

**RULES  
OF  
TENNESSEE DEPARTMENT OF MENTAL HEALTH  
AND DEVELOPMENTAL DISABILITIES  
DIVISION OF ALCOHOL AND DRUG ABUSE SERVICES**

**CHAPTER 0940-06-01  
CONTROLLED SUBSTANCES**

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**0940-06-01-.01 CONTROLLED SUBSTANCES IN SCHEDULE I.**

- (1) Schedule I consists of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this rule. Each drug or substance bears the federal controlled substance code number assigned to it by the Drug Enforcement Administration.
  
- (2) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, salts is possible within the specific chemical designation. For the purposes of subparagraph (hh) 3-Methyfenanyl, only, the term isomer includes the optical and geometric isomers.
  - (a) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidnyl]-N-phenyl-acetamide)..... 9815
  - (b) Acetylmethadol ..... 9601
  - (c) Allyprodine ..... 9602
  - (d) Alphacetylmethadol (except levoalphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM)..... 9603
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  - (f) Alphamethadol..... 9605
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  - (h) Alpha-methylthiofentanyl (N-[1-(1-methyl-2-(2-thienyl) ethyl-4-piperidyl]-N-phenylpropanamide ..... 9832
  - (i) Benzethidine ..... 9606
  - (j) Betacetylmethadol ..... 9607

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(k)	Beta-hydroxyfentanyl phenylpropanamide .....	(N-[1-(2-hydroxy-2-phenethyl)-4-piperidiny]-N-phenylpropanamide .....	9830
(l)	Beta-hydroxy-3-methylfentanyl.....	Other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidiny]-Nphenylpropanamide .....	9831
(m)	Betameprodine .....		9608
(n)	Betamethadol .....		9609
(o)	Betaprodine .....		9611
(p)	Clonitazene.....		9612
(q)	Dextromoramide .....		9613
(r)	Diampromide .....		9615
(s)	Diethylthiambutene.....		9616
(t)	Difenoxin.....		9168
(u)	Dimenoxadol.....		9617
(v)	Dimepheptanol .....		9618
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(y)	Dipipanone .....		9622
(z)	Ethylmethylthiambutene .....		9623
(aa)	Etonitazene.....		9624
(bb)	Etoxidine.....		9625
(cc)	Furethidine.....		9626
(dd)	Hydroxypethidine.....		9627
(ee)	Ketobemidone .....		9628
(ff)	Levomoramide.....		9629
(gg)	Levophenacymorphan .....		9631
(hh)	3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piper-idyl]-N-phenylpropanamide)		9813
(ii)	3-Methylthiofentanyl phenylpropanamide .....	(N-{3-methyl-1-[2-(2-thienyl) ethyl]-4-piperidyl}-N-phenylpropanamide .....	9833
(jj)	Morpheridine.....		9632

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(kk) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine) .....	9661
(ll) Noracymethadol .....	9633
(mm) Norlevorphanol .....	9634
(nn) Normethadone.....	9635
(oo) Norpipanone .....	9636
(pp) Para-fluorofentanyl (N-[1-(2-phenylethyl)-4-piperidyl]-N-(4-fluorophenyl)-propanamide.....	9812
(qq) PEPAP (1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine .....	9663
(rr) Phenadoxone .....	9637
(ss) Phenampromide .....	9638
(tt) Phenomorphan .....	9647
(uu) Phenoperidine .....	9641
(vv) Piritramide.....	9642
(ww) Proheptazine .....	9643
(xx) Properidine .....	9644
(yy) Propiram .....	9649
(zz) Racemoramide .....	9645
(aaa) Thiofentanyl (N-[1-(2-(2-thienyl) ethyl-4-piperidyl]-N-phenylpropanamide.....	9835
(bbb) Tilidine .....	9750
(ccc) Trimeperidine.....	9646
(3) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:	
(a) Acetorphine .....	9319
(b) Acetyldihydrocodeine.....	9051
(c) Benzylmorphine.....	9052
(d) Codeine methylbromide.....	9070
(e) Codeine-N-Oxide.....	9053
(f) Cyprenorphine .....	9054

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(g)	Desomorphine .....	9055
(h)	Dihydromorphine .....	9145
(i)	Drotebanol .....	9335
(j)	Etorphine (except hydrochloride salt .....	9056
(k)	Heroin .....	9200
(l)	Hydromorphinol .....	9301
(m)	Methyldesorphine .....	9302
(n)	Methyldihydromorphine .....	9304
(o)	Morphine methylbromide .....	9305
(p)	Morphine methylsulfonate .....	9306
(q)	Morphine-N-Oxide .....	9307
(r)	Myrophine .....	9308
(s)	Nicocodeine .....	9309
(t)	Nicomorphine .....	9312
(u)	Normorphine .....	9313
(v)	Pholcodine .....	9314
(w)	Thebacon .....	9315
(4)	Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers, is possible within the specified chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position and geometric isomers):	
(a)	Alpha-ethyltryptamine..... Other names: etryptamine; Monase; a-ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole; a-ET; and AET, ET, Trip.	7249
(b)	Alpha-methyltryptamine..... Other name: AMT.	7432
(c)	4-Bromo-2, 5-dimethoxy-amphetamine..... Other names: 4-bromo-2, 5-dimethoxy-a-methylphenethylamine; 4-bromo-2, 5-DMA.	7391
(d)	4-Bromo-2, 5-dimethoxyphenethylamine .....	7392
	Other names: 2-(4-bromo-2, 5-dimethoxyphenyl)-1-aminoethane; alpha-desmethyl DOB; 2C-B; Nexus.	

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- (e) Bufotenine ..... 7433  
Other names: 3-(B-Di-methylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylsminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-di-methyltryptamine; mappine
- (f) Diethyltryptamine..... 7434  
Other names: N, N-Diethyl-tryptamine; DET
- (g) 2, 5-Dimethoxyamphetamine..... 7396  
Other names: 2, 5 dimethoxy-a-methylphenethylamine; 2, 5-DMA
- (h) 2, 5-Dimethoxy-4-ethylamphetamine ..... 7399  
Other name: DOET.....
- (i) 2, 5 Dimethoxy-4-(n)-propylthiophenethylamine ..... 7348  
Other name: 2C-T-7
- (j) Dimethyltryptamine..... 7435  
Other name: DMT
- (k) Ethylamine analog of phencyclidine ..... 7455  
Other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE
- (l) Ibogaine..... 7260  
Other names: 7-Ethyl-6, 6B, 7, 8, 9, 10, 12, 13 octahydro-2-methoxy-6, 9-methano-5H-pyrido [1', 2':1, 2] azepina [5, 4-b] indole; Tabenanthe iboga.
- (m) Lysergic acid diethylamide ..... 7315  
Other name: LSD
- (n) Mescaline..... 7381  
Other name: Constituent of "Peyote" cacti
- (o) 4-Methoxyamphetamine..... 7411  
Other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine, PMA
- (p) 5-Methoxy-3, 4-methylenedioxy-amphetamine ..... 7401
- (q) 5-Methoxy-N, N-diisopropyltryptamine ..... 7439  
Other name: 5-MeO-DIPT
- (r) 4-Methyl-2, 5-dimethoxy-amphetamine..... 7395  
Other names: 4-methyl-2,5-dimethoxy-a-methylphenethylamine, DOM, and STP
- (s) 3, 4-Methylenedioxy amphetamine ..... 7400
- (t) 3, 4-Methylenedioxymethamphetamine ..... 7405  
Other name: MDMA
- (u) 3,4-Methylenedioxy-N-ethylamphetamine..... 7404  
Other names: N-ethyl-alpha-methyl-3,4(methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA
- (v) N-ethyl-3-piperidyl benzilate ..... 7482

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- (w) N-hydroxy-3, 4-methylenedioxyamphetamine..... 7402  
Other names: N-hydroxy-alpha-methyl-3, 4 (methylenedioxy) phenethylamine; N-hydroxy MDA
- (x) N-methyl-3-piperidyl benzilate ..... 7484
- (y) Parahexyl..... 7374  
Other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-trimethyl-6H-dibenzo [b, d] pyran; Synhexyl
- (z) Peyote..... 7415  
Meaning all parts of the plant presently classified botanically as *Lophophora williamsii* Lamaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant its seeds or extracts. (Interprets 21 USC 812 (c), Schedule 1 (c) (12)(o))
- (aa) Psilocybin (constituent of magic mushrooms) ..... 7437
- (bb) Psilocyn (constituent of magic mushrooms) ..... 7438
- (cc) Pyrrolidine analog of phencyclidine (1-(1-phenylcyclohexyl)-pyrrolidine) ..... 7458  
Other names: PCPy; PHP
- (dd) 1-[1-(2-Thienyl)cyclohexyl] pyrrolidine..... 7473  
Other names: TCPy
- (ee) Thiophene analog of phencyclidine..... 7470  
Other names: 1-[1-(2-Thienyl) cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine; TPCP; TCP
- (ff) 3, 4, 5-Trimethoxy amphetamine..... 7390
- (5) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specified chemical designation:
  - (a) Gamma-hydroxybutyric Acid ..... 2010  
Other names: GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodiumoxybate; sodium oxybutyrateGHB, gamma hydroxybutyrate, 4-hydroxybulanoic acid
  - (b) Mecloqualone ..... 2572
  - (c) Methaqualone..... 2565
- (6) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:
  - (a) Aminorex..... 1585  
Other names: aminoxophen; 2-amino-5-phenyl-2-oxazoline; or 4, 5-dihydro-5-phenyl-2-oxazolamine

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(b) Cathinone .....	1235
Other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, norphedrone, constituent of <i>catha edulis</i> or "Khat" plant	
(c) Fenethylamine .....	1503
(d) Methcathinone .....	1237
Other names: 2-(methylamino)-propiofenone; alpha-(methylamino) propiofenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrine; N-methylcathinone; methylcathinone; AL-464; AL 422; AL-463; and UR 1432), its salts, optical isomers and salts of optical isomers	
(e) (+/-) <i>cis</i> -4-Methylaminorex ( <i>cis</i> isomer) .....	1590
Other name: (=/-) <i>cis</i> -4,5 dihydro-4-methyl-5-phenyl-2-oxazolamine	
(f) N-benzylpiperazine .....	7493
Other names: BZP, 1-benzylpiperazine	
(g) N-ethylamphetamine .....	1475
(h) N, N-dimethylamphetamine .....	1480
Other names: N, N-alpha-trimethyl-benzeneethanamine; N, N-alpha-trimethylphenethylamine	

**Authority:** T.C.A. §§4-4-103, 33-1-302, 33-10303, 33-1-305, 33-1-309 and 39-17-403. **Administrative History:** Original rule filed April 29, 1981; effective June 18, 1981. Repeal and new rule filed May 25, 1984; effective June 24, 1984. Repeal and new rule filed September 6, 1985; effective October 10, 1985. Repeal and new rule filed December 17, 1986; effective January 31, 1987. Amendment filed July 10, 1997; effective September 23, 1997. Repeal and new rule filed January 7, 2011; effective April 7, 2011.

**0940-06-01-.02 CONTROLLED SUBSTANCES IN SCHEDULE II.**

- (1) Schedule II consists of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this rule. Each drug or substance bears the federal controlled substance code number assigned to it by the Drug Enforcement Administration.
- (2) Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
  - (a) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextroprhan, thebaine-derived butorphanol, nalmeferne, nalbuphine, naloxone, and naltrexone, and their respective salts, but including the following:
    1. Codeine..... 9050
    2. Dihydroetorphine ..... 9334
    3. Ethylmorphine..... 9190
    4. Etorphine hydrochloride..... 9059
    5. Granulated opium ..... 9640

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6.	Hydrocodone .....	9193
7.	Hydromorphone .....	9150
8.	Metopon .....	9260
9.	Morphine .....	9300
10.	Opium extracts.....	9610
11.	Opium fluid extracts.....	9620
12.	Oripavine.....	9330
13.	Oxycodone.....	9143
14.	Oxymorphone .....	9652
15.	Powdered opium.....	9639
16.	Raw opium.....	9600
17.	Thebaine .....	9333
18.	Tincture of opium .....	9630
(b)	Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (2)(a) of this rule, except that these substances shall not include the isoquinoline alkaloids of opium.	
(c)	Opium poppy and poppy straw.	
(d)	Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.	
(e)	Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder from which contains the phenanthrine alkaloids of the opium poppy).....	
(3)	Opiates. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrophan and levopropoxyphene excepted:	
(a)	Alfentanil.....	9737
(b)	Alphaprodine .....	9010
(c)	Anileridine .....	9020
(d)	Bezitramide.....	9800

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(e)	Carfentanil .....	9743
(f)	Dextropropoxyphene (bulk, non dosage forms) .....	9273
(g)	Dihydrocodeine.....	9120
(h)	Diphenoxylate.....	9170
(i)	Fentanyl.....	9801
(j)	Isomethadone.....	9226
(k)	Levoalphacetylmethadol.....	9648
	Other names: levo-alpha-acetylmethadol, levomethadyl acetate, LAAM	
(l)	Levomethorphan.....	9210
(m)	Levorphanol.....	9220
(n)	Metazocine .....	9240
(o)	Methadone9250	
(p)	Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.....	9254
(q)	Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid9802	
(r)	Pethidine (meperidine) .....	9230
(s)	Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine .....	9232
(t)	Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate .....	9233
u)	Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.....	9234
(v)	Phenazocine.....	9715
(w)	Piminodine .....	9730
(x)	Racemethorphan .....	9732
(y)	Racemorphan .....	9733
(z)	Remifentanil.....	9739
(aa)	Sufentanil.....	9740
(bb)	Tapentadol.....	9780
(4)	Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:	
	(a) Amphetamine, its salts, optical isomers, and salts of its optical isomers.....	1100
	(b) Methamphetamine, its salts, isomers, and salts of its isomers .....	1105

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(c)	Phenmetrazine and its salts .....	1631
(d)	Methylphenidate .....	1724
(e)	Lisdexamfetamine, its salts, isomers, and salts of its isomers.....	1205
(5)	Depressants. Unless specifically excepted or unless listed in another schedule any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:	
(a)	Amobarbital .....	2125
(b)	Glutethimide .....	2550
(c)	Pentobarbital .....	2270
(d)	Phencyclidine .....	7471
(e)	Secobarbital.....	2315
(6)	Hallucinogenic substances.	
(a)	Nabilone.....	7379
(7)	Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances:	
(a)	Immediate precursor to amphetamine and methamphetamine:	
1.	Phenylacetone .....	8501
	Other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;	
(b)	Immediate precursors to phencyclidine (PCP):	
1.	1-phenylcyclohexylamine.....	7460
2.	1-piperidinocyclohexanecarbonitrile .....	8603
(c)	Immediate precursor to fentanyl:	
1.	4-anilino-N-phenethyl-4-piperidine (ANPP) .....	8333

**Authority:** T.C.A. §§4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309 and 39-17-403. **Administrative History:** Original rule filed April 29, 1981; effective June 18, 1981. Repeal and new rule filed May 25, 1984; effective June 24, 1984. Repeal and new rule filed September 6, 1985; effective October 10, 1985. Repeal and new rule filed December 17, 1986; effective January 31, 1987. Amendment filed July 10, 1997; effective September 23, 1997. Repeal and new rule filed January 7, 2011; effective April 7, 2011.

**0940-06-01-.03 CONTROLLED SUBSTANCES IN SCHEDULE III.**

- (1) Schedule III consists of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated, listed in this rule. Each drug or substance bears the federal controlled substance code number assigned to it by the Drug Enforcement Administration.
  
- (2) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - (a) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under 21 C.F.R. 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances..... 1405
  - (b) Benzphetamine..... 1228
  - (c) Clorphentermine ..... 1645
  - (d) Clortermine ..... 1647
  - (e) Phendimetrazine..... 1615
  
- (3) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect in the central nervous system:
  - (a) Any compound, mixture, or preparation containing:
    - 1. Amobarbital and non-controlled active ingredients ..... 2126
    - 2. Secobarbital and non controlled active ingredients..... 2316
    - 3. Pentobarbital and non-controlled active ingredients ..... 2271  
Or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.
  - (b) Any suppository dosage form containing:
    - 1. Amobarbital..... 2126
    - 2. Secobarbital..... 2316
    - 3. Pentobarbital..... 2271  
Or any salt of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.
  - (c) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof. Examples include the following drugs: ..... 2100

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1.	Aprobarbital.....	2100
2.	Butabarbital (secbutabarbital) .....	2100
3.	Butalbital .....	2100
4.	Butobarbital (butethal).....	2100
5.	Talbutal .....	2100
6.	Thiamylal.....	2100
7.	Thiopental .....	2100
8.	Vinbarbital .....	2100
(d)	Chlorhexadol .....	2510
(e)	Embutramide .....	2020
(f)	Gamma hydroxybutyric acid preparations. Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application of § 505 of the federal Food, Drug, and Cosmetic Act, codified in 21 U.S.C. §_355. ....	2012
(g)	Ketamine, its salts, isomers, and salts of .....	7285
	Other name: (±)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone	
(h)	Lysergic acid.....	7300
(i)	Lysergic acid amide.....	7310
(j)	Methypylon .....	2575
(k)	Sulfondiethylmethane .....	2600
(l)	Sulfonethylmethane.....	2605
(m)	Sulfonmethane .....	2610
(n)	Tiletamine and zolazepam or any salt of tiletamine or zolazepam.....	7295
1.	Other name for a tiletamine-zolazepam combination product:: Telazol®;	
2.	Other name for tiletamineis 2-(ethylamino)-2-(2-thienyl)-cyclohexanone.	
3.	Other names for zolazepam are 4-(2-fluorophenyl)-6,8- dihydro-1,3,8-trimethylpyrazolo [3,4-e], [1,4]-diazepin-7(1H)-one and flupyrazapon	
(4)	Nalorphine .....	9400
(5)	Narcotic Drugs.	
(a)	Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or	

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their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

1. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium..... 9803
  2. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts ..... 9804
  3. Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium..... 9805
  4. Not more than 300 milligrams of dihydrocodeinenone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active non-narcotic ingredients in recognized therapeutic amounts ..... 9806
  5. Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit with one or more active non-narcotic ingredients in recognized therapeutic amount ..... 9807
  6. Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit with one or more active non-narcotic ingredients in recognized therapeutic amounts ..... 9808
  7. Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts ..... 9809
  8. Not more than 50 milligrams of morphine per 10 milliliters or per 100 grams, with one or more active, non-narcotic ingredients in recognized therapeutic amounts ..... 9810
- (b) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts:
1. Buprenorphine ..... 9064
- (6) Anabolic steroids. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation:
- (a) Anabolic steroids ..... 4000
    1. 3Alpha, 17beta-dihydroxy-5alpha-androstane
    2. 5Alpha-androstan-3, 17-dione
    3. 17Alpha-methyl-3alpha, 17beta-dihydroxy-5alpha-androstane
    4. 17Alpha-methyl-3beta, 17beta-dihydroxy-5alpha-androstane
    5. 17Alpha-methyl-3beta, 17beta-dihydroxyandrost-4-ene

(Rule 0940-06-01-.03, continued)

6. 17Alpha-methyl-delta1-dihydrotestosterone (17beta-hydroxy-17alpha-methyl-5alpha-androst-1-en-3-one)
7. 17Alpha-methyl-4-hydroxynandrolone (17alpha-methyl-4-hydroxy-17beta-hydroxyestr-4-en-3-one)
8. 1-Androstenediol (3alpha, 17beta-dihydroxy-5alpha-androst-1-ene)
9. 1-Androstenediol (3beta, 17beta-dihydroxy-5alpha-androst-1-ene)
10. 4-Androstenediol (3beta, 17beta-dihydroxy-androst-4-ene)
11. 5-Androstenediol (3beta, 17beta-dihydroxy-androst-5-ene)
12. 1-Androstenedione (5alpha-androst-1-en-3, 17-dione)
13. 4-Androstenedione (androst-4-en-3, 17-dione)
14. 5-Androstenedione (androst-5-en-3, 17-dione)
15. 3Beta,17-dihydroxy-5alpha-androstane)
16. 13Beta-ethyl-17beta-hydroxygon-4-en-3-one
17. Bolasterone (7alpha, 17alpha-dimethyl-17beta-hydroxyandrost-4-en-3-one)
18. Boldenone (17beta-hydroxyandrost-1, 4-diene-3-one)
19. Boldione (androsta-1,4-diene-3,17-dione)
20. Calusterone (7beta, 17alpha-dimethyl-17beta-hydroxyandrost-4-en-3-one)
21. Chlorotestosterone
22. Clostebol (4-chloro-17beta-hydroxyandrost-4-en-3-one)
23. Dehydrochloromethyltestosterone (4-chloro-17beta-hydroxy-17alpha-methylandrost-1,4-dien-3-one)
24. Delta1-dihydrotestosterone (17beta-hydroxy-5alpha-androst-1-en-3-one)
25. Desoxymethyltestosterone (17alpha-methyl-5alpha-androst-2-en-17beta-ol)  
Other name: madol
26. 4-Dihydrotestosterone (17beta-hydroxyandrost-4-en-3-one)
27. Drostanolone (17beta-hydroxy-2alpha-methyl-5alpha-androst-3-one)
28. Ethylestrenol (17alpha-ethyl-17beta-hydroxyestr-4-ene)
29. Fluoxymesterone (9-fluoro-17alpha-methyl-11beta, 17beta-dihydroxyandrost-4-en-3-one)
30. Formebolone (2-formyl-17alpha-methyl-11alpha, 17beta-dihydroxyandrost-1, 4-dien-3-one)

(Rule 0940-06-01-.03, continued)

31. Furazabol (17alpha-methyl-17beta- hydroxyandrostano[2,3-c]-furan)
32. 4-Hydroxy-19-nortestosterone (4,17beta- dihydroxyestr-4-en-3-one)
33. 4-Hydroxytestosterone (4,17beta-dihydroxyandrost- 4-en-3-one)
34. Mestanolone (17alpha-methyl-17beta-hydroxy- 5alpha-androstan-3-one)
35. Mesterolone (1alpha-methyl-17beta-hydroxy- 5alpha-androstan-3-one)
36. Methandienone (17alpha-methyl-17beta- hydroxyandrost-1, 4-diene-3-one)
37. Methandranone
38. Methandriol (17alpha-methyl-3beta, 17beta- dihydroxyandrost-5-ene)
39. Methandrostenolone
40. Methenolone (1-methyl-17beta-hydroxy-5alpha- androst-1-en-3-one)
41. Methyldienolone (17alpha-methyl-17beta- hydroxyestra-4, 9 (10)-dien-3-one)
42. Methyltestosterone (17alpha-methyl-17beta- hydroxyandrost-4-en-3-one)
43. Methyltrienolone (17alpha-methyl-17beta- hydroxyestra-4, 9, 11-trien-3-one)
44. Mibolerone (7alpha, 17alpha-dimethyl-17beta- hydroxyestr-4-en-3-one)
45. Nandrolone (17beta-hydroxyestr-4-en-3-one)
46. 19-Nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione)
47. 19-Nor-4-androstenediol (3alpha, 17beta-dihydroxyestr-4-ene)
48. 19-Nor-4-androstenediol (3beta, 17beta-dihydroxyestr- 4-ene)
49. 19-Nor-5-androstenediol (3alpha, 17beta-dihydroxyestr-5-ene)
50. 19-Nor-5-androstenediol (3beta, 17beta-dihydroxyestr- 5-ene)
51. 19-Nor-4-androstenedione (estr-4-en-3, 17-dione)
52. 19-Nor-5-androstenedione (estr-5-en-3, 17-dione)
53. Norbolethone (13beta, 17alpha-diethyl-17beta- hydroxygon-4-en-3-one)
54. Norclostebol (4-chloro-17beta-hydroxyestr-4-en-3-one)
55. Norethandrolone (17alpha-ethyl-17beta- hydroxyestr-4-en-3-one)
56. Normethandrolone (17alpha-methyl-17beta- hydroxyestr-4-en-3-one)
57. Oxandrolone (17alpha-methyl-17beta-hydroxy-2- oxa-5alpha-androstan-3-one)
58. Oxymesterone (17alpha-methyl-4,17beta- dihydroxyandrost-4-en-3-one)

(Rule 0940-06-01-.03, continued)

59. Oxymetholone (17alpha-methyl-2-hydroxymethylene- 17beta-hydroxy-5alpha-androstan-3-one)
60. Stanolone
61. Stanozolol (17alpha-methyl-17beta-hydroxy- 5alpha-androst-2-eno[3,2-c]-pyrazole)
62. Stenbolone (17beta-hydroxy-2-methyl-5alpha-androst-1-en-3-one)
63. Testolactone (13-hydroxy-3-oxo-13, 17- secoandrosta-1, 4-dien-17-oic acid lactone)
64. Testosterone (17beta-hydroxyandrost-4-en-3-one)
65. Tetrahydrogestrinone (13beta, 17alpha-diethyl- 17beta-hydroxygon-4, 9, 11-trien-3-one)
66. Trenbolone (17beta-hydroxyestr-4, 9, 11-trien-3-one)

- (b) Any salt, ester, or isomer of a drug or substance described or listed in subparagraph (a), if such salt, ester, or isomer promotes muscle growth.
- (c) Anabolic steroids intended for administration to cattle or other non-human species are exempt from this rule unless such steroids are prescribed, dispensed, or distributed for human use.
- (d) Anabolic steroids with a combination of estrogens intended for administration to hormone deficient women are exempt from this rule unless such steroids are prescribed, dispensed, or distributed to women who are not hormone deficient.

## (7) Hallucinogenic Substances

- (a) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States food and drug administration approved drug product..... 7369  
Other names: (6a R-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6 H-dibenzo [bd]pyran-1-ol] or (-)-delta-9-(trans)-tetrahydrocannabinol]

**Authority:** T.C.A. §§4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, and 39-17-403. **Administrative History:** Original rule filed April 29, 1981; effective June 18, 1981. Repeal and new rule filed May 25, 1984; effective June 24, 1984. Repeal and new rule filed September 6, 1985; effective October 10, 1985. Repeal and new rule filed December 17, 1986; effective January 31, 1987. Amendment filed July 10, 1997; effective September 23, 1997. Repeal and new rule filed January 7, 2011; effective April 7, 2011.

**0940-06-01-.04 CONTROLLED SUBSTANCES IN SCHEDULE IV.**

- (1) Schedule IV consists of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this rule. Each drug or substance bears the federal controlled substance code number assigned to it by the Drug Enforcement Administration.
- (2) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(Rule 0940-06-01-.04, continued)

- (a) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit ..... 9167
- (b) Dextropropoxyphene dosage forms (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane)..... 9278
- (3) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substance, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - (a) Alprazolam..... 2882
  - (b) Barbital..... 2145
  - (c) Bromazepam ..... 2748
  - (d) Camazepam ..... 2749
  - (e) Carisoprodol ..... N/A  
Other name: Soma®
  - (f) Chloral betaine ..... 2460
  - (g) Chloral hydrate ..... 2465
  - (h) Chlordiazepoxide..... 2744
  - (i) Clobazam..... 2751
  - (j) Clonazepam ..... 2737
  - (k) Clorazepate ..... 2768
  - (l) Clotiazepam..... 2752
  - (m) Cloxazolam ..... 2753
  - (n) Delorazepam ..... 2754
  - (o) Diazepam..... 2765
  - (p) Dichloralphenazone..... 2467
  - (q) Estazolam ..... 2756
  - (r) Eszopiclone ..... N/A
  - (s) Ethchlorvynol ..... 2540
  - (t) Ethinamate ..... 2545
  - (u) Ethyl Loflazepate ..... 2758
  - (v) Fludiazepam ..... 2759

(Rule 0940-06-01-.04, continued)

(w) Flunitrazepam.....	2763
(x) Flurazepam.....	2767
(y) Fospropofol.....	2138
(z) Halazepam .....	2762
(aa) Haloxazolam.....	2771
(bb) Ketazolam.....	2772
(cc) Loprazolam.....	2773
(dd) Lorazepam.....	2885
(ee) Lormetazepam.....	2774
(ff) Mebutamate.....	2800
(gg) Medazepam.....	2836
(hh) Meprobamate .....	2820
(ii) Methohexital.....	2264
(jj) Methylphenobarbital (mephobarbital).....	2250
(kk) Midazolam .....	2884
(ll) Nimetazepam .....	2837
(mm) Nitrazepam .....	2834
(nn) Nordiazepam .....	2838
(oo) Oxazepam .....	2835
(pp) Oxazolam.....	2839
(qq) Paraldehyde .....	2585
(rr) Petrichoral .....	2591
(ss) Phenobarbital.....	2285
(tt) Pinazepam.....	2883
(uu) Prazepam .....	2881
(vv) Quazepam .....	2764
(ww) Temazepam.....	2925
(xx) Tetrazepam .....	2886

(Rule 0940-06-01-.04, continued)

- (yy) Tramadol..... N/A  
Other names: Ultram® and Ultracet®
- (zz) Triazolam..... 2887
- (aaa) Zaleplon..... 2781
- (bbb) Zolpidem..... 2783
- (ccc) Zopiclone..... 2784
- (4) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances including its salts, isomers (whether optical, positional, or geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:
  - (a) Fenfluramine..... 1670
  - (b) Dexfenfluramine ..... 1670
- (5) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - (a) Cathine ((+)-norpseudoephedrine)..... 1230
  - (b) Diethylpropion..... 1610
  - (c) Fencamfamin..... 1760
  - (d) Fenproporex ..... 1575
  - (e) Mazindol ..... 1605
  - (f) Mefenorex..... 1580
  - (g) Modafinil ..... 1680
  - (h) Pemoline (including organometallic complexes and chelates thereof) ..... 1530
  - (i) Phentermine ..... 1640
  - (j) Pipradol..... 1750
  - (k) Sibutramine ..... 1675
  - (l) SPA ((-)-1-dimethylamino-1,2-diphenylethane)..... 1635
- (6) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts:
  - (a) Pentazocine..... 9709

(Rule 0940-06-01-.04, continued)

(b) Butorphanol (including its optical isomers) ..... 9720

**Authority:** T.C.A. §§4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, and 39-17-403. **Administrative History:** Original rule filed April 29, 1981; effective June 18, 1981. Repeal and new rule filed May 25, 1984; effective June 24, 1984. Repeal and new rule filed September 6, 1985; effective October 10, 1985. Repeal and new rule filed December 17, 1986; effective January 31, 1987. Amendment filed July 10, 1997; effective September 23, 1997. Repeal and new rule filed January 7, 2011; effective April 7, 2011.

**0940-06-01-.05 CONTROLLED SUBSTANCES IN SCHEDULE V.**

- (1) Schedule V consists of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this rule. Each drug or substance bears the federal controlled substance code number assigned to it by the Drug Enforcement Administration.
- (2) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:
  - (a) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
  - (b) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
  - (c) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
  - (d) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
  - (e) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.
  - (f) Not more than 0.5 milligrams of difenoxin (DEA Drug Code No. 9168) and not less than 25 micrograms of atropine sulfate per dosage unit.
- (3) Stimulants. Unless specifically exempted or excluded, or unless listed in another schedule, any material, compound, mixture or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of the isomers:
  - (a) Pyrovalerone ..... 1485
- (4) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances have a depressant effect on the central nervous system, including its salts:
  - (a) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide] ..... 2746
  - (b) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] ..... 2782

**Authority:** T.C.A. §§4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, and 39-17-403. **Administrative History:** Original rule filed April 29, 1981; effective June 18, 1981. Repeal and new rule filed May 25, 1984; effective June 24, 1984. Repeal and new rule filed September 6, 1985; effective October 10, 1985.

(Rule 0940-06-01-.05, continued)

*Repeal and new rule filed December 17, 1986; effective January 31, 1987. Repeal and new rule filed January 7, 2011; effective April 7, 2011.*

**0940-06-01-.06 CONTROLLED SUBSTANCES IN SCHEDULE VI.**

- (1) Marijuana..... 7360
- (2) Tetrahydrocannabinols..... 7370
- (3) Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity. Examples include the following drugs or their compounds regardless of numerical designation of atomic positions covered:
  - (a) \_\_\_\_\_ 1 cis or trans tetrahydrocannabinol, and its optical isomers.
  - (b) \_\_\_\_\_ 6 cis or trans tetrahydrocannabinol, and its optical isomers.
  - (c) \_\_\_\_\_ 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers.

**Authority:** T.C.A. §§4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, and 39-17-403. **Administrative History:** Original rule filed April 29, 1981; effective June 18, 1981. Repeal and new rule filed May 25, 1984; effective June 24, 1984. Repeal and new rule filed September 6, 1985; effective October 10, 1985. Repeal and new rule filed December 17, 1986; effective January 31, 1987. Repeal and new rule filed January 7, 2011; effective April 7, 2011.

**0940-06-01-.07 CONTROLLED SUBSTANCE IN SCHEDULE VII.**

- (1) Butyl nitrite and any isomer of butyl nitrite

**Authority:** T.C.A. §§4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, and 39-17-403. **Administrative History:** Original rule filed April 29, 1981; effective June 18, 1981. Repeal and new rule filed May 25, 1984; effective June 24, 1984. Repeal and new rule filed September 6, 1985; effective October 10, 1985. Repeal and new rule filed December 17, 1986; effective January 31, 1987. Repeal and new rule filed January 7, 2011; effective April 7, 2011.

**0940-06-01-.08 NON-NARCOTIC SUBSTANCES EXCLUDED FROM CONTROLLED SUBSTANCES.**

- (1) Non-narcotic substances listed in the most current edition of 21 C.F.R. 1308.22, are excluded from all schedules.

**Authority:** T.C.A. §§4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, and 39-17-403. **Administrative History:** Original rule filed April 29, 1981; effective June 18, 1981. Repeal and new rule filed May 25, 1984; effective June 24, 1984. Repeal and new rule filed September 6, 1985; effective October 10, 1985. Repeal and new rule filed December 17, 1986; effective January 31, 1987. Amendment filed July 10, 1997; effective September 23, 1997. Repeal and new rule filed January 7, 2011; effective April 7, 2011.

**0940-06-01-.09 FINDINGS ABOUT THE POTENTIAL FOR ABUSE OF CARISOPRODOL.**

- (1) The actual or relative potential for abuse:

The majority of drug abuse, dependence and withdrawal cases involving carisoprodol or Soma® have been reported with prolonged use of the drug beyond several months of treatment or in combination with other depressant or psychotropic drugs.<sup>1</sup> One of the metabolites of carisoprodol, meprobamate, is a

<sup>1</sup> Soma® package insert. (2005). [Brochure].

(Rule 0940-06-01-.09, continued)

Schedule IV controlled substance at the federal level with potential for abuse.<sup>2</sup>

Abusers typically ingest carisoprodol orally in combination with other drugs to enhance the effects of alcohol, codeine, diazepam, heroin, hydrocodone (especially Vicodin®), meprobamate, and propoxyphene.<sup>3</sup> The effects of an overdose of carisoprodol and alcohol or other central nervous system depressants or psychotropic agents can be additive even when one of the drugs has been taken in the usual recommended dosage.<sup>4</sup> According to the National Drug Intelligence Center, some street names for Soma® are Ds, Dance, Las Vegas Cocktail (when mixed with hydrocodone), and Soma® Coma (when mixed with codeine).<sup>5</sup>

Due to concerns about the abuse potential and efficacy of Soma® in 2007, the Bureau of TennCare and the TennCare Pharmacy Advisory Committee reviewed the class of skeletal muscle relaxants and concluded all carisoprodol agents (brand, generic, and combination products) would be considered non-preferred on the TennCare Preferred Drug List.<sup>6</sup>

Tennessee community pharmacists also expressed concern about the abuse of carisoprodol in 2007 by responding to a brief survey developed by the Tennessee Department of Mental Health and Developmental Disabilities. Ninety-two percent (92%) of the 222 pharmacists surveyed indicated that carisoprodol was abused in Tennessee while 87.7% indicated that carisoprodol should be a controlled substance.

Although carisoprodol is not scheduled at the federal level, the following states have scheduled carisoprodol as a controlled substance. Alabama, Arizona, Arkansas, Florida, Georgia, Hawaii, Indiana, Kentucky, Louisiana, Nevada, New Mexico, Oklahoma, Oregon, Texas, Utah, Washington State, and West Virginia.<sup>7</sup> This list indicates that over half of the states bordering Tennessee (Alabama, Arkansas, Georgia and Kentucky) schedule carisoprodol as a controlled substance. In addition, several major wholesale pharmaceutical distributors, including Cardinal and Amerisource Bergen, are already shipping carisoprodol in secured totes designated for controlled substances.

(2) The scientific evidence of its pharmacological effect, if known:

Carisoprodol is a skeletal muscle relaxant metabolized into hydroxycarisoprodol, hydroxymeprobamate, and meprobamate.<sup>8</sup> One of its metabolites, meprobamate is a Schedule IV controlled substance at the federal level with known abuse potential. A 2004 study indicated that carisoprodol by itself probably has an impairing effect, similar to that of benzodiazepines, even taken in therapeutic dosages.<sup>9</sup> Studies conducted more recently indicate that carisoprodol has the potential to produce sedative effects similar to those of meprobamate, and it can do so without being metabolized to meprobamate.<sup>10</sup> Gonzalez (2009) reports "carisoprodol can directly produce notable CNS [central nervous system] depressant activity, and

<sup>2</sup> Soma® fast facts. (2004). [Brochure]. National Drug Intelligence Center, U.S. Department of Justice. Retrieved October 26, 2009 from <http://www.usdoj.gov/ndic/pubs10/10913/10913p.pdf>

<sup>3</sup> Soma® fast facts. (2004). [Brochure]. National Drug Intelligence Center, U.S. Department of Justice. Retrieved October 26, 2009 from <http://www.usdoj.gov/ndic/pubs10/10913/10913p.pdf>

<sup>4</sup> Soma® package insert. (2005).

<sup>5</sup> Soma® fast facts. (2004). [Brochure]. National Drug Intelligence Center, U.S. Department of Justice. Retrieved October 26, 2009 from <http://www.usdoj.gov/ndic/pubs10/10913/10913p.pdf>

<sup>6</sup> TennCare Pharmacy Program (11.27.2006). [Soma® provider notification letter]

<sup>7</sup> Sacks, H.J. (June 29, 2010) Written direct testimony In the matter of scheduling of carisoprodol. U.S. Department of Justice, Drug Enforcement Administration, Docket No. 10-46.

<sup>8</sup> Boothby, L.A., Doering, P.L., & Hatton, R.C. (2003). Carisoprodol: A marginally effective skeletal muscle relaxant with serious abuse potential. *Hospital Pharmacy*. 38, 337-345.

<sup>9</sup> Bramness, J.G., Skurtveit, S., & Morland, J. (2004). Impairment due to intake of carisoprodol. *Drug and Alcohol Dependence*. 74, 311-318.

<sup>10</sup> Gonzalez, L.A., Gatch, M.B., Taylor, C.M., Bell-Horner, C.L., Forster, M.J., & Dillon, G.H. (2009) Carisoprodol-mediated modulation of GABAA receptors: In vitro and in vivo studies. *The Journal of Pharmacology and Experimental Therapeutics*, 329, 827-837. doi: 10.1124/jpet.109.151142

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this activity may contribute to its abuse potential.”<sup>11</sup>

Carisoprodol is also pharmacologically similar to barbiturates (Schedule IV controlled substances) having an indirect agonist effect on the same GABA-A receptor site to which barbiturates bind. Supporting this assertion is a 2004 case study which found that individuals taking high doses of carisoprodol had the highest rate of barbiturate tolerance.<sup>12</sup>

When carisoprodol is taken in combination with hydrocodone, it produces an effect similar to the consumption of heroin.<sup>13</sup> Carisoprodol may also be used to augment the effect of sedatives, such as benzodiazepines or alcohol. Taken in combination with tramadol, the two (2) medications may produce psychotropic effects.<sup>14</sup>

(3) The state of current scientific knowledge regarding the substance:

A 2003 review paper<sup>15</sup> examined the literature on the efficacy and abuse potential of carisoprodol. The authors of this paper found little data supporting the efficacy of carisoprodol in the relief of skeletal muscle pain. Other classes of drugs were found to be more effective than carisoprodol for pain relief. Patients with a history of previous substance abuse were more likely to abuse carisoprodol. To decrease the possibility of dependence, the authors recommend carisoprodol only be used for short-term therapy since long-term use is associated with the development of tolerance, dependence and addiction. A 2004 review paper<sup>16</sup> found fair evidence that carisoprodol is effective compared to placebo in patients with musculoskeletal conditions, primarily acute neck and back pain.

A 2007 retrospective analysis of Medicaid claims data in Idaho found that long-term users of carisoprodol displayed abuse potential more frequently than long-term users of other skeletal muscle relaxers. Carisoprodol users were more likely than other users of skeletal muscle relaxers to use opioids, to have histories of drug abuse, and to continue to pay out of pocket when third party coverage was discontinued.<sup>17</sup>

(4) The history and current pattern of abuse:

A comparison of the Drug Abuse Warning Network (DAWN) data on emergency department visits attributed to the non-medical use of carisoprodol indicates an increase of 84% between 2004 and 2007. Carisoprodol was involved in 14,736 emergency department visits related to non-medical use in 2004 and carisoprodol was the most frequently named muscle relaxant (56.8%) in visits involving muscle relaxants. By 2007, the number of emergency department visits involving the non-medical use of carisoprodol had increased 84% or 27,128 visits related to non-medical use.<sup>18</sup>

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<sup>11</sup> Gonzalez, L.A., Gatch, M.B., Taylor, C.M., Bell-Horner, C.L., Forster, M.J., & Dillon, G.H. (2009) Carisoprodol-mediated modulation of GABAA receptors: In vitro and in vivo studies. *The Journal of Pharmacology and Experimental Therapeutics*, 329, 827-837. doi: 10.1124/jpet.109.151142

<sup>12</sup> Ni, K., Cary, M., & Zarkowski, P. (2007), Carisoprodol withdrawal induced delirium: A case study, *Neuropsychiatric Disease and Treatment*, 3, 679-682.

<sup>13</sup> Soma® fast facts. (2004). [Brochure]. National Drug Intelligence Center, U.S. Department of Justice. Retrieved October 26, 2009 from <http://www.usdoj.gov/ndic/pubs10/10913/10913p.pdf>

<sup>14</sup> Reeves, R.R., & Liberto, V. (2001). Abuse of combinations of carisoprodol and tramadol. *Southern Medical Journal*, 94, 512-514.

<sup>15</sup> Boothby, L.A., Doering, P.L., & Hatton, R.C. (2003). Carisoprodol: A marginally effective skeletal muscle relaxant with serious abuse potential. *Hospital Pharmacy*. 38, 337-345.

<sup>16</sup> Chou, R., Peterson, K., & Helfand, M. (2004) Comparative efficacy and safety of skeletal muscle relaxants for spasticity and musculoskeletal conditions: A systematic review. *Journal of Pain and Symptom Management*. 28, 140-175.

<sup>17</sup> Owens, C. et al. (2007). Abuse potential of carisoprodol: A retrospective review of Idaho Medicaid pharmacy and medical claims data. *Clinical Therapeutics*. 29, 2222-2225.

<sup>18</sup> Drug Abuse Warning Network. 2007: National estimates of drug-related emergency department visits and 2004: Selected tables of national estimates of drug-related emergency department visits. Office of

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Possible contributing factors to the increased numbers may be the ready availability of the drug, the social acceptability of the use of prescription drugs versus illicit drugs, and the notion that prescription drugs are safer to use than illicit drugs.<sup>19 20</sup> The table below shows historical data for case mentions of carisoprodol to Poison Control Centers<sup>21</sup> over seven (7) years.

Poison Control Centers' Case Mentions	
Year	Carisoprodol
2001	6,991
2002	7,364
2003	7,848
2004	8,368
2005	8,337
2006	8,007
2007	8,658

## (5) The scope, duration and significance of abuse:

Soma® (carisoprodol) is one of the top ten prescription drugs listed on death certificates in Tennessee. Tennessee deaths from prescription drug overdoses increased 53% between 2002 and 2006. In 2006, deaths from prescription drug overdoses far exceeded those from illicit drugs (323 to 73). Tennessee's prescription drug overdose rate is 26% above the national average and Tennessee leads the nation in the number of controlled substance prescriptions per capita.<sup>22</sup> According to the National Survey on Drug Utilization and Health, 2,276,000 U.S. residents ages 12 and older admitted using carisoprodol for non-medical purposes.<sup>23</sup>

## (6) The risk to the public health:

To the extent that carisoprodol may be abused or may be used in concert with other drugs producing addictive results, it may be a risk to the public health. Carisoprodol has been linked to intoxication while driving and death.<sup>24</sup>

## (7) The potential of the substance to produce psychic or physiological dependence liability:

The inappropriate use of carisoprodol causes its meprobamate metabolite to accumulate in the body

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Applied Studies, Substance Abuse and Mental Health Services Administration. Retrieved 7/15/2010 from <https://dawninfo.samhsa.gov/pubs/edpubs/>

<sup>19</sup> Reeves, R.R. & Burke, R.S. (2008). Is it time for carisoprodol to become a controlled substance at the federal level? *Southern Medical Journal*, 101, 127-128.

<sup>20</sup> Skellen, D. & Novak, S., & Ball, J. Emergency department visits involving nonmedical use of selected pharmaceuticals. (2006). *The New Dawn Report of the Office of Applied Studies, Substance Abuse and Mental Health Services Administration*, 23.

<sup>21</sup> Annual reports of the American Association of Poison Control Centers. Retrieved October 26, 2009 from <http://www.aapcc.org/dnn/NPDS/AnnualReports/tabid/125/Default.aspx>

<sup>22</sup> Former Hawkins County doctor convicted on health care fraud, drug, and tax charges. (July 17, 2009). *Press release by United States Attorney James R. Dedrick, Eastern District of Tennessee Department of Justice*.

<sup>23</sup> Reeves, R.R. & Burke, R.S. (2008). Is it time for carisoprodol to become a controlled substance at the federal level? *Southern Medical Journal*, 101, 127-128.

<sup>24</sup> Hoiseth, G. et al. (2009). The effect of scheduling and withdrawal of carisoprodol on prevalence of intoxications with the drug. *Nordic Pharmacological Society Basic & Clinical Pharmacology & Toxicology*. 1-5.

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resulting in sedative and subjective mood-altering effects. Carisoprodol is also known to potentiate the sedating and euphoria-inducing properties of ethanol as well as other drugs of abuse.<sup>25</sup> Carisoprodol and related compounds are considered addictive agents that may induce withdrawal symptoms upon discontinuation.<sup>26 27</sup> Withdrawal symptoms consist of insomnia, palpitations, vomiting, tremors, muscle twitching, anxiety, disorientation, ataxia, hallucinations, delusions, delirium, and suicidal ideations. These symptoms are similar to withdrawal symptoms for meprobamate.<sup>28</sup> Since 2007, at least four case reports have documented carisoprodol withdrawal syndrome which results in becoming anxious, jittery, and having hallucinations.<sup>29 30 31</sup>

- (8) Whether the substance is an immediate precursor of a substance already controlled under this chapter:

Carisoprodol is not an immediate precursor of a controlled substance; however, it is a parent drug of meprobamate. Carisoprodol both metabolizes to meprobamate, a controlled substance, and produces sedative effects similar to meprobamate without being metabolized.<sup>32</sup>

**Authority:** T.C.A. §§ 4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, and 39-17-403. **Administrative History:** Original rule filed January 7, 2011; effective April 7, 2011.

#### 0940-06-01-.10 FINDINGS ABOUT THE POTENTIAL FOR ABUSE OF TRAMADOL.

- (1) The actual or relative potential for abuse:

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<sup>25</sup> TennCare Pharmacy Program (11.27.2006). [Soma® provider notification letter]

<sup>26</sup> Soma® package insert. (2005). [Brochure]

<sup>27</sup> Ni, K., Cary, M., & Zarkowski, P. (2007). Carisoprodol withdrawal induced delirium: A case study. *Neuropsychiatric Disease and Treatment*, 3, 679–682.

<sup>28</sup> Reeves, R.R., Hammer, J.S., & Pendarvis, R.O. (2007). Is the frequency of carisoprodol withdrawal syndrome increasing? *Pharmacotherapy*, 27, 1462-1466.

<sup>29</sup> Reeves, R.R., Hammer, J.S., & Pendarvis, R.O. (2007) Is the frequency of carisoprodol withdrawal syndrome increasing? *Pharmacotherapy*, 27, 1462-1466.

<sup>30</sup> Eleid, M.F., Krahn, L.E., Agrwal, N., & Goodman, B.P. (2010) Carisoprodol withdrawal after internet purchase. *Neurologist*, 16, 262-264.

<sup>31</sup> Ni, K., Cary, M., & Zarkowski, P. (2007) Carisoprodol withdrawal induced delirium: A case study. *Neuropsychiatric Disease and Treatment*, 3, 679-682.

<sup>32</sup> Gonzalez, L.A., Gatch, M.B., Taylor, C.M., Bell-Horner, C.L., Forster, M.J., & Dillon, G.H. (2009) Carisoprodol-mediated modulation of GABAA receptors: In vitro and in vivo studies. *The Journal of Pharmacology and Experimental Therapeutics*, 329, 827-837. doi: 10.1124/jpet.109.151142

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Tramadol or ULTRAM ER® is an opioid agonist of the morphine-type.<sup>33</sup> Tramadol can cause dependence and abuse, including drug-seeking behavior and illicit action to obtain the drug not limited to those patients with a history of opioid dependence.<sup>34</sup>

Recent revisions in the package insert for ULTRACET® reflect growing concern about the abuse and diversion potential of tramadol. In March 2010, PriCara®, Division of Ortho-McNeil Janssen Pharmaceuticals, Inc., in cooperation with the U.S. Food and Drug Administration, sent out a letter to healthcare professionals warning them to not prescribe ULTRACET® (tramadol) for patients who are addiction-prone, who use alcohol in excess, or are depressed or suicidal, or who suffer from emotional disturbance. The letter also warns that tramadol can be abused and may be subject to criminal diversion.<sup>35</sup>

Tramadol is abused by ingesting, inhaling or injecting crushed tablets. These practices result in the uncontrolled delivery of the opioid and pose a significant risk to the abuser that could result in overdose and death.<sup>36 37</sup> Excessive dosages of tramadol can result in seizures, respiratory depression and death.<sup>38</sup>

Tramadol-related emergency room visits nationwide reached 6,048 in 2006, up from 5,918 in 2005 and 4,849 in 2004.<sup>39</sup> The American Association of Poison Control Centers also reports increasing case mentions of tramadol. In 2007, there were 7,500 case mentions of tramadol up from 5,965 in 2006; and 4,053 single exposures (1 death) up from 3, 247 in 2006 (2 deaths).<sup>40</sup>

In 2008, the National Forensic Laboratory System (NFLIS) reported that law enforcement submissions of drug items/exhibits involving tramadol increased 36% over 2007. From 1995-2004 the FDA received 766 case reports of tramadol abuse and 482 cases of withdrawal associated with tramadol.<sup>41</sup>

Currently tramadol is controlled in 2 bordering states, Kentucky and Arkansas and reported to controlled substance databases in several other states. In 2006-2007, Arkansas, Kentucky, and Tennessee ranked in the top fifth of states nationwide for non-medical use of pain relievers.<sup>42</sup>

(2) The scientific evidence of its pharmacological effect, if known:

Tramadol is a central acting analgesic having both opioid and non-opioid mechanisms of action. Opioid activity is due to both the parent compound and its M1 metabolite (O-desmethylated tramadol). The M1

<sup>33</sup> ULTRAM® ER package insert. (2007). [Brochure].

<sup>34</sup> Soyka, M. Backmund, M, & Hasemann, S. (2004). Tramadol use and dependence in chronic noncancer pain patients. *Pharmacopsychiatry*, 37, 191-192.

<sup>35</sup> Rosenthal, N. (2010, March) Important Drug Warning. (Letter to healthcare professionals describing changes in prescribing information for ULTRACET®) PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. 1-3.

<sup>36</sup> Ultam ER® package insert. (2007). [Brochure].

<sup>37</sup> Tjaderborn, M. et al. (2007). Fatal unintentional intoxications with tramadol during 1995–2005. *Forensic Science International*, 173, 107–111.

<sup>38</sup> Skipper, G.E. et al. (2004). Research letter: Tramadol abuse and dependence among physicians. *JAMA*. 292, 1818-1819.

<sup>39</sup> Drug Abuse Warning Network: 2004, 2005, 2006 (2008). Retrieved from <https://dawninfo.samhsa.gov/pubs/edpubs/tables.asp>

<sup>40</sup> Annual reports of the American Association of Poison Control Centers. Retrieved October 26, 2009 from <http://www.aapcc.org/dnn/NPDS/AnnualReports/tabid/125/Default.aspx>

<sup>41</sup> Drugs and chemicals of concern: Tramadol. (2009). Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice. Retrieved October 26, 2009 from [http://www.deadiversion.usdoj.gov/drugs\\_concern/tramadol.htm](http://www.deadiversion.usdoj.gov/drugs_concern/tramadol.htm)

<sup>42</sup> State estimates of substance use from the 2006–2007 National Surveys on Drug Use and Health. (May, 2009). Office of Applied Studies, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services. 18. Retrieved November 5, 2009 from <http://oas.samhsa.gov/2k7state/2k7State.pdf>

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metabolite of tramadol has significant affinity for opioid receptors.<sup>43</sup> Tramadol also acts on the monoamine reuptake systems by inhibiting the reuptake into nerve terminals of both norepinephrine and serotonin.<sup>44</sup>

Tramadol is shown to have the equivalent potency to low doses of meperidine, metamizole, and morphine used to relieve various types of pain, such as lung, heart, abdomen post-operative, musculoskeletal, and obstetrical.<sup>45</sup>

Apart from analgesia, tramadol may produce a number of symptoms including dizziness, somnolence, nausea, and constipation similar to other opioids. High doses of tramadol, often in combination with monoamine oxidase inhibitors (MAOIs) or serotonin-selective reuptake inhibitors (SSRIs), have been associated with a serotonin syndrome consisting of convulsions, hyperthermia, muscle rigidity and pain. Seizures have occurred in patients taking recommended doses but are more likely at high doses associated with abuse of this medication.<sup>46</sup>

(3) The state of current scientific knowledge regarding the substance:

A 2008 article in the *Journal of Clinical Pharmacy and Therapeutics* describes studies which explored the analgesic mechanisms of tramadol. Early studies identified the opioid mechanism of action. Later studies found that its analgesic effect stems from a dual mechanism of action.<sup>47</sup>

A 2006 research review<sup>48</sup> indicates that tramadol substitutes for morphine in rats. Based on analgesic studies in humans, tramadol is thought to be approximately one-tenth as potent as morphine when each is administered parenterally and approximately one-third as potent when each is administered orally. Human studies indicate that maximum ratings on “feel drug” and “liking” scales occur much later than the maximum responses to oxycodone. This delayed response is consistent with the observation that tramadol’s mu-agonist properties require its biotransformation to an active metabolite that mimics the effect of opiates and acts on the same receptors as hydrocodone, oxycodone, and morphine.

In the first three years of postmarketing surveillance of Ultram®, 1,248 adverse events were reviewed by an Independent Steering Committee.<sup>49</sup> Approximately one-third (N = 422) were rated as withdrawal, with most (N = 367) indicating typical opioid withdrawal-like signs and symptoms, but with a small proportion (N = 55) identified as atypical (not opioid withdrawal-like).

A number of post-marketing surveillance studies have explored the abuse of tramadol in high-risk populations such as impaired health professionals with easy access to the drug. The incidence rate of tramadol use in one study of impaired professionals in Florida, Illinois, Pennsylvania, and Washington

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<sup>43</sup> Raffa, R.B. (2008). Basic pharmacology relevant to drug abuse assessment. *Journal of Clinical Pharmacy and Therapeutics*, 33, 101-108.

<sup>44</sup> Drugs and chemicals of concern: Tramadol. (2009). Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice. Retrieved October 26, 2009 from [http://www.deadiversion.usdoj.gov/drugs\\_concern/tramadol.htm](http://www.deadiversion.usdoj.gov/drugs_concern/tramadol.htm)

<sup>45</sup> Knisely, J.S. et al. (2002). Tramadol post-marketing surveillance in health care professionals. *Drug and Alcohol Dependence*, 68, 15-22.

<sup>46</sup> Drugs and chemicals of concern: Tramadol. (2009). Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice. Retrieved October 26, 2009 from [http://www.deadiversion.usdoj.gov/drugs\\_concern/tramadol.htm](http://www.deadiversion.usdoj.gov/drugs_concern/tramadol.htm)

<sup>47</sup> Raffa, R.B. (2008) Basic Pharmacology Relevant to Drug Abuse Assessment. *Journal of Clinical Pharmacy and Therapeutics*. 33, 101-108.

<sup>48</sup> Epstein, D.H., Preston, K.L., & Jasinski, D.R. (2006). Abuse liability, behavioral pharmacology, and physical-dependence potential of opioids in humans and laboratory animals: Lessons from tramadol. *Biological Psychology*, 73, 90-99.

<sup>49</sup> Senay, E.C. et al. (2003) Physical Dependence on Ultram® (tramadol hydrochloride): Both Opioid-like and Atypical Withdrawal Symptoms Occur. *Drug and Alcohol Dependence*. 69, 233-241.

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was 69 per 1,000 per year.<sup>50</sup> Professionals with prescription privileges specializing in internal medicine, emergency medicine or family practice were more likely to use tramadol than other specialties. The most frequent primary substance of abuse for tramadol users was opioids. Tramadol users reported more relapse episodes than the non-tramadol users.

(4) The history and current pattern of abuse:

According to a 2006 article in the *Journal of Addictive Diseases*<sup>51</sup>, drug abuse-related emergency department visits involving opioid pain relievers have been increasing steadily, from 45,254 in 1995 to 119,185 in 2002. The number of persons ages twelve (12) and older reporting lifetime nonmedical use of opioid pain relievers increased from 29.6 million in 2002 to 31.2 million in 2003. The data for lifetime nonmedical use of tramadol increased from 52,000 in 2002 to 186,000 in 2003. Comparatively, the increases of lifetime nonmedical use of hydrocodone and oxycodone was less dramatic, showing an increase from 17.7 million to 21.4 million for hydrocodone and an increase from 11.6 million to 13.6 million for oxycodone.

The table and graph below show historical data for case mentions of tramadol and oxycodone to Poison Control Centers<sup>52</sup> since 2002. Both illustrate that case mentions for tramadol increased at a faster rate than case mentions for oxycodone during this time period.

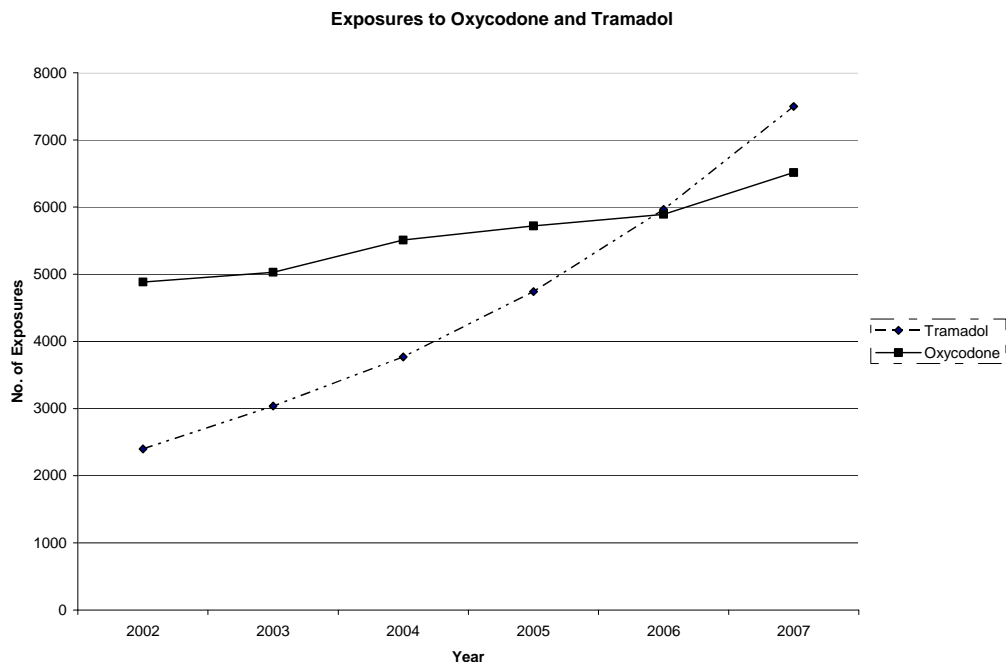
Year	Tramadol	Oxycodone
2002	2,400	4,883
2003	3,039	5,030
2004	3,769	5,510
2005	4,740	5,719
2006	5,965	5,893
2007	7,500	6,515

<sup>50</sup> Knisely, J.S. et al. (2002). Tramadol post-marketing surveillance in health care professionals. *Drug and Alcohol Dependence*, 68, 15-22.

<sup>51</sup> Inciardi, J.A., et. al. (2006). The diversion of Ultram®, Ultracet® and Generic Tramadol HCl. *Journal of Addictive Diseases*. 25, 53-58.

<sup>52</sup> Annual reports of the American Association of Poison Control Centers. Retrieved October 26, 2009 from <http://www.aapcc.org/dnn/NPDS/AnnualReports/tabid/125/Default.aspx>

(Rule 0940-06-01-.10, continued)



## (5) The scope, duration and significance of abuse:

The package insert indicates that ULTRAM ER®, like other opioids, can be abused and may be diverted for non-medical use. Dependence and drug-seeking behavior and taking illicit actions to obtain the drug are not limited to patients with a history of opioid dependence. The risk in patients with substance abuse has been observed to be higher. Tramadol is associated with craving and tolerance development.<sup>53</sup>

Emergency room visits involving nonmedical use of tramadol increased 58% from 3,948 in 2004 to 7,662 in 2007 according to a recent Drug Abuse Warning Network (DAWN) report.<sup>54</sup> This report indicates that between 2005 and 2007, the use of tramadol related to suicide attempts increased 147% nationwide. An estimated 2,669 patients using tramadol visited emergency departments for a suicide attempt in 2007. This represents 1,590 more visits than in 2005. Of the 7,662 emergency room visits related to tramadol in 2007, 11% were patients seeking detoxification services. The number of patients seeking detoxification services (858) in 2007 represents a 76% increase in the number of patients seeking such services (486) in 2005.

The risk of tramadol abuse and dependence in patients with a history of substance abuse has been observed to be higher than pain patients. The abuse of tramadol in pain patients is estimated to be 0.5 to 1/100,000 cases according to a 2005 study of abuse and diversion of tramadol. Actual abuse of tramadol occurred almost exclusively, ninety-five percent (95%), in individuals with a past history of substance abuse.<sup>55</sup>

Tramadol is a drug abused by health professionals. Both the Tennessee Pharmacy Recovery Network (pharmacists) and the Tennessee Professional Assistance Program (nurses, occupational and physical therapists, respiratory therapists, emergency management professionals, and physician assistants)

<sup>53</sup> ULTRAM® ER package insert. (2007). [Brochure].

<sup>54</sup> Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (2010) *Drug Abuse Warning Network, 2007: National Estimates of Drug-Related Emergency Department Visits*. Accessed 7/22/2010 from <http://dawninfo.samhsa.gov/files/ed2007/dawn2k7ed.pdf>

<sup>55</sup> Cicero, T.J., et al. (2005). Rates of abuse of tramadol remain unchanged with the introduction of new branded and generic products: Results of an abuse monitoring system, 1994–2004. *Pharmacoepidemiology and Drug Safety*, 14, 851–859.

(Rule 0940-06-01-.10, continued)

screen impaired health professionals for tramadol substance abuse. According to the Tennessee Professional Assistance Program, drug screens indicate that eleven percent (11%) of impaired health professionals test positive for tramadol.

A study of case records of physicians from Alabama and Michigan being monitored for substance abuse found that physicians mentioning tramadol as a drug of abuse constituted ten percent (10%) of all physicians mentioning any opioid in case records. For comparison, the most frequently abused drug, hydrocodone, was mentioned in forty-one percent (41%) of opioid abuse cases. Of thirty-three (33) physicians abusing tramadol, twenty-four percent (24%) indicated tramadol as a primary drug of abuse, forty-two percent (42%) experienced relapse with tramadol, and thirty percent (30%) substituted tramadol for their drug of choice.<sup>56</sup>

In Appalachia, the proportion of admissions to treatment for primary abuse of other opiates and synthetics, including tramadol, is considerably higher than in the U.S. Between 2000 and 2004, admissions more than doubled from 3.49% in 2000 to 7.54% in 2004.<sup>57</sup> Such drugs are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.

(6) The risk to the public health:

To the extent that this drug may be abused or may be used in concert with other drugs producing addictive and sometimes fatal results, it may be a risk to the public health. Tramadol may be a contributor in patients' deaths when taken in excess with other drugs that depress central nervous functions, such as analgesics, muscle relaxants and antidepressants.<sup>58</sup>

(7) The potential of the substance to produce psychic or physiological dependence liability:

Tolerance, dependence and addiction to tramadol have been demonstrated. Based on the pharmacological effect of tramadol when consumed alone or with other drugs as well as the withdrawal effects when abruptly discontinued, it may produce a psychological dependence depending on the dosage consumed and the patient's past history of drug abuse.

Withdrawal symptoms may occur if tramadol is discontinued abruptly and may include the following: anxiety, sweating, insomnia, rigors, nausea, tremors, diarrhea, upper respiratory tract symptoms, piloerection, and in some cases, hallucinations. Abrupt cessation from tramadol has been associated with two types of withdrawal syndromes.<sup>59</sup> One is typical of opioid drugs with flu-like symptoms, restlessness and drug craving. This type of withdrawal syndrome is encountered in about 90 percent of cases of withdrawal from tramadol. Another withdrawal syndrome (encountered in about 10 percent of cases of tramadol withdrawal) is atypical of opioids and is associated with hallucinations, paranoia, extreme anxiety, panic attacks, confusion, and numbness and tingling in the extremities.<sup>60</sup>

(8) Whether the substance is an immediate precursor of a substance already controlled under this chapter:

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<sup>56</sup> Skipper, G.E., Fletcher, C., & Rocha-Judd, R. Tramadol abuse and dependence among physicians. *JAMA*. 292, 1818-1819.

<sup>57</sup> Office of Applied Studies of the Substance Abuse and Mental Health Services Administration. (2008). Treatment Episode Data Set (TEDS) 2000-2004: National Admissions to Substance Abuse Treatment Services. Retrieved October 26, 2009 from <http://www.oas.samhsa.gov/dasis.htm#teds2>

<sup>58</sup> Tjaderborn, M. et al. (2007). Fatal unintentional intoxications with tramadol during 1995-2005. *Forensic Science International*. 173, 107-111.

<sup>59</sup> Senay, E.C. et al. (2003). Physical dependence on Ultram® (tramadol hydrochloride): Both opioid-like and atypical withdrawal symptoms occur. *Drug and Alcohol Dependence*, 69, 233-241.

<sup>60</sup> Drugs and chemicals of concern: Tramadol. (2009). Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice. Retrieved October 26, 2009 from [http://www.deadiversion.usdoj.gov/drugs\\_concern/tramadol.htm](http://www.deadiversion.usdoj.gov/drugs_concern/tramadol.htm)

(Rule 0940-06-01-.10, continued)

This substance is not an immediate precursor of a substance already controlled under this chapter.

**Authority:** T.C.A. §§ 4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, and 39-17-403. **Administrative History:** Original rule filed January 7, 2011; effective April 7, 2011.

**0940-06-01-.11 NOTICE OF AUTOMATIC SCHEDULING OF CERTAIN SUBSTANCES**

- (1) Under T.C.A. § 39-17-403, the Tennessee Department of Mental Health and Developmental Disabilities, upon agreement of the Tennessee Department of Health, has the responsibility for controlling substances 30 days after a substance is designated, rescheduled or deleted as a controlled substance under federal law. Based on action by the U.S. Department of Justice Drug Enforcement Administration (DEA), changes in the scheduling status of the following substances have been automatically incorporated into these rules.
  - (a) Schedule I substances deleted by final rule of the DEA. (June 29, 2010) *Federal Register*, 75, 37300-37301.
    - 1. Benzylfentanyl (N-[1-benzyl-4-piperidyl]-N-phenylpropanamide)..... 9818
    - 2. Thenylfentanyl (N-[1-(2-thienyl) methyl-4-piperdy]-N-phenylpropanamide) ... 9834
  - (2) Schedule II substance not listed in the *Electronic Code of Federal Regulations*. Accessed on September 10, 2010.
    - Diprenorphine..... 9058
  - (3) Schedule II substance added by final rule of the DEA (June 29, 2010). *Federal Register*, 75, 37295-37299.
    - (a) Immediate precursor to fentanyl:
      - 1. 4-anilino-N-phenethyl-4-piperidine (ANPP) ..... 8333
  - (4) Schedule III substances added to the list of anabolic steroids by final rule of the DEA. (December 4, 2009) *Federal Register*, 74, 63603-63609.
    - (a) Boldione (androsta-1,4-diene-3,17-dione)
    - (b) Desoxymethyltestosterone (17alpha-methyl-5alpha-androst-2-en-17beta-ol)  
Other names: Madol.
    - (c) 19-Nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione)

**Authority:** T.C.A. §§ 4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, and 39-17-403. **Administrative History:** Original rule filed January 7, 2011; effective April 7, 2011.