DEPARTMENT OF COMMUNITY HEALTH

DIRECTOR'S OFFICE

PHARMACY - CONTROLLED SUBSTANCES

(By authority conferred on the director of the department of community health by sections 16145(3) and 7301 of 1978 PA 368 MCL 333.16145(3) and 333.7301 et seq. and Executive Reorganization Order Numbers 1996-1, 1996-2 and 2003-1, MCL 330.3101, 445.2001 and 445.2011)

PART 1. GENERAL PROVISIONS

R 338.3101 Definitions; A to H.

Rule 1. As used in these rules:

(a) "Act" means 1978 PA 368, MCL 333.1101 et seq.

(b) "Deleterious drug" means a drug, other than a proprietary medicine, that is likely to be destructive to adult human life in quantities of 3.88 grams or less.

(c) "Department" means the department of community health.

(d) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. An electronic signature also is a unique identifier protected by appropriate security measures such that it is only available for use by the intended individual and ensures nonrepudiation so that the signature may not be rejected based on its validity.

History: 1979 AC; 1992 AACS; 2002 AACS; 2004 AACS.

R 338.3102 Definitions; I to P.

Rule 2. (1) As used in these rules:

(a) "Inventory" means all stocks in finished form of a controlled substance that is manufactured or otherwise acquired by a licensee, whether in bulk or commercial containers or contained in pharmaceutical preparations in the possession of the licensee.

(b) "Licensee" means a person who is licensed pursuant to section 7303 of the act.

(c) "Michigan automated prescription system (maps) claim form" means a form, to be determined by the department, that is in the format and includes the information as specified by the american society for automation in pharmacy (asap) and contains the information specified in R 338.3162b.

(d) "National drug code number (ndc)" means a number that identifies the labeler/vendor, product, and package size and is assigned to each drug product listed under section 510, registration of producers of drugs and devices, of the federal food, drug, and cosmetic act.

(e) "Officer" means a state, county, or local law enforcement officer who has a duty to enforce the laws of this state.

(f) "Patient identifier" includes all of the following information about a patient:

(i) Full name.

(ii) Address, including zip code.

(iii) Date of birth.

(iv) Any 1 of the following:

(A) A Michigan driver's license number.

(B) An identification number obtained from a photo identification card issued by the state of Michigan.

(C) The number zero. Zeroes shall be entered as the identification number, if the positive identification presented by the patient or the patient's agent or caregiver does not include a license number or an identification number, as listed in subparagraphs (A) and (B) of this paragraph.

(g) "Positive identification" means identification that includes a photograph of an individual in addition to his or her date of birth. Positive identification shall include an identification card issued by a governmental agency, provided the identification card meets the requirements of this rule.

(2) As used in part 5 of these rules:

(a) "Medical institution" means an inpatient health facility which is licensed or approved by the state and which directly or indirectly provides or includes pharmacy services.

(b) "Pharmacy services" means the direct and indirect patient care services associated with the practice of pharmacy.

History: 1979 AC; 1980 AACS; 1992 AACS; 2002 AACS; 2003 AACS; 2004 AACS;2007 AACS.

R 338.3104 Definitions; R, S.

Rule 4. As used in these rules:

(a) "Readily retrievable" means a record which is kept in such a manner that it can be separated from all other records within 48 hours and in which a listed controlled substance shall be marked with an asterisk, redlined, or in some other manner be visually identifiable apart from the other substances listed in the record.

(b) "Scientific investigator" means a person, other than a physician, who is licensed to conduct research with a controlled substance listed in schedules 1 to 5.

(c) "Sign" means to affix a signature manually in the same manner as signing a check or legal document or to use an electronic signature, as defined in subdivision (d) of R 338. 3101. Stamped signatures are not valid for any controlled substance prescription.

(d) "Substance" means a controlled substance unless the context indicates otherwise.

History: 1979 AC; 1992 AACS; 2003 AACS.

R 338.3108 Terms defined in act.

Rule 8. Terms defined in the act have the same meanings when used in these rules.

History: 1992 AACS.

R 338.3109 Rescission.

Rule 9. Rules 14, 21, and 22 of the board, being R 338.484, R 338.491 and R 338.492 of the Michigan Administrative Code and appearing on pages 2880 and 2885 of the 1963 Annual Supplement of the Code, are rescinded.

History: 1979 AC.

PART 2. SCHEDULES

R 338.3111 Schedule 1; opiates.

Rule 11. Unless specifically excepted, the following opiates including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, when the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, are included in schedule 1:

(a) Acetyl-alpha-methylfentanyl.

(b) Acetylmethadol.

(c) Allylprodine.

(d) Alphacetylmethadol, except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM.

(e) Alphameprodine.

(f) Alphamethadol.

(g) Alpha-methylfentanyl.
(h) Alpha-methylthiofentanyl.
(i) Benzethidine.
(j) Betacetylmethadol.
(k) Beta-hydroxyfentanyl.
(l) Beta-hydroxy-3-methylfentanyl.
(m) Betameprodine.
(n) Betamethadol.
(o) Betaprodine.
(p) Clonitazene.
(q) Dextromoramide.
(r) Diampromide.
(s) Diethylthiambutene.
(t) Difenoxin.
(u) Dimenoxadol.
(v) Dimepheptanol.
(w) Dimethylthiambutene.
(x) Dioxaphetyl butyrate.
(y) Dipipanone.
(z) Ethylmethylthiambutene.
(aa) Etonitazene.
(bb) Etoxeridine.
(cc) Furethidine.
(dd) Hydroxypethidine.
(ee) Ketobemidone.
(ff) Levomoramide.
(gg) Levophenacylmorphan.
(hh) MPPP(1-methyl-4-phenyl-4-propionoxypiperidine).
(ii) 3-methylfentanyl(n-(3-methyl-1-2-phenylethyl)-4- piperidyl)-n-phenylpropanamide).
(jj) 3-Methylthiofentanyl.
(kk) Morpheridine.
(ll) Noracymethadol.
(mm) Norlevorphanol.
(nn) Normethadone.
(oo) Noripipanone.
(pp) Para-fluorofentanyl.
(qq) PEPAP(1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine.
(rr) Phenadoxone.
(ss) Phenampromide.
(tt) Phenomorphan.
(uu) Phenoperidine.
(vv) Piritramide.
(ww) Proheptazine.
(xx) Properidine.
(yy) Propiram.
(zz) Racemoramide.
(aaa) Thiofentanyl.
(bbb) Tilidine.
(ccc) Trimeperidine.

History: 1979 AC; 1982 AACS; 1985 AACS; 1986 AACS; 1988 AACS; 1995 AACS.

R 338.3112 Schedule 1; opium derivatives.

Rule 12. Unless specifically excepted the following opium derivatives, their salts, isomers and salts of isomers, when the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation, are included in schedule 1:

Acetorphine
Acetyldihydrocodeine
Benzylmorphine
Codeine methylbromide
Codeine-N-Oxide
Cyprenorphine
Desomorphine
Dihydromorphine
Drotebanol
Etorphine (except hydrochloride salts)
Heroin
Hydromorphinol
Methyldesorphine
Methyldihydromorphine
Morphine methylbromide
Morphine methylsulfonate
Morphine-N-Oxide
Myrophine
Nicocodeine
Nicomorphine
Normorphine
Pholcodine
Thebacon

History: 1979 AC.

R 338.3113 Schedule 1; hallucinogenic substances.

Rule 13. Unless specifically excepted, 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 when the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, is included in schedule 1:

(a) Alpha-ethyltryptamine.
Some trade or other names:
(i) etryptamine.
(ii)monase.
(iii)a-ethyl- 1h-indole-3-ethanamine.
(iv)3-(2-aminobutyl) indole.
(v) a-et.
(vi) AET.
(b) 4-bromo-2,5-dimethoxyamphetamine Some trade or other names:
(i) 4-bromo-2,5 dimethoxy-alpha-methylphenethylamine.
(ii) 4-bromo-2,5-DMA.
(c) 2,5-dimethoxyamphetamine.
Some trade or other names:
(i) 2,5-dimethoxy-alpha-methylphenethylamine.
(ii) 2,5-DMA.
(d) 4-bromo-2,5-dimethoxphenethylamine.
Some trade or other names:
(i) 2-(4-bromo-2-5-dimethoxyphenyl)-1-aminoethae.
(ii) desmethyl DOB.
(iii) 2c-b, nexus.
(e) 2,5-dimethoxy-4-ethylamphetamine.

A trade or other name:
DOET.
(f) 4-methoxyamphetamine.
Some trade or other names:
(i) 4-methoxy-alpha-methylphenethylamine.
(ii) paramethoxyamphetamine.
(iii) PMA.
(g) 5-methoxy-3,4-methylenedioxyamphetamine.
(h) 4-methyl-2,5-dimethoxyamphetamine.
Some trade or other names:
(i) 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine.
(ii) DOM.
(iii) STP.
(i) 3,4-methylenedioxyamphetamine.
(j) 3,4-methylenedioxymethamphetamine(MDMA).
(k) 3,4-methylenedioxy-n-ethylamphetamine.
(l) N-hydroxy-3,4-methylenedioxyamphetamine.
(m) 3,4,5-trimethoxyamphetamine.
(n) Bufotenine.
Some trade or other names:
(i) 3-(beta-dimethylaminoethyl)-5-hydroxyindole.
(ii) 3-(2-dimethylaminoethyl)-5-indolol.
(iii) N,N-dimethyserotonin.
(iv) 5-hydroxy-N-N-dimethyltryptamine mappine.
(o) Diethyltryptamine.
Some trade or other names:
(i) N,N-Diethyltryptamine.
(ii) DET.
(p) Dimethyltryptamine.
A trade or other name:
DMT.
(q) Ibogaine.
Some trade or other names:
(i) 7-Ethyl-6,6beta,7,8,9,10,12,13-octahydro-2-methoxy-6, 9-methano-5H-pyrido.
(ii) [1',2':1,2]azepino[5,4-b] indole.
(iii) tabernanthe iboga.
(r) Lysergic acid diethylamide.
(s) Marihuana.
(t) Mescaline.
(u) Parahexyl.
Some trade or other names:
(i) 3-hexyl-l-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-
6H-dibenzo[b,d]pyran.
(ii) synhexyl.
(v) Peyote.
(w) N-ethyl-3-piperidyl benzilate.
(x) N-methyl-3-piperidyl benzilate.
(y) Psilocybin.
(z) Psilocyn.
(aa) Ethylamine analog of phencyclidine.
Some trade or other names:
(i) n-ethyl-l-phenylcyclohexylamine.
(ii) (l-phenylcyclohexyl) ethylamine.
(iii) n-(l-phenylcyclohexyl)ethylamine.
(iv) cyclohexamine.
(v) PCE.

(bb) Pyrrolidine analog of phencyclidine.
Some trade or other names:
(i) 1-(l-phenylcyclohexyl)-pyrrolidine.
(ii) PCPy.
(iii) PHP.
(cc) Thiophene analog of phencyclidine.
Some trade or other names:
(i) 1-[l-(2-thienyl)-cyclohexyl]-piperidine.
(ii) 2-thienyl-analog of phencyclidine.
(iii) TPCP.
(iv) TCP.
(dd) 1-(l-(2-thienyl)cyclohexyl)pyrrolidine.
Another name:
TCPY.

For the purpose of this rule only, "isomer" includes the optical, position, and geometric isomers.

History: 1979 AC; 1986 AACS; 1988 AACS; 1994 AACS; 2002 AACS.

R 338.3113a Schedule 1; depressants.

Rule 13a. 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 when the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation is included in schedule 1:

(a) Gamma-hydroxbutyric acid.
Some other names:
(i) GHB.
(ii) gamma-hydroxybutyrate.
(iii) 4-hydroxybutyrate.
(iv) 4-hydroxybutanoic acid.
(v) sodium oxybate.
(vi) sodium oxybutyrate.
(b) Mecloqualone.
(c) Methaqualone.

History: 1988 AACS; 2002 AACS.

R 338.3114 Schedule 1; tetrahydrocannabinols.

Rule 14. Synthetic equivalents of the substances contained in the plant or in the resinous extractives of cannabis and synthetic substances, derivatives, and their isomers with similar chemical structure or pharmacological activity, or both, such as the following, are included in schedule 1:

(a)Δ^{1}cis or trans tetrahydrocannabinol and their optical isomers, excluding dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States food and drug administration.

(b)Δ^{6}cis or trans tetrahydrocannabinol and their optical isomers.

(c)$\Delta^{3,4}$cis or trans tetrahydrocannabinol and their optical isomers.Since the nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions, are included.

History: 1979 AC; 1986 AACS.

R 338.3114a Schedule 1; stimulants.

Rule 14a. 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, is included in schedule 1:

(a) Aminorex.

Some other names:

(i) aminoxaphen.

(ii) 2-amino-5-phenyl-2-oxazoline.

(iii) 4,5-dihydro-5-phenly-2-oxazolamine.

(b) Cathinone.

Some trade or other names:

(i) 2-amino-1-phenyl-1-propanone.

(ii) alpha-aminopropiophenone.

(iii) 2-aminopropiophenone.

(iv) norephedrone.

(c) Methcathinone.

Some trade or other names:

(i) 2-methyiamino-l-phenylpropan-1-one.

(ii) CAT.

(iii) Ephedrone.

(d) Fenethylline.

(e) (±)cis-4-methylaminorex([(±)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine).

(f) N-ethylamphetamine.

(g) N,N-dimethylamphetamine.

Some trade or other names:

(i) N,N-alpha-trimethyl-benzeneethanimine.

(ii) N,N-alpha-trimethylphenethylamine.

History: 1988 AACS; 1994 AACS; 2002 AACS.

R 338.3116 Schedule 2; substances of vegetable origin or chemical synthesis.

Rule 16. (1) Unless specifically excepted, the following substances of vegetable origin, or independently derived by means of chemical synthesis or by combination of extraction and chemical synthesis, are included in schedule 2:

(a) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including all of the following:

(i) Raw opium.

(ii) Opium extracts.

(iii) Opium fluid extracts.

(iv) Powdered opium.

(v) Granulated opium.

(vi) Tincture of opium.

(vii) Codeine.

(viii) Ethylmorphine.

(ix) Etorphine hydrochloride.

(x) Hydrocodone.

(xi) Hydromorphone.

(xii) Metopon.

(xiii) Morphine.

(xiv) Oxycodone.
(xv) Oxymorphone.
(xvi) Thebaine.
(b) A salt, compound, derivative, or preparation thereof which is chemically equivalent to or identical with a substance referred to in subdivision (a) of this subrule, except that these substances do not include the isoquinoline alkaloids of opium.
(c) Opium poppy, poppy straw, and concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form, which contains the phenathrine alkaloids of the opium poppy).
(d) Coca leaves, and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation which is chemically equivalent to or identical with any of these substances.
(e) Cocaine; its salts; isomers; whether optical, position, or geometric; and salts of isomers.
(2) Decocainized coca leaves or the extraction of coca leaves, which extractions do not contain cocaine or ecgonine, are specifically excepted from schedule 2.

History: 1979 AC; 1986 AACS; 1994 AACS.

R 338.3117 Schedule 2; opiates.
Rule 17. Unless specifically excepted, the following opiates, including their isomers, esters, and ethers, when the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation, are included in schedule 2:
(a) Alfentanil.
(b) Alphaprodine.
(c) Anileridine.
(d) Benzitramide.
(e) Bulk dextropropoxyphene (nondosage forms).
(f) Carfentanil.
(g) Dihydrocodeine.
(h) Diphenoxylate.
(i) Fentanyl.
(j) Isomethadone.
(k) Levo-alphacetylmethadol.
Some other names:
(i) Levo-alpha-acetylmethadol.
(ii) Levomethadyl Acetate.
(iii) LAAM.
(l) Levomethorphan.
(m) Levorphanol.
(n) Metazocine.
(o) Methadone.
(p) Methadone-Intermediate, 4 cyano-2-dimethylamino-4,4 diphenyl butane.
(q) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid.
(r) Pethidine (meperidine).
(s) Pethidine-Intermediate-A, 4-cyano-1-1 methyl-4-phenylpiperidine.
(t) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(u) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
(v) Phenazocine.
(w) Piminodine.
(x) Racemethorphan.
(y) Racemorphan.
(z) Remifentanil.
(aa) Sufentanil.

History: 1979 AC; 1985 AACS; 1988 AACS; 1995 AACS; 2002 AACS.

R 338.3118 Schedule 2; stimulants.

Rule 18. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances and which has a stimulant effect on the central nervous system is included in schedule 2:

(a) Amphetamine, its salts, optical isomers and salts of its optical isomers.

(b) Methamphetamine, its salts, isomers and salts of its isomers.

(c) Phenmetrazine and its salts.

(d) Methylphenidate and its salts.

History: 1979 AC; 1992 AACS.

R 338.3119 Schedule 2; depressants.

Rule 19. 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, when the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, is included in schedule 2:

(a) Amobarbital.

(b) Glutethimide.

(c) Pentobarbital.

(d) Phencyclidine.

(e) Secobarbital.

(f) Any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital, or any salt thereof in combination with itself, one another, or 1 or more other controlled substances.

History: 1979 AC; 1986 AACS; 1992 AACS.

R 338.3119a Schedule 2; hallucinogenic substances.

Rule 19a. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of nabilone, including its salts, isomers, and salts of isomers when the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation, is included in schedule 2.

History: 1986 AACS; 1994 AACS; 2002 AACS.

R 338.3119b Schedule 2; immediate precursors.

Rule 19b. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains
any quantity of the following substances:

(a) Immediate precursor to amphetamine and methamphetamine:

Phenylacetone

Some trade or other names:

Phenyl-2-propanone;

P2P;

Benzyl methyl ketone;

Methyl benzyl ketone.

(b) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine.

(ii) 1-Piperidinocyclohexanecarbonitrile (PCC).

History: 1994 AACS.

R 338.3120 Schedule 3; stimulants; depressants; nalorphine.

Rule 20. (1) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture, or preparation that 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 the salts of such isomers, when the existence of such salts, isomers. and the salts of isomers is possible within the specific chemical designation, is included in schedule 3:

(a) Benzphetamine.

(b) Chlorphentermine.

(c) Clortermine.

(d) Phendimetrazine.

(2) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers whether optical, position, or geometric, and the salts of such isomers, when the existence of such salts, isomers, and the salts of isomers is possible within the specific chemical designation, is included in schedule 3:Chlorhexadol. Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal food, drug, and cosmetic act of 1938, 21 U.S.C.§301 et seq. Ketamine.

(d) Lysergic acid.

(e) Lysergic acid amide.

(f) Methyprylon.

(g) Pentazocine.

(h) Sulfondiethylmethane.

(i) Sulfonethylmethane.

(j) Sulfonmethane.

(k) Tiletamine-zolazepam.

(3) A compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital, or a salt thereof and 1 or more other active medicinal ingredients that are not listed in a schedule is included in schedule 3.

(4) A suppository dosage form which contains amobarbital, secobarbital, pentobarbital, or a salt of any of these drugs and which is approved by the food and drug administration for marketing only as a suppository is included in schedule 3.

(5) A substance that contains any quantity of a derivative of barbituric acid or any salt thereof is included in schedule 3.

(6) Nalorphine is included in schedule 3.

(7) Buprenorphine is included in schedule 3.

History: 1979 AC; 1982 AACS; 1988 AACS; 1992 AACS; 2002 AACS; 2007 AACS.

R 338.3121 Schedule 3; narcotic drugs.

Rule 21. Unless specifically excepted, any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof is included in schedule 3:

(a) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit when combined with an equal or greater quantity of an isoquinoline alkaloid of opium.

(b) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit, with 1 or more active ingredients in recognized therapeutic amounts.

(c) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters and not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(d) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters and not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients.

(e) Not more than 1.8 grams of dihydrocodeine per 100 milliliters and not more than 90 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Not more than 300 milligrams of ethylmorphine per 100 milliliters and not more than 15 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeuticamounts.

(g) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams and not more than 25 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(h) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams and not more than 2.5 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts, including paregoric.

History: 1979 AC.

R 338.3121a Schedule 3; hallucinogenic substances.

Rule 21a. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States food and drug administration approved drug product and that has a hallucinogenic effect on the nervous system, including its salts, isomers, and salts of isomers when the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation, is included in schedule 3.

History: 2002 AACS.

R 338.3122 Schedule 3; anabolic steroids; exemptions.

Rule 22. (1) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of an anabolic steroid, including its salts, isomers, and salts of isomers if the existence of such salts of isomers is possible within the specific chemical designation, is included in schedule 3. As used in this rule, the term "anabolic steroid" means any of the following drugs or hormonal substances which are chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, and which promote muscle growth:

(a) Boldenone.
(b) 4-chlortestosterone (clostebol).
(c) Dehydrochlormethyltestosterone.
(d) Drostanolone.
(e) Ethylestrenol.
(f) Fluoxymesterone.
(g) Formebolone.
(h) Mesterolone.
(i) Methandriol.
(j) Methandrostenolone (methandienone).
(k) Methenolone.
(l) Methyltestosterone.
(m) Mibolerone.
(n) Nandrolone.
(o) Norethandrolone.
(p) Oxandrolone.
(q) Oxymesterone.
(r) Oxymetholone.
(s) Stanolone (4-dihydrotestosterone).
(t) Stanozolol.
(u) Testolactone.
(v) Testosterone.
(w) Trenbolone.
(x) Any salt, ester, or isomer of a drug or substance described or listed in this subrule, if that salt, ester, or isomer promotes muscle growth.

(2) An anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the United States drug enforcement administration for such administration is specifically excepted from schedule 3.

(3) The following anabolic steroid products are exempted from all schedules of controlled substances:

(a) Esterified estrogens 1.25 milligrams and methyl testosterone 2.5 milligram tablets.

(b) Esterified estrogens 0.625 milligrams and methyl testosterone 1.25 milligram tablets.

(c) Conjugated estrogens 1.25 milligrams and methyl testosterone 10 milligram tablets.

(d) Conjugated estrogens 0.625 milligrams and methyl testosterone 5 milligram tablets.

(e) Testosterone enanthate 90 milligram/milliliter and estradiol valerate 4 milligram/milliliter injection.

(f) Testosterone cypionate 50 milligram/milliliter and estradiol cypionate 2 milligram/milliliter injection.

History: 1992 AACS; 1994 AACS.

R 338.3123 Schedule 4; depressants; drugs affecting the central nervous system: stimulants; exempt chemical preparations for industrial use; exceptions; narcotic drugs.

Rule 23. (1) Unless specifically excepted, a material, compound, mixture, or preparation that contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system, including its salts, isomers, and the salts of isomers when the existence of such salts, isomers, and the salts of isomers is possible within the specific chemical designation, is included in schedule 4:

(a) Alprazolam.

(b) Barbital.

(c) Bromazepam.

(d) Camazepan.

(e) Chloralbetaine.

(f) Chloral hydrate.

(g) Chlordiazepoxide.

(h) Clobazam.

(i) Clonazepam.

(j) Clorazepate.

(k) Clotiazepam.

(l) Cloxazolam.

(m) Dichloralphenazone.

(n) Delorazepam.

(o) Dextropropoxyphene.

(p) Diazepam.

(q) Estazolam.

(r) Eszopiclone.

(s) Ethchlorvynol.

(t) Ethinamate.

(u) Ethyl loflazepate.

(v) Fludiazepam.

(w) Flunitrazepam.

(x) Flurazepam.

(y) Halazepam.

(z) Haloxazolam.

(aa) Ketazolam.

(bb) Loprazolam.

(cc) Lorazepam.

(dd) Lormetazepam.

(ee) Mebutamate.

(ff) Medazepam.

(gg) Meprobamate.

(hh) Methohexital.

(ii) Methylphenobarbital (mephobarbital)

(jj) Midazolam.

(kk) Modafinil.

(ll) Nimetazepam.
(mm) Nitrazepam.
(nn) Nordiazepam.
(oo) Oxazepam.
(pp) Oxazolam.
(qq) Paraldehyde.
(rr) Petrichloral.
(ss) Phenobarbital.
(tt) Pinazepam.
(uu) Prazepam.
(vv) Quazepam.
(ww) Temazepam.
(xx) Tetrazepam.
(yy) Triazolam.
(zz) Zaleplon.
(aaa) Zolpidem.

(2) Unless specifically excepted, a material, compound, mixture, or preparation that contains any quantity of fenfluramine having a potential for abuse associated with an effect on the central nervous system, including its salts, isomers, whether optical, position, or geometric, and the salts of such isomers when the existence of such salts, isomers, and the salts of isomers is possible, is included in schedule 4:

(3) Unless specifically excepted, a material, compound, mixture, or preparation that contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system, including its salts, isomers, whether optical, position, or geometric, and the salts of such isomers when the existence of such salts, isomers, and the salts of isomers is possible within the specific chemical designation, is included in schedule 4: Cathine ((+)-norpseudoephedrine).Dexfenfluramine.
(c) Diethylpropion.
(d) Fencamfamin.
(e) Fenproporex.
(f) Mazindol.
(g) Mefenorex.
(h) Phentermine.
(i) Pemoline, including organometallic complexes and chelates thereof.
(j) Pipradrol.
(k) Sibutramine.
(l) SPA((-)-l-dimethylamino-1,2-diphenylethane).

(4) Unless specifically excepted or unless listed in another schedule, any natural compound, mixture, or prescription which contains butorphanol, including its optical isomers and its salts, is included in schedule 4.

(5) Chloral hydrate is designated as an exempt chemical preparation for industrial use when packaged in a sealed, oxygen free environment under nitrogen pressure and safeguarded against exposure to air.

(6) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture, or preparation containing limited quantities of not more than 1 milligram of difenoxin and not less that 25 micrograms of atropine sulfate per dosage unit or any salts thereof is included in schedule 4.

History: 1979 AACS; 1982 AACS; 1984 AACS; 1985 AACS; 1988 AACS; 1992 AACS;1994 AACS; 2002 AACS; 2007 AACS.

R 338.3125 Schedule 5; narcotics added to nonnarcotic compounds.

Rule 25. (1) Schedule 5 includes the drug pregabalin by whatever official, common, usual, chemical, or brand name designated.

(2) A compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which includes 1 or more nonnarcotic active medicinal ingredients in

sufficient proportion to confer upon the compound, mixture, or preparation a valuable medicinal quality other than that possessed by the narcotic drug alone, is included in schedule 5:

(a) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams, and not more than 10 milligrams per dosage unit.

(b) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams, and nor more than 4 milligrams per dosage unit.

(c) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams, and not more than 5 milligrams per dosage unit.

(d) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams, and nor more than 5 milligrams per dosage unit.

(e) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(f) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(3) Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of either of the following substances which have a stimulate effect on the central nervous system, including its salts,isomers, and salts of isomers, is included in schedule 5:

(a) Propylhexedrine.

(b) Pyrovalerone.

History: 1979 AC; 1985 AACS; 1994 AACS; 2002 AACS; 2007 AACS.

R 338.3126 Schedule 5; ephedrine; exceptions.

Rule 26. (1) Except as otherwise provided in subrule (2) of this rule, ephedrine, a salt of ephedrine, an optical isomer of ephedrine, a salt of an optical isomer of ephedrine, or a compound, mixture, or preparation containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine is included in schedule 5.

(2) The following are not included in schedule 5:

(a) A product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine if the drug product may lawfully be sold over the counter without a prescription under federal law, is labeled and marketed in a manner consistent with the pertinent over the counter tentative final or final monograph, is manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse, and is not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement and if the drug product is 1 of the following:

(i) A solid dosage form, including but not limited to a soft gelatin caplet, that combines as active ingredients not less than 400 milligrams of guaifenesin and not more than 25 milligrams of ephedrine per dose, packaged in blister packs with not more than 2 tablets or caplets per blister.

(ii) An anorectal preparation containing not more than 5% ephedrine.

(b) A food product or a dietary supplement containing ephedrine, if the food product or dietary supplement meets all of the following criteria:

(i) It contains, per dosage unit or serving, not more than the lesser of 25 milligrams of ephedrine alkaloids or the maximum amount of ephedrine alkaloids provided in applicable regulations adopted by the United States food and drug administration and contains no other controlled substance.

(ii) It does not contain hydrochloride or sulfate salts of ephedrine alkaloids.

(iii) It is packaged with a prominent label securely affixed to each package that states all of the following:

(A) The amount in milligrams of ephedrine in a serving or dosage unit.

(B) The amount of the food product or dietary supplement that constitutes a serving or dosage unit.

(C) That the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of 100 milligrams in a 24-hour period or the maximum recommended dosage or period of use provided in applicable regulations adopted by the United States food and drug administration.

(D) That improper use of the product may be hazardous to a person's health.

History: 2002 AACS.

R 338.3127 Exclusions for nonnarcotic substances which are not scheduled.

Rule 27. (1) A nonnarcotic substance which, under the federal food, drug, and cosmetic act of 1938, 21 U.S.C. §301 et seq., may be lawfully dispensed without a prescription is excluded from all schedules pursuant to the provisions of section 7208(2) of the act. A substance which contains 1 or more controlled substances in such a proportion or concentration to vitiate the potential for abuse is an excluded substance.

(2) An excluded substance is a deleterious drug as defined in section 7104(6) of the act and may only be manufactured, distributed, or dispensed by a person who is licensed to manufacture, distribute, or dispense a controlled substance under the act.

History: 1979 AC; 1992 AACS; 2002 AACS.

R 338.3129 Excepted components.

Rule 29. A compound, mixture, or preparation which contains a depressant or stimulant substance, which is of a similar quantitative composition shown in federal regulations as an excepted compound, or which contains a lesser quantity of a controlled substance or other substances which do not have a stimulant, depressant, or hallucinogenic effect, and which is restricted by law to dispensing by prescription is excepted from the provisions of sections 7212, 7214, 7216, 7218, and 7220 of the act. Compliance with the federal law concerning an excepted compound is deemed compliance with this rule.

History: 1979 AC; 1992 AACS.

PART 3. LICENSES

R 338.3131 Rescinded.

History: 1979 AC; 1992 AACS; 1997 AACS.

R 338.3132 Activities requiring separate licenses.

Rule 32. (1) The following activities are deemed to be independent of each other, shall be conducted under separate licenses, and shall comply with all of the requirements and duties prescribed by law for persons who are licensed to engage in such coincidental activities:

(a) Manufacturing and distributing a controlled substance. A person who is licensed to manufacture a controlled substance listed in schedules 2 to 5 may conduct chemical analysis and research with a substance that is listed in the schedules.

(b) Dispensing a controlled substance listed in schedules 2 to 5. A physician who is licensed to prescribe or dispense controlled substances listed in schedules 2 to 5 may conduct research with those substances.

(c) Conducting research and instructional activity with a controlled substance listed in schedule 1 as follows:

(i) A person who is licensed to conduct research with controlled substances listed in schedule 1 may do both of the following:

(A) Manufacture the substances as set forth in the research protocol that is filed and approved by the federal food and drug administration and the drug enforcement administration (DEA) pursuant to the provisions of 21 C.F.R.§1301.18 and submitted with the application for licensure. The Code of Federal Regulations, Title 21, Food and Drugs, part 1301, containing §1301.18 is available free of charge via the Internet at web-site http://www.gpoaccess.gov. Printed copies may be purchased by mail order from the United States Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954, USA, by calling toll free at 1-866-512-1800, or via the Internet at web-site http://bookstore.gpo.gov at a cost of $24.00 as of the time of adoption of

these amendments. Printed copies of 21 C.F.R. §1301.18 also are available for inspection and for distribution to the public at cost at the Department of Community Health, Bureau of Health Professions, Ottawa Building - First Floor, 611 West Ottawa, Lansing, MI 48909.

(B) Distribute the substances to other persons who are licensed or authorized to conduct research or chemical analysis with the schedule 1 substances.

(ii) A licensed physician who is authorized to conduct research with schedule 1 substances under federal law may conduct research with those substances, upon furnishing the administrator with evidence of that federal authorization. A separate license is not required for the research activity.

(d) Conducting research with a controlled substance listed in schedules 2 to 5. A person who is licensed or authorized to conduct research with the controlled substances listed in schedules 2 to 5 may conduct chemical analysis with the substances listed in those schedules, manufacture the substances if, and to the extent that, such manufacture is set forth in a statement filed with the application for licensure, distribute the substances to other persons who are licensed or authorized to conduct research, chemical analysis, or instructional activity with the substances, and conduct instructional activities with the substances.

(e) Conducting instructional activities with a controlled substance listed in schedules 2 to 5.

(f) Prescribing, dispensing, or administering a controlled substance to a drug-dependent person in a drug treatment and rehabilitation program.

(g) Conducting chemical analysis with a controlled substance listed in any schedule. A person who is licensed or authorized to conduct chemical analysis with all controlled substances may manufacture such substances for analytical or instructional purposes, distribute the substances to other persons who are licensed or authorized to conduct chemical analysis, instructional activity or research with the substances, and conduct instructional activities with the substances.

(2) A separate license is required for each principal place of business or professional practice. A principal place of business or a professional practice is the physical location where controlled substances are manufactured, grown, cultivated, processed, or by other means produced or prepared, distributed, stored, or dispensed by a licensee.

(3) If a principal place of business or professional practice consists of multiple locations, then each location shall obtain a separate controlled substance license if controlled substances are received, stored, administered, or dispensed at that location.

(4) A prescriber or practitioner who holds a controlled substance license to prescribe, administer, or dispense controlled substances at a principal place of business or professional practice consisting of multiple locations shall not be required to obtain a separate controlled substance license for each physical location of the principal place of business or professional practice if the prescriber or practitioner only prescribes at the location.

(5) A pharmacist who holds a controlled substance license may dispense from any licensed pharmacy.

(6) A separate controlled substances license is required, as provided in R 338.3154(4), when controlled substances are stored in an automated device and the automated device is not located at the same address as the pharmacy responsible for the device.

History: 1979 AC; 1992 AACS; 2002 AACS; 2004 AACS; 2007 AACS.

R 338.3133 Rescinded.

History: 1979 AC; 1992 AACS; 2002 AACS.

R 338.3134 Rescinded.

History: 1979 AC; 1992 AACS; 2002 AACS.

R 338.3136 Information in applications.

Rule 36. (1) A researcher shall include, in his or her application for licensure, all of the following information:

(a) His or her credentials to conduct the proposed research.
(b) The protocol and description of the nature of the proposed research.
(c) A list of the controlled substances and doses to be used.
(2) A person who conducts instructional activity shall include, with his or her application for licensure, all of the following information:
(a) His or her credentials to conduct the proposed instructional activity.
(b) A course outline for the proposed instructional activity.
(c) A list of the controlled substances and doses to be used.

History: 1979 AC; 1992 AACS; 2002 AACS.

R 338.3137 Waiver of license requirement.
Rule 37. (1) The requirement of licensure is waived for the following persons in the circumstances described in this rule:
(a) An officer or employee of the drug enforcement administration while engaged in the course of official duties.
(b) An officer of the United States customs service while engaged in the course of official duties.
(c) An officer or employee of the United States food and drug administration while engaged in the course of official duties.
(d) A federal officer who is lawfully engaged in the enforcement of a federal law relating to controlled substances, drugs, or customs and who is duly authorized to possess controlled substances in the course of that person's official duties.
(e) An officer or employee of the state of Michigan, or a political subdivision or agency thereof, who is engaged in the enforcement of a state or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of that person's duties.
(2) An official who is exempted from licensure by this rule may, when acting in the course of that person's official duties, possess a controlled substance and may transfer a controlled substance to any other official who is also exempted by this rule and who is acting in the course of that person's official duties.
(3) An official who is exempted by this rule may procure a controlled substance in the course of a criminal investigation involving the person from whom the substance was procured or in the course of an administrative inspection or investigation.

History: 1979 AC; 1992 AACS.

R 338.3138 Animal euthanasia; permit application; records; storage of pentobarbital; facility inspections; facility registration; personnel training; written administration procedures.
Rule 38. (1) A dog pound, class b dealer, or animal shelter licensed or registered by the Michigan department of agriculture pursuant to 1969 PA 287, MCL 287.331 et seq., may apply for a permit to store, handle, and use a commercially prepared, pre-mixed solution of sodium pentobarbital to practice euthanasia on animals.
(2) A dog pound, class b dealer, or animal shelter holding a current registration or license issued by the Michigan department of agriculture shall apply, on a form provided by the administrator, for a permit to store, handle, and use sodium pentobarbital. The application submitted to the administrator shall contain all of the following information:
(a) The name, address, and department of agriculture registration number of the dog pound, class b dealer or animal shelter.
(b) The name, address, and biographical data of the person who is in charge of the day-to-day operation of the dog pound, class b dealer, or animal shelter and who is responsible for the storage and recordkeeping of the sodium pentobarbital.
(c) The name, address, and biographical data of the person responsible for designating employees who will practice euthanasia pursuant to the act.

(d) The name and address of each individual certified to have received a minimum of 8 hours of training in the use of sodium pentobarbital to practice euthanasia, and the name of the veterinarian who trained each individual.

(3) Records of the receipt and dispensation of sodium pentobarbital shall be maintained at the animal shelter or dog pound. These records shall indicate all of the following information:

(a) The date of acquisition.

(b) The quantity acquired.

(c) The trade name.

(d) The lot number and strength of a commercially prepared, pre-mixed solution of sodium pentobarbital.

(e) A complete record of the dispensation of the pre-mixed solution for the purpose of practicing euthanasia, showing the quantity used, time, date, and the name of the administering individual.

(4) Records of receipt shall be kept on drug enforcement administration (DEA) order forms pursuant to 21 C.F.R. part 1305. The Code of Federal Regulations, Title 21, Food and Drugs, part 1305 is available via the Internet at web-site http://www.access.gpo.gov/nara/cfr.Printed copies may be purchased from the United States Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA, 15250-7954, USA, by calling toll free at 1-866-512-1800, or via the Internet at web-site: http://bookstore.gpo.gov at a cost of $20.00 as of the time of adoption of these amendments. Printed copies of 21 C.F.R. part 1305 also are available for inspection and for distribution to the public at cost at the Department of Consumer and Industry Services, Bureau of Health Services, Ottawa Building - First Floor, 611 West Ottawa, Lansing, MI 48909.

(5) Records of dispensation shall be kept pursuant to 21 C.F.R. part 1304. The Code of Federal Regulations, Title 21, Food and Drugs, part 1304 is available via the Internet at web-site http://www.access.gpo.gov/nara/cfr. Printed copies may be purchased from the United States Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA, 15250-7954, USA, by calling toll free at 1-866-512-1800, or via the Internet at web-site: http://bookstore.gpo.gov at a cost of $20.00 as of the time of adoption of these amendments. Printed copies of 21 C.F.R. part 1304 also are available for inspection and distribution to the public at cost at the Department of Consumer and Industry Services, Bureau of Health Services, Ottawa Building - First Floor, 611 West Ottawa, Lansing, MI 48909.

(6) Records shall be kept for a period of 2 years and shall be available for inspection by the department.

(7) The controlled substance covered by this permit shall be a commercially prepared, pre-mixed solution of sodium pentobarbital.

(8) All stocks of the sodium pentobarbital shall be stored in a securely locked, substantially constructed cabinet located in the facility, with access limited to the persons described in subrule (2)(b) and (d) of this rule.

(9) An inspection of the facility may be conducted by the department before issuance of the permit. Unannounced additional inspections may be made from time to time thereafter.

(10) The permit issued by the administrator shall show the name and address of the facility and the name of the person in charge of the day-to-day operation. This permit is not transferable. The administrator shall be notified, in writing, within 10 days of a change in the person in charge of the day-to-day operation.

(11) The facility shall promptly obtain a registration from the United States department of justice, drug enforcement administration, or its successor agency, before stocking, purchasing, and using sodium pentobarbital to practice euthanasia. Purchases shall be made in accordance with procedures established by the drug enforcement agency.

(12) If the dog pound, class b dealer, or animal shelter issued a permit pursuant to section 7333(8) of the act, does not have in its employ an individual trained as described in section 7333(8), then the dog pound, class b dealer, or animal shelter shall immediately notify the administrator and shall securely store, and cease to administer, any commercially-prepared, pre-mixed solution of sodium pentobarbital until the administrator is notified that either of the following has occurred:

(a) An individual trained as described in section 7333(8) of the act has been hired by the facility.

(b) An employee of the facility has been trained as described in section 7333(8) of the act .

(13) The administrator shall be notified of any change in the name

and address of the individual trained as described in section 7333(8) of the act within 10 days of such change.

(14) The list of persons certified to have received training and the veterinarians who trained them shall be updated in writing every 6 months, kept on site and available for inspection.

(15) The dog pound, class b dealer or animal shelter shall establish and maintain written procedures for the administration of a commercially prepared, pre-mixed solution of sodium pentobarbital. These procedures shall be kept on the licensed premises and shall be available for inspection.

History: 1981 AACS; 2002 AACS.

R 338.3139 Animal euthanasia; personnel training.

Rule 39. (1) An employee of a dog pound, class b dealer, or animal shelter who will practice euthanasia on animals shall be able to document completion of a minimum of 8 hours of training given by a licensed veterinarian in the use of sodium pentobarbital.

(2) Training of the individual shall be under the instruction of a doctor of veterinary medicine currently licensed in this state. The training shall include both lecture and self-study instruction and clinical experience. At a minimum, the individual shall demonstrate competency to give inter-cardial, intraperitoneal, and intravenous injections, in addition to making a positive determination of death.

(3) Upon receipt of notification of the individual's successful completion of the minimum 8 hours of training from the licensed veterinarian/instructor, the department shall issue a permit to the dog pound or animal shelter. Proficiency may be shown by completion of a self-assessment program or other evaluation by the board of veterinary medicine. The permit is subject to the provisions of section 7334 of the act.

(4) Continued proficiency and compliance with written procedures, in addition to compliance with all rules and regulations, may be monitored by the administrator or the board of veterinary medicine.

History: 1981 AACS; 2002 AACS.

PART 4. SECURITY

R 338.3141 Thefts and diversions.

Rule 41. (1) An applicant or licensee shall provide effective controls against theft and diversion of controlled substances.

(2) A licensee shall determine that a person is licensed to possess a controlled substance before distributing the substance to the person.

(3) Within 10 days following discovery of a theft or loss of any controlled substance, a licensee shall notify the administrator of the theft or loss by submitting a United States drug enforcement administration theft and loss report form 106, a copy thereof, or equivalent document, whether or not the controlled substance is subsequently recovered or the responsible party is identified and action is taken against the party, and whether or not it is also reported to the DEA.

History: 1979 AC; 1980 AACS; 1992 AACS; 2002 AACS.

R 338.3143 Storage of controlled substances.

Rule 43. (1) A controlled substance that is listed in schedule 1 of R 338.3111 to R 338.3114a shall be stored in a securely locked, substantially constructed cabinet that is anchored to a wall or the floor.

(2) A controlled substance that is listed in schedules 2, 3, 4, and 5 of R 338.3116 to R 338.3126 shall be stored in a securely locked, substantially constructed cabinet, room, or cart. However, in a pharmacy, the controlled substances may be dispersed throughout the stock of noncontrolled substances in a manner to obstruct the theft or diversion of controlled substances.

(3) Parenteral dosage forms which contain amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs and which are required by the federal food, drug, and cosmetic act of 1938, 21 U.S.C.§301 et seq., or by regulations promulgated thereunder, to be kept under refrigeration may be stored in compliance with the schedule III regulations set forth in the provisions of 21 C.F.R. §§1301.71 to 1301.76. The Code of Federal Regulations, Title 21, Food and Drugs, part 1301, containing 21 C.F.R.§§1301.71 to 1301.76, is available via the Internet at web-site http://www.access.gpo.gov/nara/cfr. Printed copies may be purchased from the United States Government Printing Office, Superintendent of Documents, P.O.Box 371954, Pittsburgh, PA 15250-7954, USA, by calling toll free at 1-866-512-1800, or via the Internet web-site: http://bookstore.gpo.gov at the cost of $20.00 as of the time of adoption of these amendments. Printed copies of 21 C.F.R. §§1301.71 to 1301.76 also are available for inspection and for distribution to the public at cost at the Department of Consumer and Industry Services, Bureau of Health Services, Ottawa Building - First Floor, 611 West Ottawa, Lansing, MI 48909.

(4) This rule applies to all licensees.

History: 1979 AC; 1980 AACS; 1992 AACS; 2002 AACS.

R 338.3145 Employees; disqualification.

Rule 45. (1) The following individuals shall not be employed or otherwise utilized, with or without compensation, by a person who is licensed by the administrator pursuant to section 7303, 17711, or 17748 of the act in any manner or capacity that allows the individuals access to controlled substances:

(a) An individual who the licensee knows, or should reasonably know, to be a substance abuser as defined in section 6107 of the act. This subdivision does not apply to a licensee enrolled in the health professional recovery program under a current monitoring agreement.

(b) An individual whose controlled substance license is suspended, revoked, or denied.

(c) An individual whose license issued by this state or another state is under suspension or revoked in this state or another state for a violation that involves controlled substances.

(d) An individual who has been convicted of a crime that involves controlled substances and who is currently under sentence for that conviction.

(2) Delegation pursuant to section 16215 of the act shall not be made by a licensed person to a licensed or unlicensed individual unless the delegation is in compliance with this rule.

History: 1979 AC; 1980 AACS; 1992 AACS; 2002 AACS.

PART 5. RECORDS

R 338.3151 Inventories.

Rule 51. (1) A licensee shall make and maintain a complete and accurate inventory of all stocks of controlled substances.

(2) The inventory shall contain a complete and accurate record of all controlled substances in the possession or control of the licensee on the date the inventory is taken as follows:

(a) If the substance is listed in schedule 1 or 2, then the licensee shall make an exact count or measure of the contents.

(b) If the substance is listed in schedule 3, 4, or 5, then the licensee shall make an estimated count or measure of the contents, but if the container holds more than 1,000 dosage units, such as tablets or capsules, then the licensee shall make an accurate account of the contents.

(3) A licensee shall make a separate inventory for each licensed location on the date that he or she first engages in the activity covered by his or her license. The beginning inventory record for a licensed location shall be kept at the licensed location and a copy shall be forwarded to the administrator upon request.

(4) A licensee shall indicate on the inventory record whether the inventory was taken as of the opening or closing of the day that the inventory is taken.

(5) A licensee shall maintain the inventory in a written, typewritten, or printed form. The inventory taken by use of an oral recording device shall be promptly transcribed.
(6) A licensee shall sign and date the inventory record.
(7) A licensee's printed name, address, and DEA number shall be recorded on the inventory.
(8) Schedule 2 drugs shall be separated on the inventory from all other drugs.

History: 1979 AC; 1982 AACS; 2002 AACS.

R 338.3152 Annual and changed inventories.
Rule 52. (1) Pursuant to the provisions of section 7321 of the act, an inventory shall be taken annually of all stocks of controlled substances in the possession or control of the licensee, in accordance with the requirements of R 338.3151.
(2) On the effective date of a rule by the administrator or DEA adding a controlled substance to a schedule, which substance was not previously listed in any schedule, a licensee who possesses the substance shall take an inventory of all stocks of the substance on hand and incorporate it in the current inventory. Thereafter, the substance shall be included in each inventory taken.

History: 1979 AC; 1992 AACS; 2002 AACS.

R 338.3153 Invoices, acquisition, dispensing, administration, and distribution records.
Rule 53. (1) A licensee shall keep and make available for inspection all records for controlled substances, including invoices and other acquisition records, but excluding sales receipts, however a copy of each receipt shall be retained for 90 days. Acquisition records, except for executed DEA 222 order forms, may be kept at a central location, subject to the approval of the administrator. The approval shall specify the nature of the acquisition records to be kept and the exact location where the acquisition records will be kept. All records shall be readily retrievable within 48 hours.
(2) A licensee shall maintain acquisition records as follows:
(a) Invoices and other acquisition records of all controlled substances listed in schedules 1 and 2 of R 338.3111 to R 338.3119a shall be maintained in a separate file.
(b) Invoices and other acquisition records of all controlled substances listed in schedules 3, 4, and 5 of R 338.3120 to R 338.3126 shall be maintained in a separate file or in such form so that the information required is readily retrievable from the ordinary acquisition records maintained by the dispenser.
(3) A licensee shall initial the invoice and indicate the date that the controlled substances are received.
(4) A licensee shall keep a record of all controlled substances dispensed by him or her.
(5) A prescriber shall keep a record separate from the patient chart which contains all of the following information for controlled substances dispensed or administered by the prescriber:
(a) Name of patient.
(b) Name of substance and strength.
(c) Quantity of substance.
(d) Date dispensed or administered.
(e) Name of individual who dispensed or administered.
(6) Except in medical institutions, patients' original prescriptions shall be sequentially numbered and maintained in chronological order as follows:
(a) A separate file shall be maintained for dispensed substances listed in schedule 2 of R 338.3116 to R 338.3119a.
(b) A separate file shall be maintained for dispensed substances listed in schedules 3, 4, and 5 of R 338.3120 to R 338.3126.
(7) Records of controlled substances distributed to another licensee, shall include all of the following information and be maintained in the appropriate file described in subrule (2) of this rule or in a separate record that is available for inspection:
(a) Name, address, and dea number of receiver.

(b) Name, address, and dea number of supplier.
(c) Name and quantity of controlled substances distributed.
(d) Date distributed.
A DEA 222 order form shall be used for schedule 2 drugs.
(8) Complete controlled substances records shall be maintained or controlled by the licensee for 2 years, except for controlled substance prescriptions, which shall be maintained for 5 years from the last date of dispensing.

History: 1979 AC; 1980 AACS; 1992 AACS; 2002 AACS.

R 338.3153a Medication orders for patients in medical institutions.
Rule 53a. (1) Prescriptions for controlled substance medications to be dispensed for administration to an inpatient in a medical institution shall contain all of the following information:
(a) The patient's name.
(b) The prescriber's name, address, and drug enforcement administration (DEA) number. In place of including the address and DEA number on each medication order, the pharmacy may maintain a separate list of authorized prescribers. The list shall contain the prescriber's name, address, and DEA number.
(c) The prescriber's signature.
(d) The name, dose, and frequency of administration of the medication.
(e) The date of the medication order.
(2) If alternative therapy has been evaluated and the immediate administration of a controlled substance, including a schedule 2 medication, is necessary for the proper treatment of a patient, then a pharmacist may dispense the controlled substance for administration to the inpatient if all of the following conditions are satisfied:
(a) The oral order of the prescriber is committed to a written or electronic order in the patient chart by a nurse licensed under part 172 of the act, a physician's assistant licensed under part 170 or 175 of the act, or a pharmacist licensed under part 177 of the act who has communicated directly with the prescriber.
(b) The order states the name of the prescriber and the name of the nurse, physician's assistant, or pharmacist who received the verbal order.
(c) The order is forwarded to the pharmacy.
(d) The prescriber signs the original order at the time of next visit or within 7 days.
(3) Original orders shall be preserved for a period of 5 years from the date of patient discharge and shall be readily retrievable for any specific time period. If patient records are kept electronically, then a printed copy shall be immediately available for a current inpatient and within 48 hours upon request of an authorized agent of the board for any patient of the previous 5 years.

History: 1980 AACS; 1992 AACS; 2002 AACS.

R 338.3154 Medication records in medical institutions.
Rule 54. (1) A patient's chart shall constitute a record of medications ordered for, and actually administered to, a patient of medical institutions.
(2) Medication records are required for all controlled substances listed in schedules 2, 3, 4, and 5 of R 338.3116 to R 338.3125. At a minimum, these records shall include all of the following information:
(a) The number of doses of controlled substances purchased.
(b) The number of doses dispensed to individual patients or distributed to nursing stations or both.
(c) The number of doses administered.
(d) The number of doses dispensed, but not administered, to the patient.
(e) An annual physical inventory and status of any discrepancies between the inventory and the records of acquisition and the dispensing records.
(3) If the controlled substance is not dispensed to an individual patient, all of the following provisions shall be complied with:

(a) Medication records for those controlled substances in schedules 2, 3, 4, and 5 of R 338.3116 to R 338.3125 shall be maintained.

(b) Distribution of a controlled substance to a nursing unit shall not be more than 25 doses per container.

(c) A distribution record for each multiple of 25 doses shall be used to account for delivery to a nursing unit. The record shall include all of the following information:

(i) The name and dose of the controlled substance.

(ii) The quantity of the substance.

(iii) The date of delivery.

(iv) The location of the nursing unit.

(v) The name of the distributing pharmacy and address if a different location from the medical institution.

(vi) Name of distributing pharmacist.

(vii) The name of the individual on the nursing unit who receives the substance.

(d) A proof of use record shall be maintained to account for all doses of an administered substance. The record shall include all of the following:

(i) The name of the substance.

(ii) The dose administered.

(iii) The date and time a dose was administered.

(iv) The name of the patient.

(v) The signature of the individual who administered the dose.

(e) Subrule 3 of this rule does not apply to automated dispensing devices.

(4) If a controlled substance or any medication or device is dispensed from an automated device, then documentation as to the type of equipment,
serial numbers, content, policies, procedures, and location within the facility shall be maintained on-site in the pharmacy for review by the department. When patient medication is stocked in an automated device, the pharmacy responsible for the device shall obtain an additional controlled substance license for each hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility as defined in 1978 PA 368, MCL 333.20109, when the pharmacy is not located at the same address as the facility and controlled substances are dispensed from the automated device. The documentation shall include at least all of the following information:

(a) Name and address of the pharmacy or facility responsible for the operation of the automated device. Manufacturer name and model number.

(c) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.

(d) Policy and procedure for system operation that includes all of the following:

(i) Safety.

(ii) Security.

(iii) Accuracy.

(iv) Patient confidentiality.

(v) Access.

(vi) Controlled substances.

(vii) Data retention or archival.

(viii) Definitions.

(ix) Downtime procedures.

(x) Emergency procedures.

(xi) Inspection.

(xii) Installation requirements.

(xiii) Maintenance.

(xiv) Medication security.

(xv) Quality assurance.

(xvi) Medication inventory.

(xvii) Staff education and training.

(xviii) System set-up and malfunction.

(xix) List of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.

(5) Automated devices shall have adequate security systems and procedures, evidenced by written pharmacy policies and procedures that
document all of the following information: Prevention of unauthorized access or use. Compliance with any applicable federal and state regulations. Maintenance of patient confidentiality.

(6) Records and electronic data kept by automated devices shall meet all
of the following requirements:

(a) All events involving access to the contents of the automated devices shall be recorded electronically.

(b) Records shall be maintained by the pharmacy responsible for the device and shall be readily retrievable. The records shall include all of the following information:

(i) The unique identity of device accessed.

(ii) Identification of the individual accessing the device.

(iii) The type of transaction.

(iv) The name, strength, dosage form and quantity of the drug accessed.

(v) The name of the patient for whom the drug was ordered.

(vi) Identification of the pharmacist checking for the accuracy of the medications to be stocked or restocked in the device.

(vii) If the pharmacist delegates the stocking of the device, then technologies shall be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing a board-approved error prevention technology that is in compliance with R 338.490. This subdivision takes effect April 11, 2003.

(viii) Additional information as the pharmacist may deem necessary.

(7) For medication removed from the system for on-site patient administration, the system shall document all of the following information:

(a) The name of the patient.

(b) The date and time medication was removed from the device.

(c) The name, initials, or other unique identifier of the person removing the drug.

(d) The name, strength, and dosage form of the drug. The documentation may be on paper or electronic medium.

(8) The automated device shall provide a mechanism for securing and accounting for medications once removed from and subsequently returned to, the automated device return bin. Neither medication nor a device may be returned directly to the system for immediate reissue or reuse. Medication or devices once removed shall not be reused or reissued, except as indicated in R 338.486(7).

(9) The automated device shall provide a mechanism for securing and accounting for wasted or discarded medications.

(10) The internal quality assurance documentation for the use and performance of the automated device shall include at least all of the following:

(a) Safety monitors that include wrong medications removed and administered to patient.

(b) Accuracy monitors that include filling errors and wrong medications removed.

(c) Security monitors that include unauthorized access, patients not in the system, system security breaches, and controlled substance audits.

(d) Policies that establish corrective measures taken to address the problems and errors identified in the internal quality assurance program and its integration to the overall quality assurance policies.

(11) Policy and procedures for the use of the automated device shall include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:

(a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(i).

(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).

(c) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.

(d) In each of the situations specified in subdivisions (a) to (c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours.

(12) A copy of all pharmacy policies and procedures related to the use of an automated device shall be maintained at the pharmacy responsible for the device's specific location and be available for review by an agent of the board.

(13) A controlled substance that is maintained at a nursing unit shall be stored in a securely locked cabinet or medication cart that is accessible only to an individual who is responsible for the administration or distribution of the medication.

(14) Records and documents required under this rule shall be maintained or controlled by the pharmacy responsible for the device for 2 years.

(15) An individual who is responsible for administering a controlled substance or a portion thereof shall record the quantity, disposition and an explanation of the destruction of the controlled substance on the proper accountability record. If the institution has a policy that reflects current practice standards and delineates the method of destruction, an explanation would only be required if policy was not followed.

History: 1979 AC; 1980 AACS; 1992 AACS; 2002 AACS; 2007 AACS.

PART 6. DISPENSING AND ADMINISTERING PRESCRIPTIONS

R 338.3161 Controlled substance prescriptions.

Rule 61. (1) A prescription that is issued for a controlled substance shall be dated and signed when issued and shall contain all of the following information:

(a) The full name and address of the patient for whom the substance is being prescribed.

(b) The prescriber's drug enforcement administration (dea) registration number, printed name, address, and professional designation.

(c) The drug name, strength, and dosage form.

(d) The quantity prescribed. For a prescription received in writing, the prescription shall contain the quantity in both written and numerical terms. A written prescription is in compliance if it contains preprinted numbers representative of the quantity next to which is a box or line the prescriber may check.

(e) The directions for use.

(f) In addition, if the prescription is for an animal, then the species of the animal and the full name and address of the owner.

(2) A written prescription for a controlled substance in schedules 2 to 5 shall be written legibly with ink or an indelible pencil, or prepared using a printer and shall be signed by the prescriber.

(3) An agent of the prescriber may prepare a prescription for the signature of the prescriber, but, pursuant to the act, the prescriber is liable if the prescription does not conform to these rules. A pharmacist who dispenses a controlled substance pursuant to a prescription not prepared in the form required by these rules is liable pursuant to the act.

(4) If the controlled substance prescription or order in a medical institution is issued pursuant to delegation under R 338.2304, R 338.2305, R 338.108a, or R 338.108b then the printed name of the delegatee, the licensure designation, the delegating prescriber, and the signature of the delegatee shall be on the written prescription. In medical facilities, orders shall contain the signatures of the delegatee and the printed name of the delegating prescriber.

(5) A prescription shall not be issued by a prescriber to obtain a stock of a controlled substance for the purpose of dispensing or administering the substance to patients.

(6) A prescriber shall not prescribe a controlled and noncontrolled substance on the same prescription form.

History: 1979 AC; 1992 AACS; 1994 AACS; 2002 AACS; 2003 AACS; 2007 AACS.

R 338.3162 Dispensing by pharmacists; delivery of controlled substances.

Rule 62. (1) A controlled substance shall be dispensed by a pharmacist or a pharmacy intern in the presence, and under the immediate supervision, of a pharmacist.

(2) A pharmacist shall require positive identification of individuals to whom controlled substances are dispensed or delivered when the individual is not known to the pharmacist or pharmacy employees. The following provide for waiver of this requirement:

(a) When positive identification is not available and a pharmacist, who in exercising his or her professional judgment, determines that a delay in dispensing the controlled substance may be detrimental to a patient.

(b) Subdivision (a) of this subrule does not exempt a pharmacist from the requirement to submit a patient identifier, as defined in R 338.3102(1)(f).

(3) The dispensing pharmacist and pharmacy are responsible for compliance with this rule.

(4) Except as provided by R 338.3162a, a pharmacist may dispense a controlled substance which is listed in schedules 3 to 5 and which is a prescription drug pursuant to the provisions of the federal food, drug, and cosmetic act of 1991, 21 U.S.C. §201.100(b)(i) et seq., only pursuant to a written, electronically transmitted, or oral order of a prescriber that contains all of the required information under R 338.3161, except that the signature of the prescriber is not required if the controlled substance is obtained pursuant to an oral order.

(5) If an oral order for a controlled substance listed in schedule 3 to 5 is transmitted by the prescriber's agent under delegation then all of the following shall be recorded on the prescription generated at the pharmacy: The information required by R 338.3161.The transmitting agent's identity. The individual who received the prescription at the pharmacy.

(6) Only an order that is issued in the usual course of professional treatment or in the course of legitimate and authorized research is a prescription.

History: 1979 AC; 1993 AACS; 2002 AACS; 2003 AACS; 2007 AACS.

R 338.3162a Electronic transmission of prescriptions; "electronically transmitted prescription drug order" defined.

Rule 62a. (1) As used in this rule, "electronically transmitted prescription drug order" means a prescription drug order that is communicated from the prescriber directly to the pharmacy by electronic means, so that the data cannot be altered, modified, extracted, viewed, or manipulated in the transmission process.

(2) An electronically transmitted prescription order shall be transmitted to the pharmacy of the patient's choice and shall occur only at the option of the patient.

(3) A pharmacist may dispense an electronically transmitted prescription drug order only if both of the following conditions are satisfied:

(a) The electronically transmitted prescription drug order includes all of the following information:

(i) The name and address of the prescriber.

(ii) An electronic signature or other board-approved means of ensuring prescription validity.

(iii) The prescriber's telephone number for verbal confirmation of the order.

(iv) The time and date of the transmission.

(v) The name of the pharmacy intended to receive the transmission.

(vi) All other information that is required to be contained in a prescription under the provisions of R 338.3161.

(b) The pharmacist exercises professional judgment regarding the accuracy or authenticity of the transmitted prescription. Technological devices shall not be used to circumvent any applicable prescription documentation and verification requirement.

(4) An electronically transmitted prescription drug order that meets the requirements of subrule (3) of this rule shall be deemed to be the original prescription.

(5) This rule does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical institutions.

History: 1993 AACS; 2002 AACS.

R 338.3162b Electronic system for monitoring schedules 2, 3, 4, and 5 controlled substances.

Rule 62b. (1) A pharmacist, dispensing prescriber, and veterinarian licensed under Part 177 who dispenses a prescription drug which is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by the state that dispenses in this state or dispenses to an address in this state a controlled substance listed in schedules 2 to 5 shall report to the department or the department's contractor by means of an electronic data transmittal process the following information for each prescription of a schedules 2 to 5 controlled substance prescription dispensed:

(a) The patient identifier, as defined in R 338.3102(1)(f). The following apply:

(i) An identification number, as specified in R 338.3102(1)(f)(iv)(A) or (B), is not required for patients under the age of 16.

(ii) If the patient is under 16 years of age, zeroes shall be entered as the identification number.

(iii) If the patient is an animal, positive identification of the animal's owner that meets the requirements of R 338.3102(1)(f)(iv).

(b) The name of the controlled substance dispensed.

(c) The metric quantity of the controlled substance dispensed.

(d) The national drug code number (ndc) of the controlled substance dispensed.

(e) The date of issue of the prescription.

(f)The date of dispensing.

(g)The estimated days of supply of the controlled substance dispensed.

(h) The prescription number assigned by the dispenser.

(i)The dea registration number of the prescriber and the dispensing pharmacy.

(j) The Michigan license number of the dispensing pharmacy.

(2) A pharmacist, dispensing prescriber, or veterinarian may presume that the patient identification information provided by a patient or a patient's representative is correct.

History: 2003 AACS; 2007 AACS.

R 338.3162c Format for electronic transmission of data; waiver.

Rule 62c. (1) A pharmacist, dispensing prescriber, or veterinarian who dispenses a prescription drug which is a controlled substance listed in schedules 2 to 5 shall transmit the data, as specified under R 338.3162b, by electronic media or other means as approved by the department or the department's contractor.

(2) The data shall be transmitted in the format established by the american society for automation in pharmacy (asap) telecommunications format for controlled substances.

(3) A pharmacist, dispensing prescriber, or veterinarian who dispenses controlled substances and who does not have an automated record-keeping system capable of producing an electronic report in the format established by subrule (2) of this rule may request a waiver from electronic reporting. The request shall be made in writing to the department.

(4) A pharmacist, dispensing prescriber, or veterinarian may be granted a waiver, if he or she demonstrates an inability to report as required by R 338.3162b and he or she agrees in writing to report the data to the department or the department's contractor by submitting a completed maps claim form as defined in R 338.3102(c) or transmitting data via an internet web portal that is provided by the Department or the Department's contractor for this purpose.

History: 2003 AACS; 2007 AACS.

R 338.3162d Required reporting of prescription data; error reporting.

Rule 62d. (1) A pharmacist, pharmacy, dispensing prescriber, or veterinarian shall report all schedules 2 to 5 controlled substances dispensed beginning on the date that these amendatory rules take effect.

(2) The data required by R 338.3162b shall be forwarded by on-line transmission, computer diskette, compact disk, or other approved medium, as specified in R 338.3162c to the department or the department'scontractor twice monthly, by the first calendar day and the 15th calendar day of each month

immediately following the month in which the prescription was dispensed, and shall include the data for all controlled substances dispensed since the previous transmission or report. A pharmacist, pharmacy, dispensing prescriber, or veterinarian may choose 2 different dates to report each month, provided that they are within 2 calendar days of the first calendar day and the 15th calendar day of each month and they include all controlled substances dispensed since the previous transmission or report.

(3) For each pharmacist, pharmacy, dispensing prescriber, or veterinarian who does not have the capacity to forward the information as specified in R 338.3162b, the information shall be mailed or delivered to a location specified by the department or the department's contractor twice monthly by the first calendar day and the 15th calendar day of the
month following the month in which the prescription was dispensed, and shall include the data for all controlled substances dispensed since the previous transmission or report. The pharmacist, pharmacy, dispensing prescriber, or veterinarian may choose 2 different dates to report each month provided they are within 2 days of the first calendar day and the 15th calendar day of each month and they include all controlled substances dispensed since the previous transmission or report.

(4) The department or the department's contractor shall notify a pharmacist, pharmacy, dispensing prescriber, or veterinarian of an error in data reporting. Upon receiving notification of an error in data reporting, a pharmacist, pharmacy, dispensing prescriber, or veterinarian shall take appropriate measures to correct the error and transmit the corrected data to the department or the department's contractor within 15 days of being notified of the error.

(5) A pharmacist, pharmacy, dispensing prescriber, or veterinarian who fails to report the dispensing of a prescription for a controlled substance listed in schedules 2 to 5 as required, beginning on the date that these amendatory rules take effect, shall be subject to the penalty provisions in sections 16221, 17741, or 17768 in article 15 of the act.

History: 2003 AACS; 2007 AACS.

R 338.3162e Exemption from reporting requirements.

Rule 62e. A pharmacist, dispensing prescriber, or veterinarian shall be exempt from the reporting requirements under the following circumstances:

(a) When a controlled substance in schedules 2 to 5 is administered directly to a patient.

(b) When a controlled substance in schedules 2 to 5 is dispensed from a health facility or agency licensed under article 17 of the act by a dispensing prescriber in a quantity adequate to treat a patient for not more than 48 hours.

History: 2003 AACS.

R 338.3163 Drug-dependent person; prescribing, dispensing, and administering controlled substance.

Rule 63. (1) A prescription shall not be issued for a controlled substance nor shall a controlled substance be dispensed or administered to a drug dependent person for the purpose of continuing his or her drug dependency, except as follows:

(a) A prescriber, licensed in accordance with federal and state law to conduct the drug treatment of a drug dependent person in a program may prescribe a controlled substance for the purpose of legitimate treatment of the drug-dependent person.

(b) A controlled substance may be administered or dispensed, or both, by a dispenser, directly to a drug-dependent person for the purpose of continuing his or her dependence who is enrolled in a drug treatment and rehabilitation program.

(2) A controlled substance may be prescribed and dispensed in an acute care hospital to continue maintenance treatment for drug dependency for a patient whose hospitalization is for treatment of a medical condition other than addiction. The enrollment of the patient in an approved maintenance treatment program shall be verified.

History: 1979 AC; 2002 AACS.

R 338.3164 Emergency dispensing of schedule 2 substances; oral prescriptions.

Rule 64. A pharmacist may dispense a controlled substance listed in schedule 2 in case of an emergency in which all of the following conditions are met:

(a) The prescriber advises the pharmacist of the following:

(i) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

(ii) Appropriate alternative treatment is not available, including administration of a drug that is not a controlled substance under schedule 2.

(iii) It is not reasonably possible for the prescriber to provide a written prescription to be presented to the person dispensing the substance before the dispensing.

(iv) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period and pursuant to a written prescription.

(b) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information that is required to be contained in a prescription under provisions of R 338.3161, except for the prescriber's signature.

(c) If the prescriber is not known to the pharmacist, then the pharmacist shall make a reasonable effort to determine that the oral authorization came from a prescriber by returning the prescriber's call, using the telephone number listed in the telephone directory and other good faith efforts to assure the prescriber's identity.

History: 1979 AC; 2003 AACS.

R 338.3165 Emergency dispensing of schedule 2 substances; written prescriptions.

Rule 65. Within 7 days after authorizing an emergency oral prescription of a controlled substance listed in schedule 2, the prescriber shall reduce the prescription to writing and have recorded on the prescription's face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription shall be delivered to the pharmacist in person or by mail within 7 days after the oral prescription is issued. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral order which earlier had been reduced to writing. The pharmacist shall notify the department of consumer and industry services if the prescriber fails to deliver a written prescription to him or her. The failure of a pharmacist to notify the department if the prescriber fails to deliver a written prescription voids the authority conferred by this rule to dispense without a written prescription of a prescriber.

History: 1979 AC; 1992 AACS; 2003 AACS.

R 338.3166 Partial dispensing of schedule 2 substances.

Rule 66. (1) A pharmacist may partially dispense a controlled substance listed in schedule 2 if he or she is unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency oral prescription. The remainder of the prescription may be dispensed within 72 hours after the first partial dispensing. If the remainder of the prescription is not or cannot be dispensed within the 72 hours, the pharmacist shall so notify the prescriber.A further quantity shall not be dispensed beyond the 72 hours without a new prescription.

(2) Prescriptions for schedule 2 controlled substances that are written for a patient in long-term care facilities or for a patient with a medical diagnosis that documents a terminal illness may be filled in partial quantities, including individual dosage units. For each partial filling, the dispensing pharmacist shall record, on the back of the prescription or on another appropriate record that is uniformly maintained and readily retrievable, all of the following information:

(a) Date of the partial filling.

(b) Quantity dispensed.

(c) Remaining quantity authorized to be dispensed.

(d) Identification of the dispensing pharmacist. The total quantity of schedule 2 controlled substances dispensed in all partial fillings shall not be more than the total quantity prescribed. Schedule 2 prescriptions for a patient in a long-term care facility or for a patient with a medical diagnosis that documents a terminal illness shall be valid for a period of not more than 60 days from the issue date unless terminated at an earlier date by the discontinuance of medication. A pharmacist shall record on the prescription whether the patient is terminally ill or is a long-term care facility patient.

History: 1979 AC; 1992 AACS; 1994 AACS; 2003 AACS.

R 338.3167 Dispensing schedule 5 substances without prescriptions.

Rule 67. (1) A pharmacist may, without a prescription, dispense a controlled substance listed in schedule 5 which is not a prescription medication as determined under the federal food, drug, and cosmetic act, 21 U.S.C. §§301 to 392, if all of the following provisions are met:

(a) The dispensing pharmacist has determined it is to be used for a medical purpose.

(b) Not more than 240 cc (8 ounces) or 48 solid doses of a substance containing opium or more than 120 cc (4 ounces) or 24 solid doses of any other substance listed in schedule 5 are distributed at retail to the same purchaser in any single 48-hour period.

(c) The purchaser is at least 18 years of age.

(d) The pharmacist requires a purchaser not known to the pharmacist to furnish suitable identification, including proof of age where appropriate.

(2) If a pharmacist dispenses a controlled substance listed in schedule 5, then he or she shall affix to the container in which the substance is dispensed a label that shows the date, his or her own name, and the name and address of the place of practice in which the substance is dispensed.

(3) The pharmacist shall maintain a record of the dispensing of controlled substances listed in schedule 5. The record shall be immediately retrievable and may be maintained in the same manner as required for schedule 5 prescription medication. The record shall contain all of the following information:

(a) The name and address of the patient.

(b) The name and address of the purchaser if different from the patient.

(c) The name and quantity of substance purchased.

(d) The date purchased.

(e) The name or initials of the pharmacist or pharmacy intern who dispensed the substance.

(f) The medical purpose for which the medication is being used as determined by the pharmacist.

History: 1979 AC; 1982 AACS; 2002 AACS; 2003 AACS.

R 338.3168 Refilling of prescriptions.

Rule 68. (1) A prescription for a controlled substance listed in schedule 2 shall not be refilled.

(2) A prescription for a controlled substance listed in schedules 3 and 4 shall not be refilled more than 6 months after the prescription's date of issuance and shall not be refilled more than 5 times. Renewal of the prescription shall be effected and recorded in the same manner as an original prescription.

(3) A partial filling of a controlled substance prescription in schedules 3, 4, and 5 is permissible if all of the following provisions are met:

(a) Each partial filling is recorded in the same manner as a refilling.

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(c) No dispensing occurs after 6 months after the date on which the prescription was issued for schedules 3 and 4.

(4) A prescription for a controlled substance listed in schedule 5 may be refilled only as expressly authorized by the prescriber on the prescription; if no authorization is indicated, then the prescription shall not be refilled.

History: 1979 AC; 2002 AACS; 2003 AACS.

R 338.3169 Labels.

Rule 69. In addition to all other labeling requirements, a practitioner who dispenses a controlled substance prescription shall affix to the container any cautionary statement required by 21 C.F.R. §290.5. The Code of Federal Regulations, Title 21, Food and Drugs, part 290, containing 21 C.F.R. §290.5, is available via the Internet at web-site http://www.access.gpo.gov/nara/cfr. Printed copies may be purchased from the United State Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954 USA, by calling toll free at 1-866-512-1800, or via the Internet at web-site: http://bookstore.gpo.gov at a cost of $16.00 as of the time of adoption of these amendments. Printed copies of 21 C.F.R. §290.5 also are available for inspection and distribution to the public at cost at the Department of Consumer and Industry Services, Bureau of Health Services, Ottawa Building - First Floor, 611 West Ottawa, Lansing, MI 48909.

History: 1979 AC; 2002 AACS.

R 338.3170 Dispensing and administering controlled substances by prescribers.

Rule 70. (1) A prescriber in the course of his or her professional practice only, may dispense or administer, or both, a controlled substance listed in schedules 2 to 5 or he or she may cause them to be administered by an assistant under personal charge supervision.

(2) A prescriber may dispense or administer, or both, in the course of professional practice, a controlled substance listed in schedules 2 to 5, directly to a drug-dependent person for the purpose of continuing the dependence in a drug treatment and rehabilitation program, if the prescriber is appropriately registered under federal law and licensed under state law to treat a drug-dependent person with controlled substances.

(3) A veterinarian, in the course of professional practice only and not for use by a human being, may dispense or administer, or both, a controlled substance listed in schedules 2 to 5 or may cause them to be administered by an assistant or orderly under his or her direction and personal charge supervision.

History: 1979 AC; 2002 AACS.

PART 7. DISTRIBUTIONS

R 338.3181 Distributions by dispensers.

Rule 81. (1) A dispenser who is not licensed as a distributor may distribute a controlled substance to another dispenser for the purpose of general dispensing to his or her patients if all of the following conditions are satisfied:

(a) The receiving dispenser is licensed to dispense the substance.

(b) The distribution is recorded by the distributing dispenser and a receipt record is maintained by the receiving dispenser.

(c) An order form for substances listed in schedules 1 and 2 is used.

(d) The total number of dosage units of all controlled substances distributed by the distributing dispenser during the 12-month period in which the dispenser is licensed is not more than 5% of the total number of all dosage units distributed and dispensed during the 12-month period.

(2) If the dispenser has reason to believe that the total number of dosage units which will be distributed by him or her pursuant to this rule will be more than 5% of the total number of dosage units of all controlled substances distributed and dispensed by him or her during the 12-month period, the dispenser shall obtain a license to distribute controlled substances.

History: 1979 AC; 1992 AACS.

R 338.3182 Distribution of aqueous and oleaginous solutions.

Rule 82. (1) A pharmacist who is licensed to dispense may distribute, without being licensed to distribute, to a licensed practitioner, an aqueous or oleaginous solution, in a quantity of not more than 1 ounce at any one time, which contains a narcotic controlled substance in a proportion that is not more than 20% of the complete solution and which is to be used by the practitioner in the course of his or her professional practice for administration to a patient. The pharmacist shall maintain a written record that contains all of the following information:

(a) The date of the transaction.

(b) The name, form, and quantity of the substance.

(c) The name, address, and license number of the pharmacist or other licensed person.

(d) The name, address, and license number of the practitioner.

(2) In the case of a controlled substance listed in schedules 1 or 2, an order form shall be used and maintained as the written record of the transaction.

History: 1979 AC; 1992 AACS.

R 338.3183 Distribution to suppliers.

Rule 83. (1) A person who is lawfully in possession of a controlled substance that is listed in any schedule may distribute the substance without being licensed to distribute to the person from whom he or she obtained the substance or to the manufacturer of the substance. The person who is in possession of the substance shall maintain a written record that contains all of the following information:

(a) The date of the transaction.

(b) The name, form, and quantity of the substance.

(c) The name, address, and license number, if any, of the person who makes the distribution.

(d) The name, address, and license number, if known, of the supplier or manufacturer.

(2) In the case of a controlled substance listed in schedules 1 or 2, an order form shall be used and maintained as the written record of the transaction.

History: 1979 AC; 1992 AACS.

R 338.3185 Discontinuances and transfers.

Rule 85. A licensee who wants to discontinue or transfer business activities or a professional practice altogether or only with respect to controlled substances shall return his or her DEA registration and any unexecuted order forms in his or her possession to the drug enforcement administration. The administrator's license shall be returned to the administrator. The transfer of controlled substances is subject to approval by the drug enforcement administration or administrator in accordance with the provisions of 21 C.F.R. S300.

History: 1979 AC; 1992 AACS.

R 338.3186 Use of order forms and invoices.

Rule 86. An order form shall be used to distribute schedule 2 substances and an invoice shall be used to distribute schedules 3 to 5 substances. The order form may be executed only by a practitioner who is licensed to prescribe or dispense controlled substances.

History: 1979 AC; 1992 AACS.

PART 8. ADMINISTRATIVE AND DISCIPLINARY PROCEDURE

R 338.3191 - 338.3198a Rescinded.

History: 1979 AC; 1980 AACS; 1996 AACS.

R 338.3199 - 338.3199q Rescinded.

History: 1979 AC; 1980 AACS; 1997 AACS.