WEST VIRGINIA LEGISLATURE

REGULAR SESSION, 1991

ENROLLED

SENATE BILL NO. 453

(By Senator Humphreys)

PASSED March 9, 1991

In Effect from **Passage**

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[Passed March 9, 1991; in effect from passage.]

AN ACT to amend and reenact sections two hundred four, two hundred six and two hundred eight, article two, chapter sixty-a of the code of West Virginia, one thousand nine hundred thirty-one, as amended; and to further amend said chapter by adding thereto a new article, designated article eight, all relating to the uniform controlled substances act; changing the lists of controlled substances in Schedule I, Schedule II and Schedule III; relating to licensing of those engaged in wholesale distribution of prescription drugs; and wholesale drug distributor advisory committee.

Be it enacted by the Legislature of West Virginia:

That sections two hundred four, two hundred six and two hundred eight, article two, chapter sixty-a of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended and reenacted; and that said chapter be further amended by adding thereto a new article, designated article eight, to read as follows:

ARTICLE 2. STANDARDS AND SCHEDULES.

§60A-2-204. Schedule I.

(a) The controlled substances listed in this section are included in Schedule I.

(b) Unless specifically excepted or unless listed 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:

(1) Acetyl-alpha-methylfentanyl (N-[1-(-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

(2) Acetylmethadol;

(3) Allylprodine;

(4) Alphacetylmethadol;

(5) Alphameprodine;

(6) Alphamethadol;

(7) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl) ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

(8) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl) ethyl-4-piperidinyl]-N-phenylpropanamide);

(9) Benzethidine;

(10) Betacetylmethadol;

(11) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

(12) Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl] - N-phenylpropanamide);

(13)Betameprodine;

(14) Betamethadol;

(15) Betaprodine;

(16) Clonitazene;

(17) Dextromoramide;

(18) Diampromide;

(19) Diethylthiambutene;

(20) Difenoxin;

(21) Dimenoxadol;

(22) Dimepheptanol;

(23) Dimethylthiambutene;

(24) Dioxaphetyl butyrate;

(25) Dipipanone;

(26) Ethylmethylthiambutene;

(27) Etonitazene;

(28) Etoxeridine;

(29) Furethidine;

(30) Hydroxypethidine;

(31) Ketobemidone;

(32) Levomoramide;

(33) Levophenacylmorphan;

(34) 3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide);

(35) 3-methylthiofentanyl (N-[3-methyl-1-(2-thienyl) ethyl-4-piperinyl]-N-phenylpropanamide);

(36) Morpheridine;

(37) MPPP (1-methyl-4-phenyl-4-propionoxy-piperidine);

(38) Noracymethadol;

(39) Norlevorphanol;

(40) Normethadone;

(41) Norpipanone;

(42) Para-fluorofentanyl (N-(4-fluorophenyl) -N-[1-(2-phenethyl)-4-piperidinyl]-propanamide);

(43) PEPAP(1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

(44) Phenadoxone;

(45) Phenampromide;

(46) Phenomorphan;

(47) Phenoperidine;

(48) Piritramide;

(49) Proheptazine;

(50) Properidine;

(51) Propiram;

(52) Racemoramide;

(53) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

(54) Tilidine;

(55) Trimeperidine.

(c) *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:

(1) Acetorphine;

(2) Acetyldihydrocodeine;

(3) Benzylmorphine;

(4) Codeine methylbromide;

(5) Codeine-N-Oxide;

(6) Cyprenorphine;

(7) Desomorphine;

(8) Dihydromorphine;

(9) Drotebanol;

(10) Etorphine (except HCl Salt);

(11) Heroin;

(12) Hydromorphinol;

(13) Methyldesorphine;

(14) Methyldihydromorphine;

(15) Morphine methylbromide;

(16) Morphine methylsulfonate;

(17) Morphine-N-Oxide;

(18) Myrophine;

(19) Nicocodeine;

(20) Nicomorphine;

(21) Normorphine;

(22) Phoclodine;

(23) Thebacon.

(d) *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 the salts, isomers and salts of isomers is possible within the specific chemical designation (for the purposes of this subsection only, the term "isomer" includes the optical, position and geometric isomers):

(1) 4-bromo-2, 5-dimethoxy-amphetamine; some trade or other names: 4-bromo-2, 5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA;

(2) 2,5-dimethoxyamphetamine; some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA;

(3) 4-methoxyamphetamine; some trade or other names: 4-methoxy-a-methylphenethylamine; para-menthoxyamphetamine; PMA;

(4) 5-methyloxy-3, 4-methylenedioxy-amphetamine;

(5) 4-methyl-2,5-dimethoxy-amphetamine; some trade and other names: 4-methyl-2,5-dimethoxy-a-methylphenethylamine; "DOM"; and "STP";

(6) 3,4-methylenedioxy amphetamine;

(7) 3,4-methylenedioxymethamphetamine (MDMA);

(8) 3,4,5-trimethoxy amphetamine;

(9) Bufotenine; some trade and other names: 3-(B-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine;

(10) Diethyltryptamine; some trade and other names: N, N-Diethyltryptamine; DET;

(11) Dimethyltryptamine; some trade or other names: DMT;

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

(13) Lysergic acid diethylamide;

(14) Marihuana;

(15) Mescaline;

(16) Parahexyl—7374; some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6, 6, 9-triethyl-6H-dibenzo [b,d] pyran; Synhexyl;

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

(18) N-ethyl-3-piperidyl benzilate;

(19) N-methyl-3-piperidyl benzilate;

(20) Psilocybin;

(21) Psilocyn;

(22) Tetrahydrocannabinols; 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 such as the following:

-1 Cis or trans tetrahydrocannabinol, and their optical isomers;

-6 Cis or trans tetrahydrocannabinol, and their optical isomers;

-3,4 Cis or trans tetrahydrocannabinol, and its optical isomers;

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

(23) Ethylamine analog of phencyclidine; some trade or other names: N-ethyl-1-phenylcyclo-hexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE;

(24) Pyrrolidine analog of phencyclidine; some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP;

(25) Thiophene analog of phencyclidine; some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine; TPCP, TCP;

(26) Pyrrolidine analog of phencyclidine; some trade or other names: l-(l-phenylcyclohexyl)-pyrrolidine, PCPy, PHP;

(27) N-ethylamphetamine;

(28) Parahexyl;

(29) 4-Methylaminorex;

(30) 3,4-Methylenedioxy-N-Ethylamphetamine;

(31) N-Hydroxy-3, 4-Methylenedioxyamphetamine.

(e) Unless specifically excepted or unless listed in another schedule, any of the following depressants, 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:

(1) Mecloqualone;

(2) Methaqualone.

(f) Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) Acetyl-alphamethylfentanyl;

(2) Alpha-methylthiofentanyl;

(3) Benzylfentanyl;

(4) Beta-hydroxyfentanyl;

(5) Beta-hydroxy-3-methylfentanyl;

(6) 3-Methylthiofentanyl;

(7) Thenylfentanyl;

(8) Thiofentanyl;

(9) 1-Methyl-4-phenyl-4-propionoxypiperidine (MPPP), its optical isomers, salts and salts of isomers;

(10) 1-(2-Phenylethyl)-4-phenyl-4-acetyloxypiperdine (PEPAP), its optical isomers, salts and salts of isomers;

(11) 3-Methylfentanyl (N-(3-methyl-1-(2-phenylethyl) - 4-piperidyl)-N-phenylpropanamide), its optical and geometric isomers, salts and salts of isomers.

§60A-2-206. Schedule II.

(a) The controlled substances listed in this section are included in Schedule II.

(b) 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:

(1) Opium and opiate, and any salt, compound, derivative or preparation of opium or opiate excluding nalorphine, nalmefene, naloxone and naltrexone and

their respective salts, but including the following:

(A) Raw opium;

(B) Opium extracts;

(C) Opium fluid extracts;

(D) Powdered opium;

(E) Granulated opium;

(F) Tincture of opium;

(G) Codeine;

(H) Ethylmorphine;

(I) Ethrophine HCL;

(J) Hydromorphone;

(K) Metopon;

(L) Morphine;

(M) Oxycodone;

(N) Oxymorphone;

(O) Thebaine;

(2) Any salt, compound, isomer derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision (1) of this subsection, except that these substances shall not include the isoquinoline alkaloids of opium;

(3) Opium poppy and poppy straw;

(4) 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 extractions of coca leaves, which extractions do not contain cocaine or ecgonine;

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of the opium poppy), 9670.

(c) *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, dextrorphan and levopropoxyphene excepted:

(1) Alfentanil;

(2) Alphaprodine;

(3) Anileridine;

(4) Bezitramide;

(5) Bulk dextropropoxyphene (nondosage forms);

(6) Carfentanil;

(7) Dihydrocodeine;

(8) Diphenoxylate;

(9) Fentanyl;

(10) Isomethadone;

(11) Levomethorphan;

(12) Levorphanol;

(13) Metazocine;

(14) Methadone;

(15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

(16) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid;

(17) Pethidine; (meperidine);

(18) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;

(19) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-ethyl-4-phenylpiperidin-4-carboxylate;

(20) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

(21) Phenazocine;

(22) Piminodine;

(23) Racemethorphan;

(24) Racemorphan;

(25) Sufentanil.

(d) *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:

(1) Amphetamine, its salts, optical isomers and salts of its optical isomers;

(2) Methamphetamine, its salts, isomers and salts of isomers;

(3) Methylphenidate;

(4) Phenmetrazine and its salts.

(e) *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:

(1) Amobarbital;

(2) Secobarbital;

(3) Pentobarbital;

(4) Phencyclidine.

(f) Hallucinogenic substances:

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States food and drug administration approved drug product. (Some other names for dronabinol: (6aRtrans)-6a, 7, 8, 10a-tetrahydro-6, 6, 9-trimethyl-3-pentyl-6H-dibenzo 9b,d) pyran-1-od or (-) delta-9-(trans)-tetrahydrocannabonil);

(2) Nabilone: THC-like antiemetic/cancer chemotherapy.

(g) 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:

(1) Immediate precursor to amphetamine and methamphetamine:

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

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine;

(B) 1-piperidinocyclohexanecarbonitrile (PCC).

§60A-2-208. Schedule III.

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

(b) *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:

(1) 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 the twenty-fifth day of August, one thousand nine hundred seventy-one, as excepted compounds under §308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances;

(2) Benzphetamine;

(3) Chlorphentermine;

(4) Clortermine;

(5) Phendimetrazine.

(c) *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:

(1) Any compound, mixture or preparation containing:

(A) Amobarbital;

(B) Secobarbital;

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

(2) Any suppository dosage form containing:

(A) Amobarbital;

(B) Secobarbital;

(C) Pentobarbital; or any salt of any of these drugs and approved by the food and drug administration for marketing only as a suppository;

(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof;

(4) Chlorhexadol;

(5) Glutethimide;

(6) Lysergic acid;

(7) Lysergic acid amide;

(8) Methyprylon;

(9) Sulfondiethylmethane;

(10) Sulfonethylmethane;

(11) Sulfonmethane;

(12) Tiletamine and zolazepam or any salt thereof; some trade or other names for a tiletamine-zolazepam combination product: Telazol; some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone; some trade or other names for zolazepam: 4-(2-fluorophenyl)-6, 8-dihydro-1, 3, 8-trimethylpyrazolo-[3,4-e] [1,4]-diazepin-7(1H)-one, flupyrazapon;

(13) Human growth hormones or anabolic steroids.

ARTICLE 8. WHOLESALE DRUG DISTRIBUTION LICENSING ACT OF 1991.

§60A-8-1. Short title.

This act may be cited as the "Wholesale Drug Distribution Licensing Act of 1991".

§60A-8-2. Scope.

This act applies to any person, partnership, corporation or business firm engaging in the wholesale distribution of human prescription drugs within this state.

§60A-8-3. Purpose.

The purpose of this act is to implement the federal prescription drug marketing act of one thousand nine hundred eighty-seven ("PDMA"), U.S. Pubic Law 100-293, 102 Stat. 95, codified at 21 U.S. Code §§321; and particularly PDMA requirements that no person or entity may engage in the wholesale distribution of human prescription drugs in any state unless such person or entity is licensed by such state in accordance with federally-prescribed minimum standards, terms and conditions as set forth in guidelines issued by United States food and drug administration (FDA)

regulations pursuant to 21 U.S. Code §§353(e)(2)(A) and (B); and such regulations as are set forth in 21 C.F.R. Part 205.

§60A-8-4. West Virginia board of pharmacy wholesale drug distributor advisory committee; composition; duties.

The board of pharmacy shall appoint a wholesale drug distributor advisory committee composed of five members. The committee shall be composed and shall perform its duties and responsibilities as follows:

(a) At least one member shall be a pharmacy distributor as defined in subdivision (c), section five of this article, but who shall be neither a member of the West Virginia board of pharmacy nor a board of pharmacy employee, except that if no such pharmacy distributor is available to be a committee member, the member required by this subdivision shall be a representative of wholesale drug distributors in addition to those representatives provided for in subdivision (b).

(b) At least two members shall be representatives of wholesale drug distributors as defined in subdivision (b), section five of this article, except that the wholesale drug distributors in this subdivision shall not include any drug manufacturer.

(c) At least one member shall be a representative of drug manufacturers.

(d) The advisory committee shall review and make recommendations to the board of pharmacy on the merit of all rules dealing with wholesale drug distributors, pharmacy distributors and drug manufacturers which are proposed by the board of pharmacy. No rule affecting wholesale drug distributors or pharmacy distributors promulgated by the board of pharmacy shall be approved without first being submitted to the committee reasonably ahead of time for review and comment.

(e) In making advisory committee appointments, the board of pharmacy shall consider recommendations

received from each of the wholesale drug distributor, pharmacy distributor and drug manufacturer classes cited in subdivisions (a) through (c) herein and shall promulgate rules which provide for solicitation of such recommendations.

§60A-8-5. Definitions.

As used in this article:

(a) "Wholesale distribution" and "wholesale distributions" mean distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the United States Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control. For purposes of this act, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(5) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for "emergency medical reasons" for purposes of this act includes

transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sales revenue of either the transferor or tranferee pharmacy during any twelve consecutive month period;

(6) The sale, purchase or trade of a drug, an offer to sell, purchase, or trade a drug or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) The sale, purchase or trade of blood and blood components intended for transfusion.

(b) "Wholesale drug distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers, repackers, own-label distributors, jobbers, private label distributors, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses, independent wholesale drug traders, prescription drug repackagers, physicians, dentists, veterinarians, birth control and other clinics, individuals, hospitals, nursing homes and/or their providers, health maintenance organizations and other health care providers, and retail and hospital pharmacies that conduct wholesale distributions, including, but not limited to, any pharmacy distributor as defined in this section. A wholesale drug distributor shall not include any for hire carrier or person or entity hired solely to transport prescription drugs.

(c) "Pharmacy distributor" means any pharmacy licensed in this state or hospital pharmacy which is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this state or to any other person or entity, including, but not limited to, a wholesale drug distributor as defined in subdivision (b) of this section engaged in the delivery or distribution of prescription drugs and who

is involved in the actual, constructive or attempted transfer of a drug in this state to other than the ultimate consumer except as otherwise provided for by law.

(d) "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling of a prescription drug.

(e) "West Virginia board of pharmacy" means the agency of this state authorized to license wholesale drug distribution except where otherwise provided.

(f) "Prescription drug" means any human drug required by federal law or regulation to be dispensed only by prescription, including finished dosage forms and active ingredients subject to section 503(b) of the federal food, drug and cosmetic act.

(g) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(h) "Blood component" means that part of blood separated by physical or mechanical means.

(i) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

§60A-8-6. Prohibited drug purchases or receipt; penalties.

It is unlawful for any person or entity to knowingly purchase or receive any prescription drug from any source other than a person or entity licensed pursuant to the laws of this state except where otherwise provided, such person or entity to include, but not be limited to, a wholesale distributor, manufacturer, pharmacy distributor or pharmacy. Any person violating the provisions of this section is guilty of a misdemeanor, and, upon conviction thereof, shall be fined not more than one thousand dollars. Any person who violates this section shall for a second offense be guilty of a misdemeanor, and, upon conviction thereof, shall be fined not less than one thousand dollars nor more

than five thousand dollars.

§60A-8-7. Wholesale drug distributor licensing requirements.

All wholesale distributors and pharmacy distributors shall be subject to the following requirements:

(a) No person or distribution outlet may act as a wholesale drug distributor without first obtaining a license to do so from the board of pharmacy and paying any reasonable fee required by the board of pharmacy, such fee not to exceed two hundred dollars per year.

(b) The board of pharmacy may grant a temporary license when a wholesale drug distributor first applies for a license to operate within this state and such temporary license shall remain valid until the board of pharmacy finds that the applicant meets or fails to meet the requirements for regular licensure, except that no such temporary license shall be valid for more than ninety days from the date of issuance. Any temporary license issued pursuant to this subdivision shall be renewable for a similar period of time not to exceed ninety days pursuant to policies and procedures to be prescribed by the board of pharmacy.

(c) No license may be issued or renewed for a wholesale drug distributor to operate unless the distributor operates in a manner prescribed by law and according to the rules promulgated by the board of pharmacy with respect thereto.

(d) The board of pharmacy may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subsidiaries, or affiliate companies within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(e) (1) As a condition for receiving and retaining any wholesale drug distributor license issued pursuant to this article, each applicant shall satisfy the board of pharmacy that it has and will continuously maintain:

(A) Acceptable storage and handling conditions plus facilities standards;

(B) Minimum liability and other insurance as may be required under any applicable federal or state law;

(C) A security system which includes after hours central alarm or comparable entry detection capability, restricted premises access, adequate outside perimeter lighting, comprehensive employment applicant screening and safeguards against employee theft;

(D) An electronic, manual or any other reasonable system of records describing all wholesale distributor activities governed by this article for the two-year period following disposition of each product and being reasonably accessible as defined by board of pharmacy regulations during any inspection authorized by the board of pharmacy;

(E) Officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, who must at all times demonstrate and maintain their capability of conducting business according to sound financial practices as well as state and federal law;

(F) Complete, updated information to be provided the board of pharmacy as a condition for obtaining and retaining a license about each wholesale distributor to be licensed under this article including all pertinent licensee ownership and other key personnel and facilities information deemed necessary for enforcement of this article, with any changes in such information to be submitted at the time of license renewal or within twelve months from the date of such change, whichever occurs first;

(G) Written policies and procedures which assure reasonable wholesale distributor preparation for protection against and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or product shipping and receiving, outdated product or other unauthorized

product control, appropriate disposition of returned goods and product recalls;

(H) Sufficient inspection procedures for all incoming and outgoing product shipments; and

(I) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(2) The board of pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs with this state:

(A) Any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

(B) Any felony convictions of the applicant under federal, state or local laws;

(C) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(E) Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drug, including controlled substances;

(F) Compliance with licensing requirements under previously granted licenses, if any;

(G) Compliance with requirements to maintain and/or make available to the board of pharmacy or to federal, state or local law enforcement officials those records required by this article; and

(H) Any other factors or qualifications the board of pharmacy considers relevant to and consistent with the public health and safety, including whether the granting of the license would not be in the public

interest.

(3) All requirements set forth in this subsection shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration (FDA); and in case of conflict between any wholesale drug distributor licensing requirement imposed by the board of pharmacy pursuant to this subsection and any food and drug administration wholesale drug distributor licensing guideline, the latter shall control.

(f) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this section and may lawfully possess pharmaceutical drugs when such agent or employee is acting in the usual course of business or employment.

(g) The issuance of a license pursuant to this act does not change or affect tax liability imposed by this state's department of tax and revenue on any wholesale drug distributor.

(h) The board of pharmacy may adopt rules pursuant to section nine of this article, which permit out-of-state wholesale drug distributors to obtain any license required by this article on the basis of reciprocity to the extent that: (i) An out-of-state wholesale drug distributor possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor of this state as prerequisites for obtaining a license under the laws of this state; and (ii) such other state would extend reciprocal treatment under its own laws to a wholesale drug distributor of this state.

§60A-8-8. License renewal application procedures.

Application blanks for renewal of any license required by this article shall be mailed to each licensee at least thirty days before the first day of July of each calendar year by the board. All licenses issued under this section are not transferable and expire on the thirtieth day of June of each calendar year. If application for renewal of such license with required

fee is not made before the expiration date of the license, the existing license, or renewal thereof, shall lapse and become null and void upon the last day of June of each calendar year.

§60A-8-9. West Virginia board of pharmacy powers to promulgate rules.

The board of pharmacy shall promulgate rules not inconsistent with law, as may be necessary to carry out the purposes and enforce the provisions of this article pursuant to chapter twenty-nine-a of this code. Rules which incorporate and set detailed standards for meeting each of the license prerequisites set forth in section seven of this article shall be promulgated in final form by no later than the fourteenth day of September, one thousand nine hundred ninety-two. All rules promulgated pursuant to this section shall conform to wholesale drug distributor licensing guidelines formally adopted by the food and drug administration at 21 C.F.R. Part 205; and in case of conflict between any rule adopted by the board of pharmacy and any food and drug administration wholesale drug distributor guideline, the latter shall control.

§60A-8-10. West Virginia board of pharmacy complaint provisions.

Complaints arising under any provision of this article shall be handled as follows:

(a) The board of pharmacy is hereby authorized and empowered, when complaints or examinations or inspections of a wholesale drug distributor disclose that a wholesale drug distributor is not operating or conducting business according to the state and federal laws to file a written complaint with the board charging the holder of a license to operate a wholesale drug distributorship operation with violations of this article which are grounds for restriction, suspension or revocation of the wholesale drug distributor's license.

(b) If the board of pharmacy concludes that a wholesale drug distributor has committed an act or is engaging in a course of conduct which constitutes a

clear and present danger to the public health and safety in this state, the board of pharmacy may hold an expedited hearing. Within fifteen days after service of the complaint on a wholesale drug distributor, the West Virginia board of pharmacy shall conduct a preliminary hearing to determine whether the alleged activities of the wholesale drug distributor appear to constitute a clear and present danger to the public health and safety which justify that the wholesale drug distributor's license be immediately restricted or suspended. The burden of proving that a wholesale drug distributor is a clear and present danger to the public health and safety shall be upon the board. The board shall issue its decision immediately after the hearing and shall dismiss the action or suspend, restrict or revoke the license. The board shall require any wholesale drug distributor found in violation of this article to take all necessary measures for compliance.

(c) If the board restricts, revokes or suspends the wholesale drug distributor's license, such temporary restriction, revocation or suspension shall become a final restriction or suspension if there is no request by the wholesale drug distributor for a final hearing within thirty days of the preliminary hearing. The board shall, if requested by the wholesale drug distributor named in the complaint, set a date to hold a final hearing which shall be held pursuant to the provisions of chapter twenty-nine-a of this code.

§60A-8-11. The West Virginia board of pharmacy inspection powers and access to wholesale drug distributor records.

(a) A person authorized by the board may inspect during normal business hours any premises being used by a wholesale drug distributor in this state in the course of its business. Any wholesale drug distributor providing adequate documentation of the most recent satisfactory inspection less than three years old of such distributor's wholesale drug distribution activities and facilities by either the food and drug administration or a state agency, or any person or entity lawfully

designated by a state agency to perform such inspection, determined to be comparable by the board shall be exempt from further inspection for a period of time to be determined by the board of pharmacy. Such exemption shall not bar the board from initiating an investigation pursuant to a public or governmental complaint received by the board regarding a wholesale drug distributor.

(b) Wholesale drug distributors may keep records regarding purchase and sales transactions at a central location apart from the principal office of the wholesale drug distributor or the location at which the drugs were stored and from which they were shipped: *Provided*, That such records shall be made available for inspection within two working days after a request to inspect by the board is made. Such records may be kept in any form permissible under federal law applicable to prescription drugs recordkeeping.

§60A-8-12. Judicial enforcement of the article.

(a) Upon proper application by the board, a court of competent jurisdiction may grant an injunction, restraining order or other order as may be appropriate to enjoin a person from offering to engage or engaging in the performance of any acts or practices for which a certificate of registration or authority, permit or license is required by any applicable federal or state law, including, but not limited to, this act upon a showing that such acts or practices were or are likely to be performed or offered to be performed without a certificate of registration or authority, permit or license.

(b) Any such judicial actions shall be commenced either in the county in which such conduct occurred or in the county in which defendant resides.

(c) Any action brought under this section shall be in addition to and not in lieu of any other penalty provided by law and may be brought concurrently with other actions to enforce this article.

§60A-8-13. Criminal penalties.

Every person who violates any provision of section seven of this act shall be guilty of a misdemeanor, and, upon conviction thereof, shall be fined not less than two hundred dollars nor more than one thousand dollars.

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman Senate Committee

Chairman House Committee

Originated in the Senate.

In effect from passage.

Clerk of the Senate

Clerk of the House of Delegates

President of the Senate

Speaker House of Delegates

The within ..is approved..this the ..1st.....

day of .....April....., 1991.

Governor

PRESENTED TO THE
GOVERNOR
Date 3/30/91
Time 5:10 pm