, derivatives and salts of isomers and derivatives and any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine 9041 or ecgonine 9180 and concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy) 9670

2. Opiates. Unless specifically excepted or unless in another schedule any of the fol-

lowing opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

A. Alfentanil	9737
B. Alphaprodine	9010
C. Anileridine	9020
D. Bezitramide	9800
E. Bulk Dextropropoxyphene (Non-dosage Forms)	9273
F. Butyl-nitrite	no designated number
G. Carfentanil	9743
H. Dihydrocodeine	9120
I. Diphenoxylate	9170
J. Fentanyl	9801
K. Isomethadone	9226
L. Levo-alphaacetylmethadol	9220

Some other names: levo-alphaacetylmethadol, levomethadyl acetate, LAAM 9648

M. Levomethorphan	9210
N. Levorphanol	9220
O. Metazocine	9240
P. Methadone	9250
Q. Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenylbutane	9254
R. Moramide-Intermediate, 2-methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid	9802
S. Pethidine (Meperidine)	9230
T. Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine	9232
U. Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate	9233
V. Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid	9234
W. Phenazocine	9715
X. Piminodine	9730
Y. Racemethorphan	9732
Z. Racemorphan	9733
AA. Remifentanil	9739
BB. Sufentanil	9740

3. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

A. Amphetamine, its salts, optical isomers and salts of its optical isomers	1100
B. Methamphetamine, its salts, isomers and salts of its isomers	1105
C. Phenmetrazine and its salts	1631
D. Methylphenidate	1724

4. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

A. Amobarbital	2125
B. Glutethimide	2550
C. Pentobarbital	2270
D. Phencyclidine	7471
E. Secobarbital	2315

5. Hallucinogenic substances:

A. Nabilone	7379
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Another name for nabilone: (\pm)trans-3-(1,1-dimethylheptyl)-6, 6a,7,8,10,10a-hexahydro-1-hydroxy-6, 6-dimethyl-9H-dibenzo(b,d)pyran-9-one.

6. Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances:

A. Immediate precursor to amphetamine and methamphetamine:

(I) Phenylacetone	8501
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Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;

B. Immediate precursors to phencyclidine (PCP):

(I) 1-phenylcyclohexylamine	7460
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(II) 1-piperidinocyclohexane-carbonitrile (PCC)	8603
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(C) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

1. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position or geometric) and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

A. Those compounds, mixtures or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures or preparations were listed on August 25, 1971, as excepted compounds under section 308.32 and any other drug of the quantitative composition shown in that list for those drugs or which is



the same except that it contains a lesser quantity of controlled substances

B. Benzphetamine	1228
C. Chlorphentermine	1645
D. Clortermine	1647
E. Phendimetrazine	1615

2. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

A. Any compound, mixture or preparation containing:

- | | |
|---------------------|------|
| (I) Amobarbital | 2126 |
| (II) Secobarbital | 2316 |
| (III) Pentobarbital | 2271 |

or any salt thereof and one (1) or more other active medicinal ingredients which are not listed in any schedule;

B. Any suppository dosage form containing:

- | | |
|---------------------|------|
| (I) Amobarbital | 2126 |
| (II) Secobarbital | 2316 |
| (III) Pentobarbital | 2271 |

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

C. Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof

- | | |
|-----------------|------|
| D. Chlorhexadol | 2510 |
|-----------------|------|

E. Any drug product containing gamma hydroxybutyric acid, including its salts, isomers and salts of isomer, for which an application is approved under section 505 of the Federal Food, Drug and Cosmetic Act;

- | | |
|-----------------------------|------|
| F. Ketamine | 7285 |
| G. Lysergic acid | 7300 |
| H. Lysergic acid amide | 7310 |
| I. Methyprylon | 2575 |
| J. Sulfondiethylmethane | 2600 |
| K. Sulfonethylmethane | 2605 |
| L. Sulfonmethane | 2610 |
| M. Tiletamine and zolazepam | |
| or any salt thereof | 7295 |

Some trade or other names for a tiletamine-zolazepam combination product: Telazol.

Some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone.

Some trade or other names for zolazepam: 4-(2-fluorophenyl)-6-8-dihydro-1,3,8-trimethylpyrazolo-(3,4-e) (1,4)-diazepin-7(1H)-one, flupyrzapon.

3. Nalorphine 9400

4. Narcotics drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

A. Not more than 1.8 grams of codeine per one hundred milliliters (100 ml)

or not more than ninety milligrams (90 mg) per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9803

B. Not more than 1.8 grams of codeine per one hundred milliliters (100 ml) or not more than ninety milligrams (90 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9804

C. Not more than three hundred milligrams (300 mg) of hydrocodone per one hundred milliliters (100 ml) or not more than fifteen milligrams (15 mg) per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium 9805

D. Not more than three hundred milligrams (300 mg) of hydrocodone per one hundred milliliters (100 ml) or not more than fifteen milligrams (15 mg) per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts 9806

E. Not more than 1.8 grams of dihydrocodeine per one hundred milliliters (100 ml) or not more than ninety milligrams (90 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9807

F. Not more than three hundred milligrams (300 mg) of ethylmorphine per one hundred milliliters (100 ml) or not more than fifteen milligrams (15 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9808

G. Not more than five hundred milligrams (500 mg) of opium per one hundred milliliters (100 ml) or per one hundred grams (100 g) or not more than twenty-five milligrams (25 mg) per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts 9809

H. Not more than fifty milligrams (50 mg) of morphine per one hundred milliliters (100 ml) or per one hundred grams (100 g), with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9810

5. Anabolic steroids. Unless specially excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, isomers and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation. DEA has assigned code 4000 for all anabolic steroids.

- | |
|---|
| A. Boldenone |
| B. Chlorotestosterone (4-Chlortestosterone) |
| C. Clostebol |

D. Dehydrochlormethyltestosterone

E. Dihydrotestosterone (4-Dihydrotestosterone)

F. Drostanolone

G. Ethylestrenol

H. Fluoxymesterone

I. Formebolone (Formebolone)

J. Mesterolone

K. Methandienone

L. Methandranone

M. Methandriol

N. Methandrostenolone

O. Methenolone

P. Methyltestosterone

Q. Mibolerone

R. Nandrolone

S. Norethandrolone

T. Oxandrolone

U. Oxymesterone

V. Oxymetholone

W. Stanolone

X. Stanozolol

Y. Testolactone

Z. Testosterone

AA. Trenbolone

BB. Any salt, ester, or isomer of a drug or substance described or listed in this subparagraph, if that salt, ester or isomer promotes muscle growth except an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the secretary of Health and Human Services for that administration.

6. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product 7369 (Some other names for dronabinol: (6aR-trans)-6a,7,8,10a-tetrahydro-6.6.9-trimethyl-3-pentyl-6H-dibenzo (b,d) pyran-1-ol, or (-)-delta-9-(trans)-tetrahydrocannabinol.)

(D) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

1. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

A. Not more than one milligram (1 mg) of difenoxin (DEA Drug Code No. 9618) and not less than twenty-five micrograms (25 mcg) of atropine sulfate per dosage unit;



B. Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane) 9278

C. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(I) Not more than two hundred milligrams (200 mg) of codeine per one hundred milliliters (100 ml) or per one hundred grams (100 g);

(II) Not more than one hundred milligrams (100 mg) of dihydrocodeine per one hundred milliliters (100 ml) or per one hundred grams (100 g); or

(III) Not more than one hundred milligrams (100 mg) of ethylmorphine per one hundred milliliters (100 ml) or per one hundred grams (100 g).

2. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

A. Alprazolam	2882
B. Barbital	2145
C. Bromazepam	2748
D. Camazepam	2749
E. Chloral betaine	2460
F. Chloral hydrate	2465
G. Chlordiazepoxide	2744
H. Clobazam	2751
I. Clonazepam	2737
J. Clorazepate	2768
K. Clotiazepam	2752
L. Cloxazolam	2753
M. Delorazepam	2754
N. Diazepam	2765
O. Dichloralphenazone	2467
P. Estazolam	2756
Q. Ethchlorvynol	2540
R. Ethinamate	2545
S. Ethyl loflazepam	2758
T. Fludiazepam	2759
U. Flunitrazepam	2763
V. Flurazepam	2767
W. Halazepam	2762
X. Haloxazolam	2771
Y. Ketazolam	2772
Z. Loprazolam	2773
AA. Lorazepam	2885
BB. Lormetazepam	2774

CC. Mebutamate	2800
DD. Medazepam	2836
EE. Meprobamate	2820
FF. Methohexital	2264
GG. Methylphenobarbital (Mephobarbital)	2250
HH. Midazolam	2884
II. Nimetazepam	2837
JJ. Nitrazepam	2834
KK. Nordiazepam	2838
LL. Oxazepam	2835
MM. Oxazolam	2839
NN. Paraldehyde	2585
OO. Petrichloral	2591
PP. Phenobarbital	2285
QQ. Pinazepam	2883
RR. Prazepam	2764
SS. Quazepam	2881
TT. Temazepam	2925
UU. Tetrazepam	2886
VV. Triazolam	2887
WW. Zaleplon	2781
XX. Zolpidem	2783

3. Fenfluramine. Any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position or geometric) and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible:

A. Fenfluramine 1670

4. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

A. Cathine ((+)-norpseudoephedrine)	1230
B. Diethylpropion	1610
C. Fencamfamin	1780
D. Fenproporex	1575
E. Mazindol	1605
F. Mefenorex	1580
G. Modafinil	1680
H. Pemoline (including organometallic complexes and chelates thereof)	1530
I. Phentermine	1640
J. Pipradrol	1750
K. Sibutramine	1675
L. SPA (-)-1-dimethylamino-1,2-diphenylethane	1635

5. Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

A. Pentazocine	9709
B. Butorphanol (including its optical isomers)	9720

6. Ephedrine. Any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system including their salts, isomers and salts of isomers:

A. Ephedrine or its salts, optical isomers or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient.

(E) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this subsection.

1. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any of the following narcotic drugs and their salts:

A. Buprenorphine 9064

2. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

A. Not more than two and five-tenths milligrams (2.5 mg) of diphenoxylate and not less than twenty-five micrograms (25 mcg) of atropine sulfate per dosage unit.

B. Not more than one hundred milligrams (100 mg) of opium per one hundred milliliters (100 ml) or per one hundred grams (100 g).

C. Not more than five-tenths milligram (0.5 mg) of difenoxin (DEA Drug Code No. 9618) and not less than twenty-five micrograms (25 mcg) of atropine sulfate per dosage unit.

3. Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system including its salts, isomers and salts of isomers:

A. Pyrovalerone 1485

(2) Excluded Nonnarcotic Substances. The following nonnarcotic substances which, under the Federal Food, Drug and Cosmetic



Act (21 U.S.C. 301), may be lawfully sold over the counter without a prescription, are excluded from all schedules pursuant to section 195.015(5), RSMo.

Excluded Nonnarcotic Products

Company	Trade Name	NDC Code	Form	Controlled Substance	mg or mg/ml
Bioline Laboratories	Theophed	00719-1945	TB	Phenobarbital	8.00
Goldline Laboratories	Guiaphed Elixir	00182-1377	EL	Phenobarbital	4.00
Goldline Laboratories	Tedrigen Tablets	00182-0134	TB	Phenobarbital	8.00
Hawthorne Products, Inc.	Choate's Leg Freeze		LQ	Chloral hydrate	246.67
Parke-Davis & Co.	Tedral	00071-0230	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Elixir	00071-0242	EX	Phenobarbital	40.00
Parke-Davis & Co.	Tedral S.A.	00071-0231	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Suspension	00071-0237	SU	Phenobarbital	80.00
Parmed Pharmacy	Asma-Ese	00349-2018	TB	Phenobarbital	8.10
Rondex Labs	Azma-Aids	00367-3153	TB	Phenobarbital	8.00
Smith Kline Consumer	Benedrex	49692-0928	IN	Propylhexedrine	250.00
Sterling Drug, Inc.	Bronkolixir	00057-1004	EL	Phenobarbital	0.80
Sterling Drug, Inc.	Bronkotabs	00057-1005	TB	Phenobarbital	8.00
Vicks Chemical Co.	Vicks Inhaler	23900-0010	IN	I-Desoxyephedrine	113.00
White Hall Labs	Primatene (P-tablets)	00573-2940	TB	Phenobarbital	8.00

AUTHORITY: sections 195.015 and 195.195, RSMo 2000. Material found in this rule previously filed as 19 CSR 30-1.010. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003.*

**Original authority: 115.015, RSMo 1971, amended 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.004 List of Exempt Substances

PURPOSE: The Department of Health is authorized to exempt by rule any compound, mixture or preparation containing any stimulant or depressant substance if one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system is included to negate the potential for abuse. The compounds, mixtures and preparations excluded are listed in this rule.

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. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office

of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) Excepted Stimulant or Depressant Compounds—Exempt Prescription Products. The listed drugs in dosage unit form and any other drug of the quantitative composition shown in Part 1300 to end of Title 21, the *Code of Federal Regulations*, April 1998 or which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant or hallucinogenic effect and which are restricted by law to dispensing or prescription, are excepted from the provisions of sections 195.030, 195.040, 195.050 and 195.100, RSMo as provided for in section 195.017.6(5) and .8(3), RSMo. The rules of the Drug Enforcement Administration, 21 CFR Part 1300 to the end of Title 21, are hereby incorporated by reference and made a part of this rule.

(2) Excepted Chemical Preparations—Exempt Chemical Preparations. The listed preparations in unit form and any other preparation of the quantitative composition shown in Part 1300 to end of Title 21, the *Code of Federal Regulations*, April 1998 which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimu-

lant, depressant or hallucinogenic effect are excepted from the provisions of sections 195.030, 195.040, 195.050 and 195.110, RSMo as provided for in section 195.017.6(5) and .8(3), RSMo. The rules of the Drug Enforcement Administration, 21 CFR Part 1300 to the end of Title 21, are hereby incorporated by reference and made a part of this rule.

AUTHORITY: section 195.195, RSMo 1994. Material found in this rule previously filed as 19 CSR 30-1.020. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.006 List of Exempt Anabolic Steroid Products

PURPOSE: This rule maintains a list of anabolic steroid products excluded from 19 CSR 30-1.002(1)(C)5. in conformance with federal law.

(1) Persons who in the course of legitimate business handle products listed in the Table of Exempt Anabolic Steroid Products in this section shall be exempt from the registration, records, reports, prescriptions, physical security and import and export requirements associated with Schedule III substances.



(A) Trade Name	Company	NDC or DIN No.
1. Androgyn L.A.	Forest Pharmaceuticals, St. Louis, MO	0456-1005
2. Andro-Estro 90-4	Rugby Laboratories, Rockville Center, NY	0536-1605
3. depANDROGYN	Forest Pharmaceuticals, St. Louis, MO	0456-1020
4. DEPO-T.E.	Quality Research Pharmaceuticals, Camel, IN	52765-257
5. depTESTROGEN	Martica Pharmaceuticals, Phoenix, AZ	51698-257
6. Duomone	Wintec Pharmaceutical, Pacific, MO	52047-360
7. DURATESTRIN	W.E. Hauck, Alpharetta, GA	43797-016
8. DUO-SPAN II	Primedics Laboratories, Gardena, CA	0684-0102
9. Estratest	Solvay Pharmaceuticals, Marietta, GA	0032-1026
10. Estratest HS	Solvay Pharmaceuticals, Marietta, GA	0032-1023
11. Menogen	Sage Pharmaceuticals, Shreveport, LA	59243-570
12. Menogen HS	Sage Pharmaceuticals, Shreveport, LA	59243-560
13. PAN ESTRA TEST	Pan American Labs, Covington, LA	0525-0175
14. Premarin with Methyltestosterone	Ayerst Labs., Inc., New York, NY	0046-0879
15. Premarin with Methyltestosterone	Ayerst Labs., Inc., New York, NY	0046-0878
16. Synovex H Pellets in process	Syntex Animal Health, Palo Alto, CA	
17. Synovex H Pellets in process granulation	Syntex Animal Health, Palo Alto, CA	
18. Synovex Plus in-process granulation	Fort Dodge Animal Health, Fort Dodge, IA	
19. Synovex Plus in-process bulk pellets	Fort Dodge Animal Health, Fort Dodge, IA	
20. Testagen	Clint Pharmaceuticals, Nashville, TN	55553-257
21. TEST-ESTRO Cypionates	Rugby Laboratories, Rockville Centre, NY	0536-9470
22. Testoderm 4 mg/d	Alza Corp., Palo Alto, CA	17314-4608
23. Testoderm 6 mg/d	Alza Corp., Palo Alto, CA	17314-4609
24. Testoderm with Adhesive 6 mg/d	Alza Corp., Palo Alto, CA	17314-2836
25. Testoderm in-process film	Alza Corp., Palo Alto, CA	
26. Testoderm with Adhesive in-process film	Alza Corp., Palo Alto, CA	
27. Testosterone Cyp 50 Estradiol Cyp 2	I.D.E.-Interstate, Amityville, NY	0814-7737
28. Testosterone Cypionate-Estradiol Cypionate Injection	Best Generics, No. Miami Beach, FL	54274-530
29. Testosterone Cypionate-Estradiol Cypionate Injection	Schein Pharmaceuticals, Port Washington, NY	0364-6611
30. Testosterone Cypionate-Estradiol Cypionate Injection	Steris Labs., Inc., Phoenix, AZ	0402-0257
31. Testosterone Cypionate-Estradiol Cypionate Injection	Goldline Labs, Ft. Lauderdale, FL	0182-3069
32. Testosterone Cypionate-Estradiol Cypionate Injection	The Upjohn Co., Kalamazoo, MI	0009-0253

Trade Name	Company	NDC or DIN No.
33. Testosterone Enanthate-Estradiol Valerate Injection	Goldline Labs., Ft. Lauderdale, FL	0182-3073
34. Testosterone Enanthate-Estradiol Valerate Injection	Schein Pharmaceuticals, Port Washington, NY	0364-6618
35. Testosterone Enanthate-Estradiol Valerate Injection	Steris Labs., Inc., Phoenix, AZ	0402-0360
36. Tilapia Sex Reversal Feed (Investigational)	Rangen, Inc., Buhl, ID	
37. Tilapia Sex Reversal Feed (Investigational)	Ziegler Brothers, Inc. Gardners, PA	

*AUTHORITY: section 195.195, RSMo 1994. * Material found in this rule previously filed as 19 CSR 30-1.025. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.008 List of Excluded Veterinary Anabolic Steroid Implant Products

PURPOSE: This rule maintains a list of veterinary anabolic steroid products excluded from 19 CSR 30-1.002(1)(C)5. in conformance with federal law.

(1) The following products containing an anabolic steroid that are expressly intended for administration through implants to cattle or other nonhuman species and which have been approved by the Secretary of Health and Human Services for such administration and are excluded from all schedules pursuant to section 195.017.5, RSMo.

Trade Name	Company	NDC or DIN No.
(A) Component E-H	Vetlife, Inc., Norcross, GA	021641-002
(B) Component E-H	Elanco, Scarborough, ON	01968327
(C) Component TE-S	Vetlife, Inc., Norcross, GA	021641-004
(D) Component T-H	Vetlife, Inc., Norcross, GA	021641-006
(E) Component T-S	Vetlife, Inc., Norcross, GA	021641-005
(F) F-TO	Animal Health, Upjohn International, Kalamazoo, MI	00093351
(G) Finaplix-H	Hoechst Roussel Vet, Somerville, NJ	12799-807-10
(H) Finaplix-S	Hoechst Roussel Vet, Somerville, NJ	12799-807-07
(I) Heifer-oid	Anchor Division, Boehringer Ingelheim, St. Joseph, MO	
(J) Heifer-oid	Bio-Ceutic Division, Boehringer Ingelheim, St. Joseph, MO	
(K) Heifer-oid	Ivy Laboratories, Inc., Overland Park, KS	
(L) Implus-H	The Upjohn Co., Kalamazoo, MI	0009-0434-01

(M) Implus-H	Upjohn Co., Animal Health Division, Orangeville, ON	06-0434-01 01968327
(N) Revalor-G	Hoechst Roussel Vet, Somerville, NJ	12799-811
(O) Revalor-H	Hoechst Roussel Vet, Somerville, NJ	12799-810
(P) Revalor-S	Hoechst Roussel Vet, Somerville, NJ	12799-809
(Q) Synovex H	Fort Dodge Labs, Fort Dodge, IA	0856-3901
(R) Synovex H	Syntex Laboratories, Palo Alto, CA	
(S) Synovex Plus	Fort Dodge Labs, Fort Dodge, IA	0856-3904

*AUTHORITY: section 195.195, RSMo 1994 and 195.017, RSMo Supp. 1999. * Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.017, RSMo 1971, amended 1987, 1989, 1994, 1996, 1997, 1998 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.010 Schedules of Controlled Substances (Rescinded November 30, 2000)

AUTHORITY: section 195.195, RSMo Supp. 1993. This rule was previously filed as 13 CSR 50-130.010 and 19 CSR 10-130.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Amended: Filed Oct. 4, 1972, effective Oct. 14, 1972. Amended: Filed April 4, 1973, effective April 14, 1973. Amended: Filed Sept. 28, 1973, effective Nov. 4, 1973. Amended: Filed Jan. 3, 1974, effective Jan. 13, 1974. Amended: Filed Oct. 9, 1974, effective Oct. 19, 1974. Amended: Filed July 17, 1975, effective July 27, 1975. Amended: Filed Oct. 8, 1975, effective Oct. 18, 1975. Refined: March 24, 1976. Amended: Filed Oct. 12, 1976, effective Jan. 13, 1977. Amended: Filed March 15, 1977, effective March 24, 1977. Amended: Filed Nov. 14, 1977, effective Nov. 6, 1977. Amended: Filed Sept. 28, 1977, effective Jan. 13, 1978. Amended: Filed March 9, 1978, effective Feb. 24, 1978. Amended: Filed Oct. 2, 1978, effective Sept. 27, 1978. Amended: Filed Nov. 14, 1978, effective June 16, 1978. Amended: Filed Nov. 14, 1978, effective Oct. 25, 1978. Amended: Filed Feb. 13, 1979, effective Feb. 9, 1979. Amended: Filed Feb. 19, 1980, effective Feb. 11, 1980. Amended: Filed Oct. 14, 1980, effective July 24, 1980. Amended: Filed Oct. 14, 1980, effective Aug. 21, 1980. Amended: Filed Oct. 14, 1981, effective Oct. 30, 1980. Amended: Filed Oct. 14, 1981, effective May 8, 1981. Amended: Filed Oct. 14, 1981, effective Aug. 20, 1981. Amended: Filed Nov. 1, 1982, effective Dec. 11, 1982. Amended: Filed Jan. 12, 1983, effective Feb. 11, 1983. Amended: Filed March 11, 1983, effective April 1, 1983.



Amended: Filed Sept. 2, 1983, effective Dec. 11, 1983. Amended: Filed Nov. 7, 1983, effective Dec. 11, 1983. Amended: Filed July 12, 1984, effective Aug. 11, 1984. Amended: Filed Sept. 20, 1984, effective Nov. 11, 1984. Amended: Filed Jan. 15, 1985, effective Feb. 11, 1985. Amended: Filed May 29, 1985, effective June 27, 1985. Amended: Filed July 24, 1985, effective Aug. 26, 1985. Amended: Filed Sept. 12, 1985, effective Oct. 11, 1985. Changed to 19 CSR 10-130.010, effective Oct. 11, 1985. Amended: Filed Jan. 3, 1986, effective Jan. 16, 1986. Changed to 19 CSR 30-1.010, effective Aug. 11, 1986. Amended: Filed April 17, 1987, effective May 14, 1987. Amended: Filed July 3, 1987, effective Aug. 27, 1987. Amended: Filed May 3, 1988, effective May 26, 1988. Amended: Filed Sept. 25, 1989, effective Oct. 27, 1989. Emergency amendment filed April 3, 1991, effective April 13, 1991, expired Aug. 10, 1991. Emergency amendment filed May 1, 1991, effective May 11, 1991, expired Sept. 7, 1991. Emergency amendment filed July 23, 1991, effective Aug. 2, 1991, expired Nov. 28, 1991. Amended: Filed April 3, 1991, effective Sept. 30, 1991. Amended: Filed May 1, 1991, effective Sept. 30, 1991. Amended: Filed March 2, 1992, effective Aug. 6, 1992. Amended: Filed July 6, 1993, effective Dec. 9, 1993. Emergency amendment filed Jan. 5, 1994, effective Jan. 15, 1994, expired May 14, 1994. Amended: Filed Jan. 5, 1994, effective July 30, 1994. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

State v. Miller, 588 SW2d 237 (Mo. App. 1979). Evidence of the presence of amphetamine is sufficient to support a controlled substances conviction; no quantitative analysis is necessary. Those rules refiled between January 1 and March 31, 1976 were not required to be published under section 536.021, RSMo. Also, courts must take judicial notice of the contents of the Code of State Regulations.

Selvey v. State, 578 SW2d 64 (Mo. App. 1979). Phenmetrazine, originally established statutorily as a Schedule III controlled substance, was rescheduled by the Division of Health to Schedule II. Such a rescheduling is within the statutory power granted the Division of Health and does not usurp the legislative power of the general assembly.

State v. Davis, 450 SW2d 168 (Mo. App. 1970). Statutes which direct the Division of Health to prepare a list of drugs classified as barbiturates and stimulants, the sale of which are made unlawful by statute, does not violate the Missouri Constitution prohibition in Arti-

cle I, section 31 against delegation of authority to an agency to make a rule fixing a fine or imprisonment as punishment for its violation.

19 CSR 30-1.011 Definitions

PURPOSE: This rule contains definitions which establish the intended meaning of certain terms used throughout this chapter.

(1) As used in this chapter, the following terms shall have the meanings specified:

(A) Commercial container means any bottle, jar, tube, ampule or other receptacle in which a substance is held for distribution or dispensing to an ultimate user and, in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drug or other package in which commercial containers are stored or are used for shipment of controlled substances;

(B) Controlled substances administration record means the form used to record information when administering individual drug doses to patients;

(C) Dispenser means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance;

(D) Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing care to dying persons and their families and meets the standards specified in 19 CSR 30-35;

(E) Hospital employee means a nurse, physician, pharmacist or other responsible patient-care employee;

(F) Individual practitioner means a physician, dentist, veterinarian, optometrist or other individual licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy or an institutional practitioner;

(G) Institutional practitioner means a hospital or other person (other than an individual) licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not include a pharmacy;

(H) Long-term care facility means a nursing home, retirement care, mental care, or

other facility or institution which provides extended health care to resident patients;

(I) Name means the official name, common or usual name, chemical name or brand name of a substance;

(J) Nurse means a registered or licensed practical nurse licensed under Chapter 335, RSMo;

(K) Patient care areas means any area of a hospital where medical attention is rendered to a patient;

(L) Pre-hospital emergency medical service means an emergency medical services system as defined in Chapter 190, RSMo providing services to persons prior to admission to a hospital;

(M) Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (For example, an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.);

(N) Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in a manner that they can be separated out from all other records; and/or records are kept on which certain items are asterisked, redlined, highlighted or in some other manner visually identifiable apart from other items appearing on the records; and records are provided within three working days of a request;

(O) Registration means a Missouri controlled substances registration;

(P) Reregistration means a registration issued to a person who was previously registered and whose application for reregistration was received by the Department of Health prior to the expiration of the previous registration;

(Q) Temporary location registration means a registration issued to an individual practitioner who:

1. Has a current Missouri professional license to practice and is registered with the Department of Health at the address listed on his/her professional license;

2. Has a federal Drug Enforcement Administration registration that is valid in Missouri;

3. Anticipates practicing in Missouri within the next 12 months;

4. Does not practice for more than 90 consecutive calendar days at any location;

5. Maintains a record of the date(s) and location(s) of all practice activity in Missouri and makes the record available to the Bureau of Narcotics and Dangerous Drugs. This record shall be retained for two years;



6. Maintains all required controlled substance records at each location;

7. Does not receive or stock controlled substances at any location;

(2) Any term not defined in this rule shall have the definition set forth in Chapter 195, RSMo.

AUTHORITY: section 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.013 Miscellaneous Fees

PURPOSE: This rule establishes and fixes certain fees and charges statutorily authorized to be made by the Department of Health in provisions codified in Chapters 195 and 610, RSMo.

(1) Fees for copies of public records or other documents:

- | | |
|----------------------------|---------|
| (A) Copy, per page | \$ 0.25 |
| (B) Research fee, per hour | \$15.00 |

(2) Payment of fee may be required in advance.

(3) Fees are nonrefundable.

AUTHORITY: section 195.030, RSMo Supp. 1999 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.015 Registrations and Fees

PURPOSE: This rule establishes fees for various types of registration, a late registration fee, manner of payment, and exemption from the registration fee.

(1) For each registration or re-registration to—

(A) Manufacture controlled substances, the registrant shall pay a fee of sixty-six dollars (\$66);

(B) Distribute controlled substances, the registrant shall pay a fee of sixty-six dollars (\$66);

(C) Dispense controlled substances listed in Schedules II–V including dispensing of controlled substances by individual practitioners in training programs or to conduct

research or instructional activities with those substances, the registrant shall pay a fee of thirty dollars (\$30);

(D) Conduct research or instructional activities with a controlled substance listed in Schedule I, the registrant shall pay a fee of thirty dollars (\$30);

(E) Conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of thirty dollars (\$30); and

(F) Import or export controlled substances listed in any schedule, the registrant shall pay a fee of sixty-six dollars (\$66).

(2) Lapsed Registration Fee. A late charge of ten dollars (\$10) must be submitted with the original registration fee if an application is submitted more than fifteen (15) days after a previous registration has expired.

(3) Time and Method of Payment and Refunds. Registration and re-registration fees shall be paid at the time when the application for registration or re-registration is submitted for filing. This is a nonrefundable processing fee. Payment should be made in the form of a personal, certified, or cashier's check or money order made payable to Department of Health and Senior Services. Payments made in the form of stamps, foreign currency, or third-party endorsed checks will not be accepted. Applications and fees submitted electronically online shall use a credit card and use the online payment system provided on the department's website.

(4) Persons Exempt From Fee. The Department of Health and Senior Services shall exempt the following persons from payment of a fee for registration or re-registration:

(A) Any official or agency of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans Administration, or Public Health Service who is authorized to procure or purchase controlled substances for official use;

(B) Any official, employee or other civil officer, or agency of the United States or state or any political subdivision or agency who is authorized to purchase controlled substances, to obtain these substances from official stocks, to dispense or administer these substances, to conduct research, instructional activities, or chemical analysis with these substances, or any combination of them, in the course of his/her official duties or employment;

(C) In order to claim exemption from payment of a registration or re-registration fee, the registrant shall apply for exemption by completing appropriate sections of the appli-

cation;

(D) Exemption from payment of a registration or re-registration fee does not relieve the registrant of any other requirements or duties prescribed by law; and

(E) Any registration that is exempt from payment pursuant to this section shall be valid only when authorized persons are conducting activities in the course of their official duties or employment at their government practice location. If the person conducts controlled substance activities away from his or her government practice location, the person shall apply and submit the required fee for a non-exempt registration.

AUTHORITY: sections 195.030 and 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

**Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.017 Registration Process

PURPOSE: This rule establishes the period and expiration of registration, the process of applying for registration, and information required to complete an application for registration.

(1) Database and Survey Process.

(A) Applicants may apply for and receive a registration that is effective for up to twelve (12) months.

(B) Applicants may apply with either a paper application or through the department's electronic online system.

(C) Simultaneously with completing an application for a controlled substances registration, practitioners may also complete an annual voluntary census to assist the department in determining practitioner shortages and underserved regions of the state. Required questions and fields for controlled substance registrations are marked with an asterisk (*) in the electronic online system and on paper applications.

(2) Period of Registration.

(A) Any registration shall be current and effective for twelve (12) months from the date issued or until the expiration date assigned at the time the registration is issued. No person who is required to be registered shall conduct any activity for which registration is required without a current registration. No controlled substance activities shall take place after a



registration expires until a new registration has been issued.

(B) At the time any registration is issued, the registration shall be assigned to one of twelve (12) groups which shall correspond to the months of the year. The expiration date of all registrations within any group shall be the last day of the month designated for that group.

(C) Registrations for manufacturers and distributors may be assigned to a single group, and the expiration date may be less than twelve (12) months from the date the registration was issued.

(D) Training program registrations may be assigned to a single group, and the expiration date may be less than twelve (12) months from the date the registration was issued.

(E) A certificate of registration shall be made available online and printable to the registrant which shall include the name and address of the registrant, the expiration date of the registration, and a registration number for the convenience of identifying a registration or a registrant. The same registration number may be used for a new registration for the same person.

(3) Requirements for All Applicants.

(A) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is processed and the registration is issued. All applications are for new registrations.

(B) Applications for registration shall be made on forms designated by the Department of Health and Senior Services. Application forms may be requested from the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or may be completed online and submitted electronically via the Missouri Department of Health and Senior Services' website at www.health.mo.gov along with the required fee.

(C) A written application in paper form shall contain the signature of the applicant and shall be provided to the Department of Health and Senior Services with any required fee. This is a nonrefundable processing fee.

(D) An application which does not contain or is not accompanied by the required information or fee may be denied sixty (60) days after notifying the applicant of the deficiency.

(E) An application may be withdrawn by making a written request to the Department of Health and Senior Services.

(F) A person who is registered may conduct activities with controlled substances in

Schedules II, III, IV, and V, as authorized by statute, unless a registration is restricted as to schedules or activities because of a settlement agreement, probation, or other disciplinary action taken by the Department of Health and Senior Services, the Drug Enforcement Administration, or a professional licensing board. Authority to conduct activities with controlled substances in Schedule I requires a separate application and registration.

(4) All applicants shall make full, true, and complete answers on the application. The Department of Health and Senior Services may require an applicant to submit documents or written statements of fact relevant to the application as considered necessary to determine whether the application should be granted. The failure of the applicant to provide these documents or statements within sixty (60) days after being requested to do so shall be considered to be a waiver by the applicant of an opportunity to present these documents or facts for consideration in granting or denying the application.

(5) Applications for Individual Practitioner Registrations. Applications by physicians, veterinarians, optometrists, podiatrists, and researchers for Missouri Controlled Substance Registrations shall include:

(A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III, gender, race, and ethnicity;

(B) A listing of all addresses and practice locations where controlled substance activities will be taking place. The applicant's street addresses, cities, zip codes, counties, and state. The number of hours worked per week for each location shall be provided for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other. The applicant shall also identify his or her primary, principle practice location, where he or she spends the most time. This will be the principle practice address that appears on the controlled substances registration. A physical street address is required and post office box addresses shall not be accepted;

(C) Whether the application is for a physician, veterinarian, optometrist, podiatrist, or researcher;

(D) His or her anticipated drug activities such as administering, prescribing, or dispensing;

(E) The required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs him or her;

(F) His or her business telephone number,

fax number, email address, federal controlled substances registration number, if applicable; professional degree, if applicable; and professional license number, if applicable. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;

(G) Whether the applicant, or any officer of a corporate applicant, or individual employed by any applicant having access to controlled substances, has ever entered a plea of guilty, no contest, *nolo contendere*, or otherwise been convicted of any violation of any state or federal law related to the possession, manufacture, distribution, dispensing, or prescribing of controlled substances. If the answer is yes, the applicant shall provide an explanation;

(H) If the applicant is an individual or a registrant that holds a professional license, whether he or she is currently licensed and registered to practice his or her profession under the laws of this state;

(I) If the applicant is not an individual or registrant that holds a professional license, the applicant shall answer yes or no to whether the applicant is currently authorized to conduct business under the laws of this state;

(J) Previous Discipline. If the applicant currently holds or has previously held a state or federal controlled substance registration or state professional license or registration, the applicant shall answer yes or no to whether the applicant's license, registration, or application or renewal thereof has ever been surrendered, revoked, suspended, denied, restricted, or placed on probation and if any such action is pending. If the answer is yes, the applicant shall provide an explanation;

(K) Whether the applicant is abusing or has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

(L) Copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (G) and (J) of this section, if the department does not already have them on file;

(M) The original signature of the individual applicant, if the application is submitted on paper;

(N) His or her Social Security number and date of birth (MM/DD/YYYY);

(O) The date the application is signed;

(P) What drug schedules the applicant is requesting authority in; and



(Q) A listing of mid-level practitioners by name and license number with whom applicant has agreements pursuant to Chapter 334, RSMo.

(6) Applications for Pharmacies and Businesses. Applications for retail pharmacies and ambulance services, ambulatory surgery centers, analytical laboratories, correctional centers, distributors, exporters, hospices, hospitals, importers, manufacturers, narcotic treatment programs, long-term care facility E-kits, teaching institutions, researchers, or other applicants not listed in sections (5)–(8), shall include:

(A) The applicant's full legal name, and if applicable, d/b/a name;

(B) The applicant's tax ID number, if applicable;

(C) The applicant's facility license number, if applicable, and federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate an application is pending;

(D) The applicant's email address;

(E) The applicant's principle Missouri business street address, city, state, county, and zip code as it will appear on the controlled substances registration certificate. Post office box numbers shall not be accepted. A separate mailing address may also be provided;

(F) The applicant's business telephone number and fax number;

(G) The applicant's type of business activity, licensure type, licensure agency, and license number;

(H) What controlled substance schedules the applicant is requesting authority in;

(I) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the owner, CEO or administrator, corporate officer, medical director, pharmacist in charge, or any employee with access to controlled drugs has ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;

(J) Whether there are any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;

(K) The application shall be submitted with the required fee and fee information. If

claiming an exemption from a fee, the applicant must identify the name of the government agency;

(L) Copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (I) and (J) of this section, if the department does not already have them on file;

(M) If the applicant is a retail business, the applicant shall provide a letter from the Missouri Department of Revenue that documents that no Missouri taxes are due and the applicant is in good standing; and

(N) The applicant shall sign and date an application submitted on paper and may use the electronic process if applying online. An application may be signed by the owner, chief executive officer or administrator, corporate officer, medical director, or pharmacist in charge.

(7) Applications for Dentists. Applications for dentists with the degrees of D.D.S. or D.M.D. shall include:

(A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III;

(B) His or her Social Security number and date of birth (MM/DD/YYYY);

(C) The applicant's federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;

(D) The applicant's gender, race, and ethnicity;

(E) The applicant's email address;

(F) The applicant's primary specialty and any board certification;

(G) Whether the applicant is licensed to practice and conduct activities and the applicant's licensure type, license number, and name of licensing agency;

(H) What drug schedules the applicant is requesting to conduct activities in;

(I) The applicant's anticipated drug activities such as administering, prescribing, or dispensing;

(J) The applicant's street addresses, city, zip code, county, and state of their primary, principle practice location, where they spend the most time. This will be the address that appears on the controlled substances registration. Post office box numbers shall not be accepted. Applicants shall also provide any secondary practice locations and the number of chair-side work hours per week at each location. The number of hours worked per week for each location shall be provided for performing direct patient care (non-hospital), administration, research, teaching, in-patient

hospital care, and other;

(K) The applicant's business phone number and fax number;

(L) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the applicant or any employees with access to controlled drugs have ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;

(M) Information regarding any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, as to whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;

(N) Whether the applicant is abusing or has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

(O) The application shall be submitted with the required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs him or her;

(P) The applicant shall provide copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (L) and (M) of this section, if the department does not already have them on file; and

(Q) The applicant shall sign and date an application submitted on paper and may use the electronic process if applying online.

(8) Applications for Mid-Level Practitioners. Applications for mid-level practitioners as defined by 21 CFR 1300.01(b)(28) such as advanced practice nurses and physician assistants shall include:

(A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III;

(B) The applicant's social security number and date of birth (MM/DD/YYYY);

(C) The applicant's federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;

(D) The applicant's gender, race, and ethnicity;



- (E) The applicant’s email address;
- (F) Whether the applicant is licensed to practice and conduct activities and the applicant’s licensure type, license number, and name of licensing agency;
- (G) What controlled substance schedules (III, IV, or V) the applicant is requesting to conduct activities in;
- (H) Which physicians the applicant has collaborative or supervision agreements with;
- (I) A copy of the applicant’s collaborative or supervision agreements with physicians, and a list of controlled substances from each physician that the mid-level practitioner is authorized to conduct activities with, in that agreement;
- (J) The applicant’s street address, city, zip code, county, and state of the applicant’s primary, principle practice location. This will be the principle address that appears on the controlled substances registration. Post office boxes shall not be accepted. Applicants shall also provide any secondary practice location addresses and the number of hours worked per week for each location for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other;
- (K) The applicant’s business phone number and fax number;
- (L) The applicant’s criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the applicant or any employee with access to controlled drugs has ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;
- (M) Information regarding any previous or pending disciplinary actions regarding the applicant’s professional license or any controlled substance registration, as to whether the applicant’s privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;
- (N) Whether the applicant has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, “abusing” or “abused” means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;
- (O) The application shall be submitted with the required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs the applicant;
- (P) The applicant shall provide copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsec-

tions (L) and (M) of this section, if the department does not already have them on file; and

(Q) The applicant shall sign and date an application submitted on paper and may use the electronic process if applying online.

*AUTHORITY: section 195.195, RSMo 2000. * Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.019 Registration Location

PURPOSE: This rule establishes requirements for the physical location of a registration.

- (1) A controlled substance registration shall be issued at a U.S. Postal Service street address.
- (2) A controlled substance registration shall be issued to an individual practitioner at a Missouri practice location where controlled substance and other patient care activities occur.

*AUTHORITY: section 195.195, RSMo 2000. * Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.020 List of Excepted Substances
(Rescinded November 30, 2000)

AUTHORITY: section 195.195, RSMo Supp. 1989. This rule was previously filed as 13 CSR 50-130.020. Original rule filed Sept. 28, 1977, effective Jan. 13, 1978. Amended: Filed Nov. 14, 1978, effective Dec. 11, 1978. Amended: Filed Oct. 12, 1979, effective Nov. 11, 1979. Amended: Filed Oct. 14, 1981, effective Nov. 2, 1981. Amended: Filed Nov. 1, 1982, effective Dec. 11, 1982. Amended: Filed Nov. 7, 1983, effective Dec. 11, 1983. Amended: Filed Oct. 2, 1991, effective Feb. 6, 1992. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.023 Registration Changes

PURPOSE: This rule establishes procedures for modifying an existing registration, describes the conditions under which a registration automatically terminates, and prohibits the transfer of a registration.

(1) Modification of Registration.

(A) Any registrant may apply to modify his/her registration to authorize the handling of controlled substances in additional schedules by submitting a request in writing to the department. No fee shall be required to be paid for the modification. The application for modification shall be handled in the same manner as an application for registration.

(B) Any registrant may request to modify his or her name or address as shown on the registration provided that such a modification does not constitute a change of ownership or location. The request shall be made in writing, and no fee shall be required to be paid for the modification. The request for changes may be submitted electronically using the department’s online database system. Requests submitted in paper form shall contain the registrant’s signature.

(C) When the registrant’s name or address as shown on the registration changes, the registrant shall notify the Department of Health and Senior Services in writing, including the registrant’s signature, prior to or within thirty (30) days subsequent to the effective date of the change. No fee shall be required to be paid for the modification.

(2) Termination of Registration.

(A) The registration of any person shall terminate—

- 1. On the expiration date assigned to the registration at the time the registration was issued;
- 2. If and when the person dies;
- 3. If and when the person ceases legal existence;
- 4. If and when a business changes ownership, except—

A. The registration shall not terminate for thirty (30) days from the effective date of the change if the new owner applies for a registration within the thirty (30)-day period and the corresponding Drug Enforcement Administration registration remains effective as provided for by the Drug Enforcement Administration;

5. If and when the person discontinues business or changes business location, except—

A. The registration shall not terminate for thirty (30) days from the effective date of the change if the person applies for a new registration or modification within the thirty (30)-day period; or



6. Upon the written request of the registrant.

(B) A mid-level practitioner's registration shall be contingent upon the physician with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, having a current and valid registration. When such physician's registration expires, closes, or is no longer valid, any mid-level practitioner(s) with whom he or she has entered into an agreement shall no longer have controlled substance authority. The mid-level practitioner(s) shall cease controlled drug activities until the physician has obtained a new registration or the mid-level practitioner(s) obtain(s) another agreement with another physician pursuant to Chapter 334, RSMo. Mid-level practitioners and any physician with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, shall notify the Department of Health and Senior Services of the termination of any such agreement.

(C) Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Department of Health and Senior Services of the effective date of this action and promptly return his/her registration certificate to the Department of Health and Senior Services.

(3) Transfer of Registration. No registration or any authority conferred by registration shall be assigned or otherwise transferred.

AUTHORITY: section 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.025 List of Exempt Anabolic Steroid Products

(Rescinded November 30, 2000)

AUTHORITY: section 195.015.4, RSMo Supp. 1989. Original rule filed July 6, 1993, effective Dec. 9, 1993. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.026 Separate Registrations

PURPOSE: This rule defines the requirements for controlled substance registrations for separate activities and for separate sites, and defines when a separate registration is not required.

(1) Independent Activities. The following eight groups of activities are deemed to be independent of each other and require separate registration:

(A) Manufacturing controlled substances;

(B) Distributing controlled substances, except:

1. A dispenser distributing less than 5% of the total combined dosage units of controlled substances distributed and dispensed in a calendar year shall be exempt from obtaining a separate registration for distributing;

2. A dispenser distributing more than 5% of the total combined dosage units of controlled substances distributed and dispensed in a calendar year must obtain a separate registration as a distributor but shall be exempt from maintaining separate inventories under 19 CSR 30-1.042;

(C) Dispensing controlled substances listed in Schedules II-V;

(D) Conducting research and instructional activities with controlled substances listed in Schedule I;

(E) Conducting research with controlled substances listed in Schedules II-V;

(F) Conducting a narcotic treatment program with narcotic controlled substances listed in Schedules II-V;

(G) Conducting instructional activities with controlled substances listed in Schedules II-V;

(H) Importing controlled substances;

(I) Exporting controlled substances;

(J) Conducting chemical analysis with controlled substances listed in any schedule.

(2) No activity shall be conducted with any controlled substance in any schedule not requested for and shown on the current registration.

(3) Separate Locations. A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed or dispensed by a person.

(A) For purposes of registration only, the following locations shall be deemed not to be places where controlled substances are manufactured, distributed or dispensed:

1. A warehouse where controlled substances are stored by or on behalf of a registered person, unless these substances are distributed directly from the warehouse to registrants other than the registered person or to persons not required to register;

2. An office used by agents of a registrant where sales of controlled substances are solicited, made or supervised but which nei-

ther contains these substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders;

3. An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at the office and where no supplies of controlled substances are maintained;

4. A location on the immediate or contiguous property of a hospital, provided that the location is owned and operated by the hospital and controlled substances are not dispensed for use away from the location;

5. A separate location from a registered pre-hospital emergency medical service location where an emergency vehicle is housed that does not have a permanent location of operation and which rotates between locations at least every 30 days for operational reasons other than controlled substance registration;

6. A pre-hospital emergency medical service located outside the state of Missouri that renders assistance to a pre-hospital emergency medical service located in the state of Missouri under a mutual aid contract in the case of an emergency, major catastrophe or other unforeseen event that jeopardizes the ability of the local Missouri pre-hospital emergency medical service to promptly respond.

(B) A separate registration is not required for each separate practice location for an individual practitioner who has a temporary location registration.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.027 Investigative and Administrative Procedures

PURPOSE: This rule establishes procedures for the handling and disposition of information indicating violations of Chapter 195, RSMo by the Department of Health, pursuant to the mandates of section 195.040.

(1) The Department of Health may allow officers of state and federal administrative agencies to attend and participate in informal conferences conducted with Missouri controlled substances registrants, Missouri regulated chemical registrants or applicants in order to



assist the Department of Health in its deliberations.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.030 Requirements for Controlled Substances Registration

(Rescinded November 30, 2000)

AUTHORITY: section 195.195, RSMo 1994. This rule was previously filed as 13 CSR 50-131.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Amended: Filed April 12, 1983, effective July 11, 1983. Amended: Filed May 31, 1989, effective Oct. 1, 1989. Amended: Filed Nov. 26, 1991, effective April 9, 1992. Amended: Filed Aug. 26, 1992, effective April 8, 1993. Amended: Filed Nov. 1, 1994, effective June 30, 1995. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.031 Physical Security Requirements

PURPOSE: This rule requires applicants and registrants to maintain security controls and procedures to prevent theft and diversion of controlled substances.

(1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirement set forth in 19 CSR 30-1.032-19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Department of Health after evaluation of the overall security system and needs of the applicant or registrant.

(2) Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security con-

trols shall be expanded and extended accordingly.

(3) All registrants who receive or transfer substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.032 Security for Nonpractitioners

PURPOSE: This rule describes specific actions required of nonpractitioner registrants to maintain effective security.

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) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the federal Drug Enforcement Administration (DEA) or with the Department of Health and Senior Services to determine that the person is registered to possess the controlled substance.

(2) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Department of Health and Senior Services of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

(3) The registrant shall notify the Department of Health and Senior Services of any theft or significant loss of any controlled substances upon discovery of this theft or loss.

(A) The registrant shall complete and submit a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals to the Department of Health and Senior Services no later than seven (7) business days after the discovery of such a loss. If the extent of the loss cannot be fully determined in that time frame, the registrant shall contact the Department of Health and Senior Services to request permission to submit an interim report and arrange for a complete report to be completed and submitted. The registrant may attach a copy of a completed Drug Enforcement Administration Loss Form in lieu of completing the back or second page of a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals form. In the event of theft, diversion or suspected theft or diversion, the report submitted to the Department of Health and Senior Services shall be accompanied by or followed by a summary of the internal investigation performed, the outcome of the investigation, and a copy of any law enforcement agency report completed if applicable.

(B) If an insignificant amount of a controlled substance is lost during lawful activities authorized under Chapter 195, RSMo, the reason for the loss or a description of what occurred, the name of the drug and the amount lost shall be documented in writing, signed by the registrant and attached or filed with the last completed annual inventory.

(4) The registrant shall not distribute any controlled substance as a complimentary sample to any potential or current customer without the prior written request of the customer, to be used only for satisfying the legitimate medical needs of patients of the customer and only in reasonable quantities. The request must contain the name, address and registration number of the customer and the name of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements for order forms shall be complied with for any distribution of a controlled substance listed in Schedule I or II.

(5) Entities registered with the Department of Health and Senior Services as distributors shall be deemed to have met security requirements for storage of Schedule V controlled substance drug products containing ephedrine or pseudoephedrine if those products are stored in compliance and consistent with the regulated chemicals requirements set forth by the United States Drug Enforcement Administration and 21 CFR 1309.71 which is hereby incorporated by reference in this rule, as



published on April 1, 2005 by the U.S. Government Printing Office, U.S. Superintendent of Documents, Washington, DC 20402-001; www.gpoaccess.gov/cfr/retrieve.html. This rule does not incorporate any subsequent amendments or additions. Distributors will be required to conduct background checks on employees with access to these substances and to report losses of controlled substances as required in 19 CSR 30-1.034.

AUTHORITY: sections 195.017, RSMo Supp. 2005 and 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Aug. 18, 2005, effective Aug. 28, 2005, expired Feb. 23, 2006. Amended: Filed Sept. 1, 2005, effective Feb. 28, 2006.*

**Original authority: 195.017, RSMo 1971, amended 1987, 1989, 1994, 1996, 1997, 1998, 2001, 2005 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.033 Hearing Procedures on Controlled Substances Registration (Rescinded November 30, 2000)

AUTHORITY: sections 195.040.II and 195.195, RSMo Supp. 1989. Original rule filed Aug. 26, 1992, effective April 8, 1993. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.034 Security for Practitioners

PURPOSE: This rule describes specific actions required of practitioner registrants to maintain effective security. This rule also creates and defines the form which must be used by a registrant to report any theft or loss of controlled substances to the Department of Health.

(1) Physical Security.

(A) Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.

(B) Controlled substances listed in Schedules III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may dispense these substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(C) This rule also shall apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

(2) Other Security.

(A) The registrant shall not employ as an agent or employee who has access to con-

trolled 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 or who has had an application for a state or federal controlled substance registration denied or has had his/her registration revoked or surrendered for cause at any time. For purposes of this subsection, the term for cause means a surrender in place of or as a consequence of any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

1. A registrant may apply in writing to the Department of Health and Senior Services for a waiver of subsection (2)(A) of this rule for a specific employee.

2. The Department of Health and Senior Services may issue a written waiver to any registrant upon determination that a waiver would be consistent with the public health and safety. In making this determination, the Department of Health and Senior Services 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 federal Drug Enforcement Administration (DEA) pursuant to 21 CFR 1301.76, the security measures taken by the employer to prevent the theft and diversion of controlled substances, and any other factors consistent with public health and safety.

(B) A registrant shall notify the Department of Health and Senior Services of the theft, diversion or significant loss of any controlled substances or regulated chemicals upon discovery.

1. The registrant shall complete and submit a report of the loss or diversion of controlled substances to the Department of Health and Senior Services no later than seven (7) business days after the discovery of such a loss. The loss report form shall contain the following information: name and address of registrant, business phone number; Missouri Controlled Substance Registration Number; federal Drug Enforcement Administration Registration number; date of theft or loss; date of discovery of theft or loss; county of location; principal type of registration such as M.D., D.O., D.P.M., O.D., D.V.M., D.D.S., D.M.D., A.N.P., emergency medical service, pharmacy, hospital, manufacturer, nursing home kit, narcotic treatment program, teaching institution, distributor, importer, exporter, or other specified business; whether or not the loss or theft was reported to law enforcement; the name and phone number of the law enforcement

agency reported to; the number of losses or thefts the registrant has experienced in the past twenty-four (24) months; the type of loss or diversion such as, break in/burglary, robbery, employee theft, forged or falsified records, lost in transit, or other explained type of loss; if lost in transit, the name of the common carrier and name of consignee; the name(s) of the individual diverting controlled substances who was responsible for the theft or loss; copy of registrant's internal investigative report involving the loss or theft; the full name, date of birth and Social Security number of the individual(s) responsible for the theft or diversion, if known; a copy of the police report if law enforcement was notified; if the loss or diversion was in transit, identify the origin of the delivery, the name of the carrier(s) used and the name of the consignee; a list of all controlled substances lost, stolen or diverted by their generic name, trade name, the dosage strength, dosage form and quantity; the signature of the person completing the loss report and their title and the date of their signature. If the extent of the loss cannot be fully determined in that time frame, the registrant shall contact the Department of Health and Senior Services to request permission to submit an interim report and arrange for a complete report to be completed and submitted. The registrant may attach a copy of a completed Drug Enforcement Administration Loss Form in lieu of completing the back or second page of a loss report form provided by the Department of Health and Senior Services. In the event of theft, diversion or suspected theft or diversion, the report submitted to the Department of Health and Senior Services shall be accompanied by or followed by a summary of the internal investigation performed, the outcome of the investigation, and a copy of any law enforcement agency report completed if applicable.

2. If an insignificant amount of a controlled substance is lost during lawful activities authorized under Chapter 195, RSMo, the reason for the loss or a description of what occurred, the name of the drug and the amount lost shall be documented in writing, signed by the registrant and attached or filed with the last completed annual inventory.

AUTHORITY: section 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*



19 CSR 30-1.035 Requirements for Prescribing, Dispensing and Administering Controlled Substances

(Rescinded November 30, 2000)

AUTHORITY: sections 195.040.3(2), 195.050.6 and 195.195, RSMo 1994. Original rule filed Nov. 14, 1988, effective Feb. 24, 1989. Amended: Filed Aug. 26, 1992, effective April 8, 1993. Amended: Filed Nov. 1, 1994, effective June 30, 1995. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.036 Disposing of Unwanted Controlled Substances

(Rescinded November 30, 2000)

AUTHORITY: section 195.050.6, RSMo 1986. Original rule filed Jan. 18, 1989, effective April 27, 1989. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.040 Dispensing and Distribution of Controlled Substances in Certain Situations

(Rescinded July 30, 2003)

AUTHORITY: section 195.195, RSMo 1986. This rule was previously filed as 13 CSR 50-132.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Rescinded: Filed Jan. 31, 2003, effective July 30, 2003.

19 CSR 30-1.041 Records Requirements

PURPOSE: This rule defines the record keeping and inventory requirements for various classes of registrants.

(1) Persons Required to Keep Records.

(A) Each registrant shall maintain the records and inventory required by 19 CSR 30-1.041-19 CSR 30-1.052, except as exempted by 19 CSR 30-1.041-19 CSR 30-1.052.

(B) Registered individual practitioners and institutional practitioners are required to keep records with respect to controlled substances which are prescribed, administered or dispensed.

(C) A registered person using any controlled substance in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the federal Food, Drug and Cosmetic Act (21 U.S.C. 355(i) or 360(j)) at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if s/he notifies the Department of Health of the name, address and registration

number of the establishment maintaining these records.

(D) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to these substances is not required to keep records if s/he notifies the Department of Health of the name, address and registration number of the establishment maintaining the records.

(E) Notice required by subsection (1)(D) of this rule shall be given at the time the person applies for registration or re-registration and shall be made in the form of an attachment to the application, which shall be filed with the application.

(2) Maintenance of Records and Inventories. Every inventory and other record required to be kept under 19 CSR 30-1.041-19 CSR 30-1.052, shall be kept by the registrant and be available, for at least two years from the date of the inventory or record, for inspecting and copying by authorized employees of the Department of Health, except that financial and shipping records (such as invoices and packing slips, but not executed order forms) may be kept at a central location rather than at the registered location if the registrant obtains from the Department of Health approval of his/her central record keeping system and a permit to keep central records. The permit to keep central records shall be subject to the following conditions:

(A) The permit shall specify the nature of the records to be kept centrally and the exact location where the records will be kept;

(B) The registrant agrees to deliver all or any part of these records to the registered location within three working days of receipt of a written request from the Department of Health for these records and if the Department of Health chooses to do so in lieu of requiring delivery of records to the registered location, to allow authorized employees of the Department of Health to inspect the records at the central location upon request by the employees without a warrant of any kind;

(C) The failure of the registrant to perform his/her agreements under the permit shall revoke, without further action, the permit and all other such permits held by the registrant under other registrations. In the event of a revocation of other permits under subsection (2)(C) of this rule, the registrant, within 30 days after the revocation, shall comply with the requirement that all records be kept at the registered location.

(3) Each registered individual practitioner, institutional practitioner, manufacturer, dis-

tributor, importer and exporter shall maintain inventories and records of controlled substances as follows:

(A) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant;

(B) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the registrant or in a form that the information required is readily retrievable from the ordinary business records of the registrant.

(4) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(A) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy and prescriptions for these substances shall be maintained in a separate prescription file;

(B) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the pharmacy or in a form that the information required is readily retrievable from ordinary business records of the pharmacy and prescriptions for those substances shall be maintained in a separate prescription file.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994 and 195.030, RSMo Supp. 1999.* Original rule filed April 14, 2000, effective Nov. 30, 2000.

**Original authority:* 195.030, RSMo 1939, amended 1971, 1989, 1993, 1997, 1999; 195.050, RSMo 1939, amended 1971, 1989; and 195.195, RSMo 1957, amended 1971, 1989, 1993.

19 CSR 30-1.042 Inventory Requirements

PURPOSE: This rule defines requirements for the form and maintenance of controlled substance inventories.

(1) General Requirements.

(A) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory was taken. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant and substances in the possession of employees of the



registrant and intended for distribution as complimentary samples.

(B) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances are in the possession or under the control of the registrant at a location for which s/he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(C) A separate inventory shall be made by a registrant for each independent activity for which s/he is registered.

(D) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

(E) An inventory must be maintained in a permanent written, typewritten or printed form. An inventory taken by use of an oral recording device must be transcribed promptly.

(2) Initial Inventory Date.

(A) Every person required to keep records who is registered with the Department of Health after May 1, 1971 and who was not registered previously shall take an inventory of all stocks of controlled substances on hand on the date s/he first engages in the manufacture, distribution or dispensing of controlled substances.

(B) Compliance with federal initial inventory date requirements is deemed satisfactory. Duplicate inventories are not required.

(3) Annual Inventory Date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least once a year. The annual inventory may be taken on any date that is within one year of the previous annual inventory date.

(4) Inventory Date for Newly Controlled Substances. On the effective date of a rule by the Department of Health adding a substance to any schedule of controlled substances, which substance was not listed immediately prior to that date in any such schedule, every registrant required to keep records who is manufacturing, distributing or dispensing that substance shall take inventory of all stocks of the substance on hand. After that, this substance shall be included in each inventory made by the registrant.

(5) Inventories of Manufacturers. Each registered manufacturer shall include the following information in his/her inventory:

(A) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or noncontrolled substances in finished form, the name of the substance and the total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, *avoirdupois* weights may be utilized where metric weights are not readily available);

(B) For each controlled substance in the process of manufacture on the inventory date the name of the substance, the quantity of the substance in each batch, stage of manufacture, or both, identified by the batch number or other appropriate identifying number and the physical form which the substance is to take upon completion of the manufacturing process (for example, granulations, tablets, capsules or solutions), identified by the batch number or other appropriate identifying number and if possible the finished form of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number or volume;

(C) For each controlled substance in finished form, the name of the substance; each finished form of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (for example, four 100 tablet bottles or three milliliter (3 ml) vials); the number of commercial containers of each finished form (for example, four 100 tablet bottles or six three milliliter (3 ml) vials);

(D) For each controlled substance not included in subsections (5)(A)–(C) of this rule (for example, damaged, defective or impure substances awaiting disposal, substances held for quality control purposes or substances maintained for extemporaneous compoundings), the name of the substance; the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; the reason for the substance being maintained by the registrant and whether the substance is capable of use in the manufacture of any controlled substance in finished form.

(6) Inventories of Distributors. Each registered distributor shall include in his/her inventory the same information required of manufacturers in subsections (5)(C) and (D) of this rule.

(7) Inventories of Dispensers and Researchers. Each person registered to dispense or conduct research with controlled substances and required to keep records shall include in his/her inventory the same information required of manufacturers in subsections (5)(C) and (D) of this rule. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(A) If the substance is listed in Schedule I or II, s/he shall make an exact count or measure of the contents;

(B) If the substance is listed in Schedule III, IV or V, s/he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case s/he must make an exact count of the contents.

(8) Inventories of Importers and Exporters. Each registered importer or exporter shall include in his/her inventory the same information required of manufacturers in subsections (5)(A), (C) and (D) of this rule. Each registered importer and exporter who also is registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that actually are separated from his/her stocks as a manufacturer or as a distributor (for example, in-transit or in storage for shipment).

(9) Inventories for Chemical Analysts. Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers in subsections (5)(A), (C) and (D) of this rule as to substances which have been manufactured, imported or received by the laboratory conducting the inventory. If less than one kilogram (1 kg) of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I) or less than twenty grams (20 g) of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide) or less than point five gram (0.5 g) of lysergic acid diethylamide, is on hand at the time of inventory, those substances need not be included in the inventory. Laboratories of the division may process up to one hundred fifty grams (150 g) of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances.

AUTHORITY: sections 195.030, RSMo Supp. 1999 and 195.195, RSMo 1994. Original*



rule filed April 14, 2000, effective Nov. 30, 2000.

**Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.044 Continuing Records General Requirements

PURPOSE: This rule sets requirements for the maintenance of ongoing controlled substance records.

(1) Every registrant required to keep records shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported or otherwise disposed of by him/her.

(2) Separate records shall be maintained by a registrant for each registered location except as provided in 19 CSR 30-1.041(2). In the event controlled substances are in the possession or under the control of a registrant at a location for which s/he is not registered, the substance shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(3) Separate records shall be maintained by a registrant for each independent activity for which s/he is registered.

(4) In recording dates of receipt, importation, distribution, exportation or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (for example, invoices or packing slips).

(5) Records must be provided to the Department of Health within three working days upon request.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.046 Records for Manufacturers, Distributors, Importers and Exporters

PURPOSE: This rule sets requirements for record keeping by manufacturers, distribu-

tors, importers and exporters of controlled substances.

(1) Records for Manufacturers. Each registered manufacturer shall maintain records with the following information:

(A) For each controlled substance in bulk form to be used in or capable of use in or being used in the manufacture of the same or other controlled or noncontrolled substances in finished form—

1. The name of the substance;
2. The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

3. The quantity received from other persons including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;

4. The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity and import permit or declaration number for each importation;

5. The quantity used to manufacture the same substance in finished form including the date and batch or other identifying number of each manufacture; the quantity used in the manufacture; the finished form (for example, ten milligram (10 mg) tablets or ten milligram (10 mg) concentration per fluid ounce or milliliter); the number of units of finished form manufactured; the quantity used in quality control; the quantity lost during manufacturing and the causes for the loss, if known; the total quantity of the substance contained in the finished form; the theoretical and actual yields and other information as is necessary to account for all controlled substances used in the manufacturing process;

6. The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (1)(A)5. of this rule;

7. The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address and registration number of each person to whom a distribution was made;

8. The quantity exported directly by the registrant, including the date, quantity and export permit or declaration number of each exportation;

9. The quantity distributed or disposed of in any other manner by the registrant (for example, distribution of complimentary samples or by destruction) including the date and manner of distribution or disposal, the name,

address and registration number of the person to whom distributed and the quantity distributed or disposed;

(B) For each controlled substance in finished form—

1. The name of the substance;
2. Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100 tablet bottle or three milliliter (3 ml) vial);

3. The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required in paragraph (1)(A)5. of this rule;

4. The number of units of finished forms, commercial containers, or both, received from other persons, including the date of and number of units, commercial containers, or both, in each receipt and the name, address and registration number of the person from whom the units were received;

5. The number of units of finished form, commercial containers, or both, imported directly by the registrant, including the date of and the number of units, commercial containers, or both, in each importation;

6. The number of units, commercial containers, or both, manufactured by the registrant from units in finished form received from others or imported including: the date and batch or other identifying number of each manufacture; the operation performed (for example, repackaging or relabeling); the number of units of finished form used in the manufacture, the number manufactured and the number lost during the manufacture, with the causes for these losses, if known, and other information as is necessary to account for all controlled substances used in the manufacturing process;

7. The number of commercial containers distributed to other persons including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

8. The number of commercial containers exported directly by the registrant, including the date, number of containers and export permit or declaration number for each exportation;

9. The number of units of finished forms, commercial containers, or both, distributed or disposed of in any other manner by the registrant (for example, by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and registration number



of the person to whom distributed and the quantity in finished form distributed or disposed.

(2) Records for Distributors. Each registered distributor shall maintain records with the following information for each controlled substance:

(A) The name of the substance;

(B) Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100 tablet bottle or three milliliter (3 ml) vial);

(C) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(D) The number of commercial containers of each finished form imported directly by the registrant including the date of and the number of containers in each importation;

(E) The number of commercial containers of each finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

(F) The number of commercial containers of the finished form exported directly by the registrant, including the date of and the number of containers in each exportation;

(G) The number of units or volume of finished forms, commercial containers, or both, distributed or disposed of in any other manner by the registrant (for example, by distribution as complimentary samples) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity of the substance in finished form distributed or disposed.

(3) Records for Importers. Each registered importer shall maintain records with the following information for each controlled substance:

(A) The name of the substance;

(B) The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume) and import permit or declaration number for each importation;

(C) The quantity (or number of units or volume in finished form) distributed to other persons, including the date, quantity (or number of units or volume) of each distribution

and the name, address and registration number of each person to whom a distribution was made;

(D) The quantity disposed of in any other manner by the registrant except quantities used in manufacturing by an importer under a registration as a manufacture, which quantities are to be recorded, including the date and manner of disposal and the quantity disposed.

(4) Records for Exporters. Each registered exporter shall maintain records with the following information for each controlled substance:

(A) The name of the substance;

(B) The quantity (or number of units or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address and registration number of each person from whom the substance was received;

(C) The quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume) and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacture, which quantities (and numbers of units and volumes) are to be recorded;

(D) The quantity disposed of in any other manner by the registrant including the date and manner of disposal and the quantity disposed.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.048 Records for Practitioners and Researchers

PURPOSE: This rule sets requirements for record keeping for individual practitioners and researchers. It also sets requirements for the use of facsimile and electronic computer transmission of controlled substance prescriptions.

(1) Each individual practitioner, institutional practitioner and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed or disposed:

(A) The name of the substance;

(B) Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100 tablet bottle or three milliliter (3 ml) vial);

(C) The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(D) The number of units or volume of the finished form dispensed including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed and the written or typewritten name or initials of the individual who dispensed or administered the substance;

(E) The number of units or volume of the finished forms, commercial containers, or both, disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

(2) Each individual practitioner shall maintain a record of the date, full name and address of the patient, the drug name, strength, dosage form and quantity for all controlled substances prescribed or administered. This record may be maintained in the patient's medical record. When the controlled substance record is maintained in the patient's medical record and the practitioner is not the custodian of the medical record, the practitioner shall make the controlled substance record available as required in 19 CSR 30-1.041 and 19 CSR 30-1.044.

(3) Individual practitioners shall maintain the records listed in subsections (1)(A)–(E) of this rule separately from patient medical records.

(4) A registrant who transfers a controlled substance to or receives a controlled substance from another registrant shall maintain a written record of the transfer which contains the following information: the date of transfer, drug name, strength, dosage form, quantity, name, address and registration number of the transferring registrant and the name, address and registration number of the receiving registrant.

(5) Drug Enforcement Administration official order forms shall be used for transfers of Schedule II controlled substances.

(6) A prescription may not be issued for an individual practitioner to obtain controlled



substances for dispensing or administering to patients.

(7) Prescriptions which are transmitted by facsimile to a pharmacy for dispensing shall include the telephone number of the facsimile machine or computer from which it is sent and the date and time of transmission. Immediately after a Schedule III, IV or V prescription or a Schedule II prescription for a long-term care facility patient or hospice patient or for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion is transmitted to a pharmacy by facsimile equipment, the practitioner or the practitioner's agent shall sign and date the face of the prescription. The prescriptions shall be maintained in chronological order separately from patient medical records in a manner so each prescription is readily retrievable for inspection at the transmitting practitioner's office. In the event the facsimile is transmitted from a long-term care facility or hospital, the prescription shall be maintained at the long-term care facility or hospital in chronological order separately from the patient medical records in a manner so each prescription is readily retrievable, or maintained in the patient medical records.

(8) Any pharmacy receiving a controlled substance prescription transmitted by facsimile equipment shall maintain the facsimile copy of the prescription along with the date and time of transmission and the telephone number of the facsimile machine from which it originated, as a part of its original prescription records.

(9) Any practitioner or practitioner's agent who transmits a controlled substance prescription by electronic computer transmission shall maintain a printout of each day's transmissions. The practitioner or practitioner's agent shall verify that the information in the printout is correct and shall sign the printout.

(10) Each pharmacist who dispenses controlled substances under a prescription transmitted by electronic computer transmission, shall verify with the practitioner within 30 days of the filling such prescription that the prescription was authorized by the practitioner. If verification is made by telephone, the pharmacist shall document the verification on the reverse of the prescription or in the computer. If verification is made by sending the practitioner a copy of a computer printout, the practitioner shall verify, sign and return the printout to the pharmacy. The pharmacy shall maintain

the verified printout in a separate file.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.050 Records for Chemical Analysts

PURPOSE: This rule sets requirements for record keeping for chemical analyst registrants.

(1) Each person registered to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him/her) for each controlled substance:

(A) The name of the substance;

(B) The form(s) in which the substance is received, imported or manufactured by the registrant (for example, powder, granulation, tablet, capsule or solution) and the concentration of the substance in that form (for example, Chemically Pure (CP), United States Pharmacopeia (USP), National Formulary (NF), ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per milliliter);

(C) The total number of the forms received, imported or manufactured (for example 100 tablets, 30 one milliliter (1 ml) vials or ten grams (10 g) powder), including the date and quantity of each receipt, importation or manufacture and the name, address and registration number, if any, of the person from whom the substance was received; and

(D) The quantity distributed, exported or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation or destruction and the name, address and registration number, if any, of each person to whom the substance was distributed or exported.

(2) Order forms, import and export permits, import invoices and export declarations relating to controlled substances shall be maintained separately from all other records of the registrant.

(3) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(4) Records relating to known or suspected

controlled substances received as samples for analysis are not required under section (1) of this rule.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.052 Records for Long-Term Care Facilities (LTCF)

PURPOSE: This rule sets requirements for record keeping by long-term care facility registrants.

(1) Long-term care facilities (LTCFs) and their suppliers shall maintain written records of transfers of controlled substances from the supplier to the LTCF emergency kit.

(2) The records shall include the date of transfer; the name of each controlled substance, the strength, dosage form and quantity; the name, address and controlled substance registration number of the supplier and the name, address and controlled substance registration number of the LTCF. Federal Drug Enforcement Administration (DEA) official order forms shall not be used to record transfers of controlled substances to LTCF emergency kits.

(3) No physician's order or prescription shall be used for initial stocking or replacement of controlled substances in the emergency kit. Controlled substances contained in the kit shall be obtained from a pharmacy, hospital or practitioner who holds a controlled substances registration.

(4) The administration and medical staff of the LTCF, in conjunction with the primary supplier, shall designate in written protocols and procedures who may have access to the emergency kit, who may administer controlled substances from the emergency kit and under what circumstances and a list of the controlled substances it intends to maintain in the emergency kit. These protocols and procedures shall be subject to review and approval by the Department of Health. Only those individuals designated in the LTCF's written policies and procedures shall have access to or administer controlled substances from the emergency kit.

(5) Each administration of controlled substances from the emergency kit shall be based upon a practitioner's order and shall be



recorded in an administration record separate from the patient's medical record. This administration record shall include: the date, patient's name, drug name, drug strength, dosage, ordering practitioner's name and name of the person administering the controlled substance.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.060 Determining Lawful Prescribing, Dispensing and Administering of Controlled Substances

PURPOSE: This rule defines the statutory and regulatory basis for determining what is lawful prescribing, dispensing and administering of controlled substances.

When determining if controlled substances are being lawfully prescribed, dispensed and administered by practitioners, the Department of Health shall enforce Chapter 195, RSMo, the Department of Health rules in 19 CSR 30 pertaining to controlled substances, and the federal Controlled Substances Act 21 U.S.C. 801-966, and its regulations, 21 CFR 1300-1399. In determining lawful prescribing, dispensing and administering of controlled substances, the Department of Health also shall consider the provisions of Chapters 330, 332, 334, 335, 336, 338 and 340, RSMo, the rules in 4 CSR 110, 4 CSR 150, 4 CSR 200, 4 CSR 210, 4 CSR 220, 4 CSR 230 and 4 CSR 270, and protocols relating to the respective practitioners established and on file at the respective licensing boards.

AUTHORITY: sections 195.030, RSMo Supp. 1999 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov 30, 2000.*

**Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1999 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.062 Transmission of Prescriptions

PURPOSE: This rule sets requirements governing the transmission of prescription information.

(1) Prescriptions in Schedule II. A pharmacist may dispense a controlled substance in Schedule II only under a written prescription

signed by the practitioner, except as provided in section 195.060.3, RSMo. A prescription for a Schedule II controlled substance may be transmitted from the prescribing practitioner to a pharmacy by facsimile equipment or electronic computer transmission, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except that—

(A) A prescription written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile or by electronic computer transmission. The facsimile or the computer transmission which has been reduced to writing shall serve as and shall be maintained in the same manner as an original written prescription.

(B) A prescription written for a Schedule II substance for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile or by electronic computer transmission. The facsimile or the computer transmission which has been reduced to writing shall serve as and shall be maintained in the same manner as an original written prescription.

(C) A prescription written for a Schedule II substance for a patient of a hospice may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile or by electronic computer transmission. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The facsimile or the computer transmission which has been reduced to writing shall serve as and shall be maintained in the same manner as an original written prescription.

(2) Prescriptions in Schedule III, IV or V. A pharmacist may dispense directly a controlled substance in Schedule III, IV or V only under a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or his/her authorized agent or under an oral prescription made by an individual practitioner whether communicated by the practitioner or his/her authorized agent or a prescription transmitted by electronic computer transmission by the authorizing practitioner or the practitioner's agent to the pharmacy. All oral prescriptions and prescriptions transmitted by electronic computer transmission shall be promptly reduced to writing by the pharmacist containing all information required in

section 195.060, RSMo, except for the signature of the practitioner.

(3) Written Prescriptions. All written controlled substance prescriptions shall be signed by the prescribing practitioner on the date prescribed. No controlled substance prescription shall be signed prior to the actual date it is issued.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.064 Partial Filling of Schedule II Prescriptions

PURPOSE: This rule sets requirements for the partial filling of Schedule II prescriptions.

(1) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and s/he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(2) A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of Chapter 195, RSMo. For each partial filling, the dispensing pharmacist shall record on the back of the prescription



(or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

*AUTHORITY: section 195.195, RSMo 1994. * Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.066 Dispensing by Individual Practitioners

PURPOSE: This rule sets requirements for individual practitioners who dispense controlled substances.

(1) An individual practitioner who dispenses controlled substances shall—

(A) Provide direct supervision to employees or agents who assist in the administering or dispensing of controlled substances. Controlled substances shall not be dispensed from an individual practitioner's inventory unless a practitioner is physically in the registered location except pursuant to the provisions of section (2) of this rule;

(B) Package all controlled substances dispensed from an individual practitioner's inventory in compliance with the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1471-1476;

(C) Permanently affix a label to the exterior of the drug container which includes: the date, the name and address of the dispensing practitioner, the name of the patient, directions for use, and the exact name and strength of the drug dispensed for all controlled substances dispensed;

(D) Dispense only to individuals with whom the practitioner has established and documented a practitioner/patient relationship. An individual practitioner shall not dispense under the order of another practitioner not practicing at that location.

(2) Mid-level practitioners shall not independently purchase, stock, administer, and dispense controlled substances. Controlled substances may be administered or dispensed

from an individual practitioner's inventory by a mid-level practitioner with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, when the practitioner is not present at the registered location.

*AUTHORITY: section 195.195, RSMo 2000. * Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.068 Administering In Emergency Rooms

PURPOSE: This rule sets requirements for administering controlled substances in hospital emergency rooms.

(1) Controlled substances may be administered to a hospital emergency room patient under a verbal order of a registered practitioner who is not physically present if—

(A) The order is for a legitimate medical purpose and the practitioner who orders the administration of a controlled substance is acting in the usual course of his/her medical practice, after sufficient examination and establishment of a practitioner/patient relationship;

(B) The practitioner who orders the administration of a controlled substance is a medical staff member of the hospital;

(C) The administration of a controlled substance is documented in a formal medical record for the patient;

(D) The patient is assessed in the hospital by a practitioner, when available, or a registered nurse. If the patient is not assessed by a practitioner in the hospital, a registered nurse shall assess the patient and confirm and document in the patient's medical record the existence of a preestablished practitioner/patient relationship with the practitioner who ordered administration of a controlled substance;

(E) The order is written in the patient's medical record and is authenticated by the ordering practitioner within a time frame and manner as defined by the medical staff in cooperation with nursing and administration. This policy shall be included in the hospital's written policies and procedures.

*AUTHORITY: section 195.195, RSMo 1994. * Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.070 Emergency Dispensing of Schedule II Substances

PURPOSE: This rule provides for the prescribing and dispensing of Schedule II drugs in an emergency situation.

(1) In the case of a bona fide emergency situation, as defined by the Department of Health, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner; provided, that—

(A) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription;

(B) The prescription immediately shall be reduced to writing by the pharmacist and shall contain all information, except for the prescribing practitioner's signature;

(C) If the prescribing practitioner is not known to the pharmacist, s/he must make reasonable effort to determine that the oral authorization came from a practitioner, by verifying his/her phone number against that listed in the directory and other good faith efforts to insure his/her identity;

(D) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner must cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription shall have written on its face authorization for emergency dispensing. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven-day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Department of Health if the prescribing practitioner fails to deliver a written prescription to him/her; failure of the pharmacist to do so shall void the authority conferred by this section to dispense without a written prescription of a prescribing practitioner.

(2) Definition of Emergency Situation. For the purpose of authorizing an oral prescription of a controlled substance listed in Schedule II of the controlled substances law (sections 195.010-195.320, RSMo), the term emergency situation means those situations in which the prescribing practitioner determines that—

(A) Immediate administration of a controlled substance is necessary for proper treatment of the intended ultimate user;

(B) No appropriate alternative treatment is



available, including administration of a drug which is not a controlled substance under Schedule II;

(C) It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.072 Dispensing of Schedule V Substances

PURPOSE: This rule provides for the prescribing, administering and dispensing of Schedule V drugs.

(1) A pharmacist may dispense directly a controlled substance listed in Schedule V pursuant to a prescription. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing individual practitioner. If this authorization is not given, the prescription may not be refilled. A pharmacist dispensing those substances pursuant to a prescription shall label the substance and file the prescription.

(2) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule V in the course of his/her professional practice without a prescription.

(3) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule V only pursuant to a written prescription signed by the prescribing individual practitioner or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required except for the signature of the prescribing individual practitioner) or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.074 Dispensing Without a Prescription

PURPOSE: This rule provides for dispensing Schedule V controlled substances without a prescription in certain situations.

(1) Definitions. For the purposes of this rule, the following terms shall apply:

(A) "Dispenser" means a pharmacist, intern pharmacist, or registered pharmacy technician who sells, dispenses, or otherwise provides methamphetamine precursor products to purchasers.

(B) "Methamphetamine precursor products" means both Schedule V pseudoephedrine products and any other drug product containing any detectable amount of ephedrine, pseudoephedrine, or phenylpropanolamine, including the salts or optical isomers or salts of optical isomers or ephedrine, its salts or optical isomers, or salts of optical isomers of ephedrine, pseudoephedrine, or phenylpropanolamine.

(C) "Valid photo identification" means a photo identification that is issued by a state or the federal government or a document that, with respect to identification, is considered acceptable and showing the date of birth of the person, including forms of identification acceptable under federal regulations 8 CFR 274a.2(b)(1)(v)(A) and (B).

(2) Dispensing Without a Prescription. A controlled substance listed in Schedule V which is not a prescription drug under the federal Food, Drug and Cosmetic Act, and is not a methamphetamine precursor product, may be dispensed by a pharmacist without a prescription to a purchaser at retail; provided, that—

(A) Dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his/her professional and legal responsibilities, the actual cash transaction, credit transaction, or delivery may be completed by a non-pharmacist); and

(B) Dispensing, sale, distribution, or otherwise providing is limited to not more than two hundred forty cubic centimeters (240 cc) or eight ounces (8 oz.) of any controlled substance containing opium, nor more than one hundred twenty cubic centimeters (120 cc) or four ounces (4 oz.) of any other controlled substance, nor more than forty-eight (48) dosage units of any controlled substance containing opium, nor more than twenty-four (24) dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given forty-eight (48)-hour period.

(3) Methamphetamine precursor products

may be sold, dispensed, distributed, or otherwise provided only as follows:

(A) Products that are designated Schedule V controlled substances which contain any detectable amount of pseudoephedrine, ephedrine, phenylpropanolamine, their salts or optical isomers, or salts of their optical isomers may be sold, distributed, or otherwise provided only by a pharmacist or pharmacy ancillary personnel as authorized by the Missouri State Board of Pharmacy;

(B) Dispensers of methamphetamine precursor products shall exercise reasonable care in assuring that the purchaser has not exceeded the three and six-tenths (3.6)-gram limit per day or the nine (9)-gram limit per thirty (30)-day period;

(C) Dispensers shall utilize the real-time electronic pseudoephedrine tracking system established and maintained by the Missouri Department of Health and Senior Services (DHSS);

(D) Methamphetamine precursor products regulated by Missouri law as controlled substances shall only be sold to customers eighteen (18) years of age or older who present a valid photo identification;

(E) Any dispenser who sells, dispenses, or otherwise provides any methamphetamine precursor product shall submit the following information to the DHSS electronic database at the time of purchase:

1. Date and time of transaction;
2. Pharmacy identification information, including:
 - A. National Council for Prescription Drug Programs identification number; or
 - B. National Association of Boards of Pharmacy identification number; or
 - C. Vendor assigned site and/or pharmacy identifier;
3. Purchaser information, including the following fields:
 - A. Purchaser's given or first name;
 - B. Purchaser's middle name (if any);
 - C. Purchaser's surname or last name;
 - D. The purchaser's full name shall be entered into the database without the use of initials or nicknames;
 - E. Purchaser's date of birth; and
 - F. Purchaser's address, including number, street, city, state, and zip code;
4. Identification of the form of valid photo identification presented by the purchaser; including issuing agency of the photo identification and identification number appearing on the photo identification;
5. Purchaser's signature;
6. Dispenser identification, including:
 - A. The name of the individual performing the transaction; or



B. The initials of the individual performing the transaction;

7. Transaction number, assigned by the database provider/vendor;

8. Purchase transaction information, including the following:

A. Product Universal Product Code (UPC);

B. Product National Drug Code (NDC) (optional);

C. Unique product description; and

D. Purchase quantity, in grams as—

(I) Product grams per box and number of boxes in transaction;

(II) Product grams per dosage form such as tablet, capsule, or milliliter, and number of dosages per transaction; or

(III) Other mechanism identified by the database provider/vendor; and

9. Form of pseudoephedrine in a manner defined by the database provider/vendor, including but not limited to:

A. Tablet;

B. Capsule;

C. Liquid-filled gelcap; or

D. Liquid;

(F) Purchaser information provided and entered into the DHSS electronic database shall be the same as that on the presented identification. Full names shall be used and not merely initials or a nickname;

(G) If the DHSS electronic database is not available at the time of the sale of the methamphetamine precursor product, the information to be provided in subsection (3)(E) above shall be recorded manually and entered into the DHSS electronic database as soon as practicable after the system is back online, as specified in subsection (3)(I). Signatures shall be captured on paper and then may be scanned to the database;

(H) Every dispenser who sells, dispenses or otherwise provides any methamphetamine precursor product shall maintain a bound logbook in addition to the electronic database system. The logbook shall be used for documenting a clear audit trail of any alterations, changes, or deletions to the original transaction record, and sales that occurred during system failures, including date and time of entry into the database, justification, and resultant contacts with law enforcement because the override button was used;

(I) In the event that the DHSS electronic database is unavailable for five (5) minutes or more due to a failure on the DHSS network or because of a failure attributable to systems other than the DHSS, the dispenser may continue with the transaction until the system is available. All information required to be captured with each transaction shall be retained and documented. The information may be

entered into the database where it may be held pending until the system comes back on line, or all of the required information for transactions occurring during the time the DHSS electronic database is unavailable must be recorded manually and entered into the DHSS electronic database by the registrant as soon as is practicable, but within no more than forty-eight (48) hours following the resumption of operability. Documentation shall also identify the reason for the late entry into the DHSS electronic database;

(J) At least once each month, the pharmacist-in-charge shall review the logbook of changes and the changes captured by the database to see what changes and alterations pharmacy employees have entered regarding sales of methamphetamine precursors. The date and time that the pharmacist-in-charge conducts this monthly review shall be documented in the bound logbook maintained by the pharmacy in addition to the electronic system;

(K) Documentation in the bound logbook shall be maintained in a readily retrievable manner for two (2) years from the date of the transaction and available for inspection and copying by authorized DHSS employees and law enforcement;

(L) Denials of Sales and Dispensings.

1. Except as provided in subsection (D) of this section, if an individual attempts to purchase a methamphetamine precursor product in violation of the three and six-tenths (3.6) gram per day or nine (9) gram per month quantity restrictions or age restriction established by sections 195.017 and 195.417, RSMo, the dispenser shall refuse to make the sale. The purchaser must be at least eighteen (18) years of age.

2. Sales of methamphetamine precursor products shall be denied to purchasers who are not able to produce a valid government issued identification card with the required information displayed on it.

3. In the event that the dispenser perceives that refusal of the purchase may place him or her in imminent physical harm, then the dispenser may use the database safety override function to proceed with the transaction, provided that—

A. When jeopardy is no longer perceived, the dispenser shall immediately contact local law enforcement to report the purchase; and

B. The dispenser shall document in their manual log, the circumstance, the individual contacted at the local law enforcement agency, and the date and time of that contact;

(M) Pharmacy Employees. Employees in a pharmacy shall be assigned individual personal passwords to identify their own trans-

actions in the database.

1. Pharmacy employees shall only use their own passwords for their own transactions and shall not dispense or make a sale under the password of another person.

2. The database computer shall not be left on and unattended so that another person can use the previous user's password. Users shall close out their personal access when their activities are completed.

3. The pharmacist-in-charge shall be responsible for insuring pharmacy employees have adequate password privileges. The pharmacist-in-charge shall insure that new employees have their own personal passwords and also insure that ex-employees have their passwords removed from the system;

(N) Access to Database by Law Enforcement and Regulatory Agencies.

1. Access to the database and controlled substance records shall be made available to those agencies with authority under Chapter 195 and Chapter 338, RSMo.

2. Law enforcement agencies and regulatory agencies shall only have the ability to read and review and shall not be able to enter data or change records.

3. It shall be the responsibility of each agency's administrator, chief, sheriff, or other chief executive officer to insure—

A. Only authorized employees have access to the database;

B. Employees only use their own passwords and passwords are not shared;

C. Each employee adheres to all state and federal laws regarding confidentiality; and

D. As employees change, that new passwords are assigned to new employees and passwords of ex-employees or transferred employees are removed. The chief, sheriff, or chief executive officer of the law enforcement or regulatory agency shall notify the DHSS in writing when an employee's access is to be added or removed; and

(O) Method for Enforcement Agencies to Gain or Alter Access to the Database.

1. Requests submitted to the DHSS to add or remove an employee from access to the database shall—

A. Be submitted in writing on the agency's letterhead;

B. State whether this is a request for an employee to be granted access to the database or a request to remove an employee's access;

C. Provide the employee's full name and title;

D. Provide the employee's Missouri POST certification number if the employee is a sworn law enforcement officer; and

E. Be signed by the chief, sheriff, or



chief executive officer of the requesting agency.

2. Multiple requests for multiple employees and actions may be submitted on one (1) letter.

3. The DHSS shall notify the provider of the database in writing of persons who are given access or have access removed.

4. The DHSS may restrict access to the database to a limited number of people in each agency, depending on the size of the agency, their locations, and number of sworn officers engaged in the actual enforcement of controlled substance laws.

AUTHORITY: sections 195.017 and 195.417, RSMo Supp. 2010 and sections 195.030, 195.050, and 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Aug. 18, 2005, effective Aug. 28, 2005, expired Feb. 23, 2006. Amended: Filed Sept. 1, 2005, effective Feb. 28, 2006. Emergency amendment filed July 9, 2010, effective Sept. 28, 2010, expired March 26, 2011. Amended: Filed June 29, 2010, effective Jan. 30, 2011.*

**Original authority: 195.017, RSMo 1971, amended 1987, 1989, 1994, 1996, 1997, 1998, 2001, 2005, 2006, 2008; 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999; 195.050, RSMo 1939, amended 1971, 1989; 195.195, RSMo 1957, amended 1971, 1989, 1993; and 195.417, RSMo 2001, amended 2003, 2005, 2008.*

19 CSR 30-1.076 Emergency Distribution by a Pharmacy

PURPOSE: This rule provides for dispensing of controlled substances by a pharmacy in emergency situations.

(1) An emergency means a situation where a quantity of a controlled substance must be dispensed by a pharmacy to a patient who does not have an alternative source for that substance reasonably available to him/her and the pharmacy cannot obtain that substance through its normal distribution channels within the time required to meet the immediate needs of the patient for that substance. In the event of an emergency, a pharmacy may distribute (without being registered as a distributor) a controlled substance in Schedule III, IV or V to a second pharmacy in order for that pharmacy to dispense the substance; provided, that—

(A) The amount distributed does not exceed the amount required by the second pharmacy for his/her immediate dispensing;

(B) The distribution is recorded as being dispensed by the first pharmacy and the second pharmacy records the substance as being received. Each pharmacy will retain a signed

receipt of the distribution;

(C) The second pharmacy is registered to dispense the controlled substance to be distributed to him/her;

(D) If the substance is a Schedule II controlled substance, the official order form designated by the federal Drug Enforcement Administration must be used to document the transfer.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.078 Disposing of Unwanted Controlled Substances

PURPOSE: This rule establishes procedures for disposing of unwanted controlled substances.

(1) A registrant in possession of any controlled substance(s) and desiring or required to dispose of such substance(s) shall:

(A) Return the controlled substances to the original supplier;

(B) Transfer the controlled substances to a distributor authorized to accept controlled substances for the purpose of disposal;

(C) Submit a DEA Form 41 to the federal Drug Enforcement Administration requesting authorization to dispose of the controlled substances in compliance with federal regulations;

(D) Contact the Bureau of Narcotics and Dangerous Drugs (BNDD), Department of Health for information pertaining to subsections (1)(A), (B) or (C).

(2) The return, transfer or disposal of any controlled substance shall be documented in accordance with 19 CSR 30-1.044.

(3) In the event the registrant is a hospital, the following procedures are to be used for the destruction of controlled substances:

(A) When disposal of controlled substances is in patient care areas—

1. Controlled substances which are contaminated by patient body fluids are to be destroyed by a physician, nurse or a pharmacist in the presence of another hospital employee;

2. An excess volume of a controlled substance which must be discarded from a dosage unit just prior to use shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee;

3. The remaining contents of opened

glass ampules of controlled substances shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee;

4. Single units of single dose packages of controlled substances which are contaminated other than by patient body fluids and are not an infectious hazard, or have been removed from their original or security packaging, or are partially used, or are otherwise rendered unsuitable for patient use shall be destroyed by a nurse, pharmacist or physician in the presence of another hospital employee or returned to the pharmacy for destruction;

5. The following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction and the patient's name and room number. The nurse, pharmacist or physician and the witnessing hospital employee shall sign the entry. The drug shall be destroyed so that it is beyond reclamation. The controlled substance administration or destruction records are to be retained for two years and available for inspection by Department of Health investigators;

6. All other controlled substances which are not patient contaminated but which are to be disposed of shall be returned to the pharmacy for disposal;

(B) When disposal of controlled substances is in the pharmacy—

1. Single units of controlled substances which are contaminated other than by patient body fluids and are not an infectious hazard, or have been removed from their original or security packaging, or are partially used, or are otherwise rendered unsuitable for patient use shall be destroyed by a pharmacist in the presence of another hospital employee or held for later destruction;

2. All other controlled substances which are not patient contaminated but are to be disposed of shall be placed in a suitable container for storage and disposed of as described in section (1) of this rule.

(4) If the registrant administers controlled substances and is not a hospital, the following procedures are to be used for the destruction of controlled substances:

(A) Controlled substances which are contaminated by patient body fluids are to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;

(B) An excess volume of a controlled substance which must be discarded from a



dosage unit just prior to use is to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;

(C) The remaining contents of opened glass ampules of controlled substances which are not patient contaminated are to be destroyed, in the presence of another employee, by the registrant or designee authorized to administer;

(D) When the controlled substance is destroyed by the registrant or designee authorized to administer, the following shall be entered in the controlled substances administration records or a separate controlled substances destruction record: the date and amount destroyed, the reason for destruction and the registrant's name and address. The registrant or designee doing the destruction and the witnessing employee shall sign the entry. The drug shall be destroyed so that it is beyond reclamation. The controlled substances administration or destruction records are to be retained for two years and available for inspection by Department of Health investigators;

(E) All other controlled substances which are not patient-contaminated but are to be disposed of shall be placed in a suitable container for storage and disposed of as described in section (1) of this rule.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*