

Outline of Key Elements of Florida Pedigree/Licensure Law (S.B. 2312)

The following is an outline of the key provisions of S.B. 2312 as enacted by the Florida legislature and signed into law on June 13, 2003. S.B. 2312 amends certain provisions of Florida's drug distributor licensure law (Chapter 499). This outline details key sections of Chapter 499 that were amended and will become new requirements. The outline does not include provisions of the current law that remain unchanged and remain in effect. This outline is not a legal analysis or interpretation of these new requirements. Unless otherwise noted, provisions of S.B. 2312 become effective on July 1, 2003.

- **Pedigree Authentication & Penalties (Section 5(2-3), page 19-20)**
 - Failure to authenticate the information contained in the pedigree is a third degree felony.
 - Falsely swearing or certifying that a pedigree has been authenticated is third degree felony.
 - Forgery of pedigree papers is a second degree felony.
 - Punishable under ss. 775.082, 775.083, and 775.084. Listing appears at end of this document.

- **Additional Penalties Regarding Purchase, Receipt, Transfer and Distribution of Legend Drugs (Section 5(4-7), pages 20-21)**
 - Knowingly purchasing, receiving, transferring, or distributing legends drugs from unauthorized persons is a second degree penalty.
 - A person who is knowingly in actual or constructive possession of any amount of contraband legend drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband legend drugs, commits a second degree felony.
 - Forging, counterfeiting, or falsely creating any prescription or legend drug label, or falsely representing any factual matter contained in the label, is a first degree felony.
 - Punishable under ss. 775.082, 775.083, and 775.084. Listing appears at end of this document.

- **Fines for Trafficking in Contraband Legend Drugs (Section 6, pages 21-22)**
 - A person who knowingly sells, purchases, manufacturers, delivers, or brings into the state, or who is knowingly in actual or constructive possession of any amount of contraband legend drugs valued at \$25,000 or more commits a first degree felony. Upon conviction, each defendant shall be ordered to pay a mandatory fine according to the following schedule if the value of the contraband legend drug involved is:
 - \$25,000 or more but less than \$100,000, the mandatory fine is \$25,000. If the defendant is a corporation, the mandatory fine is \$75,000;
 - \$100,000 or more but less than \$250,000, the mandatory fine is \$100,000. If the defendant is a corporation, the mandatory fine is \$300,000;
 - \$250,000 or more, the mandatory fine is \$200,000. If the defendant is a corporation, the mandatory fine is \$600,000.

- **Fines & Penalties for the Sale or Purchase of Contraband Legend Drugs Resulting in Bodily Harm or Death (Sections 7 & 8, pages 23)**
 - A person who knowingly sells, purchases, manufacturers, delivers, or brings into the state, or who is knowingly in actual or constructive possession of any amount of contraband legend drugs, and whose acts result in great bodily harm, commits a felony of the first degree, as provided in ss. 775.082, 775.083, 775.084.
 - A person who knowingly manufacturers, sells, purchases, delivers, or brings into the state, or who is knowingly in actual or constructive possession of any amount of contraband legend drugs, and whose acts result in the death of a person, commits a felony of the first degree, punishable by a term of years, not exceeding life, as provided in ss. 775.082, 775.083, 775.084.

- **Permits Required/Expiration Dates (Section 11(1)(g), pages 28-29)**
 - Prescription drug wholesaler and out-of-state prescription drug wholesaler permits will be issued for one year and will expire on the expiration date of the original permit or one year after the date of issuance of the new permit, whichever is earlier. (*NOTE: Florida currently issues two-year permits.*)

- **Accelerated Permit Expiration Dates (Section 11(3)(b), page 29)**
 - New permits issued on July 1, 2003 through December 31, 2003 expire one year after the last day of the anniversary month in which the permit was issued.
 - Permits issued on or before June 30, 2003, with expiration dates between January 1, 2005 and June 30, 2005, will expire one year prior to the expiration date noted on the permit. A credit of one-half of the permit fee will be given for renewals with these expiration dates.
 - Permits issued on or before June 30, 2003, with expiration dates between July 1, 2004 and December 31, 2004, will expire 6 months prior to the expiration

date noted on the permit. A credit of one-quarter of the permit fee will be given for permits with these expiration dates.

- **Primary & Secondary Wholesaler Definitions (Section 13(5)(1)(d), (e), and (f), pages 44-45)**
 - A primary wholesaler means any distributor that:
 - Purchased 90% or more of the total dollar volume of its purchases of prescription drugs directly from manufacturers in the previous year, and directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or
 - Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.
 - “Directly from manufacturer” means purchases made by a distributor directly from a manufacturer and includes transfers from a member of an affiliated group if:
 - the affiliated group purchases 90% or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year, and
 - the distributor discloses to the department the names of all members of the affiliated group of which the distributor is a member and the affiliated group agrees in writing to provide records on the prescription drug purchases by the members of the affiliated group not later than 48 hours after requested by the department.
 - “**Secondary wholesaler**” means a wholesale distributor that is not a primary wholesaler.
- “**Affiliated group**” as used in the statute is defined by s. 1504 of the U.S. Internal Revenue Code. A copy of this definition can be found at the end of this outline.
- **\$100,000 Bond Requirement (Section 13(5)(2)(a) and (b), pages 46-47)**
 - After July 1, 2003, applications for new or renewal permits (includes out-of-state permits) require submission of a \$100,000 bond or other equivalent means of security acceptable to the department. Equivalent means of security may include an “irrevocable letter of credit or a deposit in a trust account or financial institution.”
- **Intracompany Transfers from Out-of-State (Section 13(5)(2)(b)(2), page 48)**
 - An out-of-state permit is not required for an intracompany sale or transfer of a prescription drug provided the out-of-state establishment is licensed in its state of residence and both distributors operate “under the same business name.”
Under prior law, an out-of-state permit was not required if both distributors were “under common control.”

- **Nonresident Prescription Drug Manufacturer (Section 14(2)(e), page 61)**
 - Effective January 1, 2004, a nonresident prescription drug manufacturer will no longer be licensed as an out-of-state distributor. Instead, it will be licensed as a nonresident prescription drug manufacturer. \$100,000 application bond will not be required.

- **Importation of Prescription Drugs by Nonresident Prescription Drug Manufacturers (Section 14(2)(e)(2), pages 61-62)**
 - Effective January 1, 2004, a nonresident prescription drug manufacturer who intends to import prescription drugs from a foreign country into Florida must provide the department a list identifying each prescription drug it intends to import and document approval by FDA.

- **Freight Forwarder Requirements (Section 14(2)(f), page 62)**
 - Effective January 1, 2004, a freight forwarder located in Florida engaging in the distribution of legend drugs must obtain a freight forwarder permit. Common carriers are exempt.

- **Permit Application Process (Section 14(3), pages 62-68)**
 - Effective January 1, 2004. This section outlines the information that will be required on the distribution permit application (new and renewal; in-state and out-of-state; pages 62-65). Such required information includes: name, business address, telephone number of the applicant; all trade or business names used by the applicant; names, addresses, telephone numbers of contact persons for each facility; type of ownership; names of the owner and operator of the establishment; the name and address of each shareholder that owns 5% or more of the outstanding stock of the corporation; whether a sole proprietorship or limited liability company; the name and address of each member of the affiliated group of which the applicant is a member; a copy of the deed or lease for the property where the establishment is located; a list of all licenses issued by other states; the name of the manager of the establishment, the next four highest ranking employees responsible for the operation of the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints; and the name of the designated representative (including fingerprints and the personal statement).
 - Additional information will be required of secondary wholesalers (page 65-68). Such additional information will include: personal background information; information regarding the five largest shareholders if any are a corporation; the names and addresses of financial institutions in which the applicant has an account, the sources of all funds used to finance the purchase of prescription drugs, together with the names of all persons that are authorized signatories on such accounts; the sources of all funds and the amounts of such funds used to purchase or finance the purchases of prescription drugs, including copies of promissory notes or loans; names and addresses of places of residence, any license revocations, details concerning

any enjoinments, descriptions of investments other than the ownership of stocks of publicly traded companies or mutual funds, a description of any criminal offenses, a photograph of the person taken within 30 days of filing the application, and the names, addresses, birth dates, etc., of immediate family members.

- Distributors applying for a new or renewal permit will also be required to provide sales information.
 - For a new permit application, the estimated annual dollar volume of prescription drug sales of the applicant, the estimated annual percentage of the applicant's total company sales that are prescription drugs, the estimated annual total dollar volume of purchases of prescription drugs, and the applicant's estimated annual total dollar volume of prescription drug purchases from a manufacturer.
 - For a renewal permit application, the total dollar volume of prescription drug sales in the previous year, the total dollar volume of prescription drug sales made in the previous 6 months, the percentage of total company sales that were prescription drugs in the previous year, the total dollar volume of purchases of prescription drugs in the previous year, and the total dollar volume of prescription drug purchases directly from manufacturers in the previous year.
 - Such portions of the required information which are a trade secret shall be maintained by the department as trade secret information.
- **Denial of an Application for a Permit (Section 14(5), pages 69-71)**
 - Outlines the grounds for denying a permit beginning on January 1, 2004.
 - **Issuance of Permits (Section 14(5)((7)(a), page 71)**
 - Effective January 1, 2004. Requires the department to adopt rules for the annual renewal of permits and to send renewal notifications 90 days before the expiration date of the permit.
 - **Designated Representative Required (Section 14(11)(a-e), pages 75-76)**
 - Effective January 1, 2004, each establishment (in-state and out-of-state) that is issued a new or renewal permit must designate in writing to the department a designated representative. Criteria for the designated representative:
 - Must be at least 18 years of age;
 - Have no less than two years verifiable experience in a pharmacy licensed in Florida, where the person's responsibilities included recordkeeping for prescription drugs, or have not less than two years verifiable managerial experience with a prescription drug distributor in Florida or another state;
 - Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing the distribution of prescription drugs (*NOTE: The department has indicated that the test will also cover Florida laws on prescription drug distribution*);
 - Must be a full-time employee of the distributor;

- Must be physically present at the establishment during normal business hours;
 - May only serve as designated representative for only one distributor company;
 - A distributor must notify the department when a designated representative leaves its employ. DOH must be notified within 10 business days of the designated representatives last day of employment.
 - A distributor may not operate for more than 10 business days after the designated representative leaves the employment of the distributor company, unless the company notifies the department within 10 business days of the identity of the new designated representative.
- **Examination of Records (Section 15(4), pages 77-78)**
 - Upon receipt, distributors must review required records for accuracy and completeness, and authenticate each transaction listed on the pedigree.
 - **Nonauthorized Distributor Requirements (Section 15(d), page 79)**
 - A nonauthorized distributor must provide each distributor a written statement, under oath, identifying each previous sale of a prescription drug back to the last authorized distributor of record, the lot number of the drug, and the sales invoice number of the invoice evidencing the sale of the drug. This statement must accompany the prescription drug to the next distributor. (*NOTE: This does not apply to a manufacturer unless the manufacturer is performing the manufacturing operation of repackaging prescription drugs.*)
 - **Authorized Distributor of Record Qualifications (Section 15(d), pages 80-81)**
 - Effective July 1, 2003, each manufacturer must file a written list of all of its authorized distributor of records with the department.
 - Effective March 1, 2004, a distributor, including an affiliated group as defined in s. 1504 of the Internal Revenue Code of which the distributor is a member, needs to meet one of the following three qualifications to be an authorized distributor of record:
 - A) Listed on the manufacturer's current list of authorized distributors of record; or
 - B) Annually purchases not less than 90 percent of all of its purchases of an individual manufacturer's product, based on dollar volume, directly from that manufacturer and has total annual prescription drug sales of \$100 million or more (company-wide); or
 - C) Has reported to the department that the distributor has total annual prescription drug sales of \$100 million or more (company-wide), and has a verifiable account number issued by the manufacturer, and makes a minimum of 12 purchases from that manufacturer using the verifiable account number in 12-months. (This provision applies with respect to a manufacturer who fails to file its ADR list with the department by July 1, 2003, or files a list of ADRs containing fewer than 10 distributors permitted in the state, or that is a result of changes

to the list of ADRs filed with the department has fewer than 10 distributors permitted in the state as an ADR. This excludes distributors described in subparagraph (b).)

- These requirements expire on July 1, 2006, when full pedigree becomes effective.
 - The department is required to publish the list of authorized distributors on its website.
- **Written Statement or Pedigree Required on Specified List of Drugs (Section 15(e)(1), page 82)**
 - **NOTE:** The department has announced that these requirements become effective on September 1, 2003.
 - For each drug specified on the list, a distributor must provide to each distributor to whom it sells the specified drug a written statement that:
 - If the establishment is not a member of an affiliated group: “This establishment purchased the specific unit of the specified drug directly from the manufacturer”, or
 - If the establishment is a member of an affiliated group: “This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer”; or
 - A written statement, under oath, identifying each previous sale of the specific unit of the specified drug back to the manufacturer, the lot number of the specific unit, and the sales invoice number of the invoice evidencing each previous sale of the specific unit. This written statement must accompany the specific unit for each subsequent wholesale distribution of the specific unit to a distributor.
 - **Criteria for Specified List of Drugs (Section 15(e)(2), pages 82-87)**
 - This section of the law establishes three situations and the criteria in which a prescription drug may be placed on the list of specified drugs.
 - **Situation I:** A drug may be placed on the specified list if the department has seized or used a stop sale notice because of adulteration, counterfeiting, or diversion from legal channels of distribution, or the FDA, a manufacturer, a distributor, a law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs in another state notifies the department in writing or through a website operated by the said entity that the prescription drug has been adulterated, counterfeited, or diverted; and the drug satisfies one of the following seven criteria:
 - The drug is included among the top 150 prescription drugs for which Florida has incurred the highest amount of Medicaid claims in the most recently ended state fiscal year; or
 - The drug is available for normal prescription use in dosages or strengths that have a wholesale cost of \$200 or more; or
 - The drug is used extensively for patients with HIV, AIDS, cancer, or other serious, life threatening conditions, where drug

nonresponsiveness would not be considered to be medically unusual;
or

- The drug is an injectable; or
 - The drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer of the prescription drug; or
 - The department has found not less than five instances where the written statements required by distributors were not passed on other than because of unintentional oversight, or have been passed on by or to a distributor and such written statements were fraudulent; or
 - A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or missing.
- **Situation II:** A drug may also be put on the specified list if it satisfies any three of the aforementioned seven criteria. Additionally:
- A drug may not be included on the list of specified drugs if it is unlikely to be counterfeited or diverted from legal channels of distribution.
 - Before the department can begin rulemaking to place a drug on the list, except when it files a rule under s. 499.0121, the Drug Wholesaler Advisory Council shall consider whether the drug should be placed on the list.
- **Situation III: Emergency Rulemaking.** If the attorney general or statewide prosecutor certifies to the Secretary of Health that a drug should be added to the list, the department may proceed to add the drug and the emergency rule shall be effective for one year from the date the emergency rule is filed, if the department begins the rulemaking process to adopt a permanent rule to place the drug on the specified list not later than 90 days after the date which the emergency rule was filed.
- The drug must meet two of the aforementioned seven criteria to be placed on the list by emergency rule, or one of the criteria if the drug has yet to become available for distribution or has been available for distribution for not more than 60 days, and
 - A drug added to the list by emergency rule may not be renewed.
- Not less than annually, the Wholesale Drug Advisory Council and the department shall evaluate whether each prescription drug included on the specified list of drugs shall remain on the list. Consideration is to be given to the availability of generic forms of the drug; changes in price of the drug since it was placed on the list, and the current status of the drug that caused it to be placed on the list.
- The advisory council shall provide a written recommendation to the secretary concerning each drug that it recommends be removed from the list.
- **Full Pedigree Requirements in 2006 (Section 15(f)(1-5), pages 87-88)**
 - Effective July 1, 2006, pedigree must be passed by each distributor, who is not a manufacturer, before each distribution of a drug and provided to each person who receives the drug. Repackagers must also comply.

- Compressed medical gases and veterinary legend drugs are exempt (page 88).
 - Each distributor must maintain the pedigree and written statements separate and distinct from other required records.
 - Annually, each distributor will be required to provide the department with a written list of all distributors and manufacturers from whom the distributor purchases prescription drugs. Distributors must notify the department of any change to the list within 10 days of such a change.
 - Manufacturers, upon request of the department, must make available distribution documentation related to its sales of prescription drugs, regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.
- **Distributor Due Diligence (Section 16(12), pages 91-92)**
 - Effective January 1, 2004, prior to the purchasing of prescription drugs, a purchasing distributor must:
 - Enter into an agreement with the selling distributor by which the selling distributor will indemnify the purchasing distributor for any loss caused to the purchasing distributor related to the purchase of prescription drugs from the selling distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs;
 - Determine that the selling distributor has insurance coverage of not less than 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department or \$500,000. Coverage does not need to exceed \$2 million;
 - Obtain background information about ownership of the selling distributor, length of time selling into Florida, a copy of any licenses or permits, the experience of the selling distributor, etc.;
 - Verify that the selling distributor's Florida permit is valid;
 - Inspect the selling distributor's facility to document that it has policies and procedures manual relating to the distribution of drugs, temperature control, security and alarm systems, procedures to ensure required records are maintained, etc., before purchasing a drug from the selling distributor, and at least once each subsequent year, or
 - Obtain a complete copy of the most recent inspection report done by the department or the regulatory agency responsible for distributors.
- **Drug Wholesaler Advisory Council (Section 17, pages 92-93)**
 - Council shall consist of 11 members to include:
 - Three primary distributors which operate nationally, 1 secondary distributor, 1 retail pharmacy, 1 member of the Board of Pharmacy, 1 physician, 1 hospital pharmacy, 1 manufacturer, and 2 Department of Health representatives.

- **Permit Fee Range Increases & Inspections (Section 20(2)(a), (c), (d), (3)(8-9), page 98-99)**
 - Increases distributor permit fee range to be between \$300 and \$800. Prior law set in-state fee at \$400; out-of-state at \$300.
 - Nonresident manufacturer fee range to be between \$300 and \$500.
 - Permits the department to charge an out-of-state distributor between \$1,000 and \$3,000 to conduct an on-site inspection.
 - Designated representative certification fee set at \$150, plus the cost of processing the criminal background check.

- **Financial Records Inspection (Section 21(4-5), pages 100-101)**
 - Clarifies the department’s authority to access, inspect, review, and copy any financial document or record related to the distribution of prescription drugs.

- **Facility Inspections & Imminent Danger (Section 23, pages 102-103)**
 - This section further clarifies that the department is authorized to inspect, as often as necessary, the establishments of prescription drug distributors, repackagers, and “retail pharmacy drug wholesalers” who are required to be permitted under this statute.
 - The department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs.
 - The owner of any property seized under this section may, within 10 days after the seizure, apply to a court for appropriate relief. At any time after 10 days, the department may destroy the drugs as contraband.
 - The department may determine that a prescription drug distributor, repackager, or “retail pharmacy drug wholesaler” is an imminent danger to the public health and require its immediate closure if such establishment fails to comply with applicable laws and rules. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.
 - A refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

- **Penalties and Remedies (Section 24, pages 104-108)**
 - The department may institute suits or other legal proceedings as are required to enforce any provision of ss. 499.001-499.081.
 - The department may issue cease and desist orders.
 - The department may issue and serve a complaint stating charges upon any affiliated party and upon the permittee whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:
 - An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued, is hazardous to the

public health, or constitutes business operations that are a detriment to the public health;

- A willful violation of ss. 499.001-499.081; however, if the violation is a misdemeanor, complaint may not be served until the affiliated party is notified in writing of the matter of the violation and has been afforded reasonable time to correct the violation and has failed to do so;
 - A violation of any other law involving fraud or moral turpitude which constitutes a felony;
 - A willful violation of any rule of the department;
 - A willful violation of any order of the department; or
 - A material misrepresentation of fact made knowingly and willfully or made with reckless disregard for the truth of the matter.
- The complaint must contain a statement of facts and notice of opportunity for a hearing.
 - If a hearing is not requested within the time allotted, or if a hearing is held and the department finds that any of the charges in the complaint are proven to be true, the department may enter an order removing the affiliated party or restricting or prohibiting participation by the person in the affairs of that permittee or of any other permittee.
 - Requires that the chief executive officer, designated representative, or person holding an equivalent office of a permittee to promptly notify the department if she or he has actual knowledge that an affiliated party is charged with a felony in a state or federal court.
 - Any affiliated party removed pursuant to this section is not eligible for reemployment by the permittee or to be an affiliated party of any permittee except upon the written consent of the department.
 - Any affiliated party who is removed, restricted, or prohibited from participating in the affairs of a permittee pursuant to this section may petition the department for modification or termination of the removal, restriction, or prohibition.
- **Denial, Suspension, or Revocation of a Permit, Certification, or Registration (Section 26, pages 109-110)**
 - Effective January 1, 2004, the department may deny, suspend, or revoke a permit if it finds that there has been substantial failure to comply with ss. 499.001-499.081, chapter 465, chapter 501, or chapter 893, the rules adopted under any of those sections or chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.
 - The department may deny an application for a permit or certification, or suspend or revoke a permit or certification if the department finds that:
 - The applicant is not of good moral character or that it would be a danger or not in the best interest of the public, health, safety, and welfare if the applicant were issued a permit or certification;

- The applicant has not met the requirements for the permit or certification;
 - The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.01 or s. 499.012;
 - The applicant, permittee, or person certified under s. 499.012(11) demonstrates any of the conditions enumerated in s. 499.01 or s. 499.012(5);
 - The applicant, permittee, or person certified under s. 499.012(11) has committed any violation of ss. 499.005-499.0054;
 - The department shall deny, suspend, or revoke the permit of any person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under ss. 499.001-499.081 will avoid an administrative penalty, civil action, or criminal prosecution.
 - If a permittee fails to comply with s. 499.01(7), the department may revoke the permit of the permittee and shall provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department, and if the permittee is not a natural person, to the permittee's registered agent on file with the Department of State.
- **Criminal Penalties (Section 28, pages 111-115)**
 - Any person who violates any of the following provisions commits a misdemeanor of the second degree, but if the violation is committed after a conviction of such person under this section has become final, such a person commits a misdemeanor of the first degree:
 - The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or has otherwise been rendered unfit for human or animal use;
 - The adulteration or misbranding of any drug intended for further distribution;
 - The receipt of any drug that is adulterated or misbranded, and the delivery or proffered delivery of such drug for pay or otherwise;
 - The dissemination of any false or misleading advertisement of a drug;
 - The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with ss. 499.001-499.081 when it does not;
 - The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed gases;
 - Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample;
 - The failure to maintain records related to a drug as required by ss. 499.001-499.081 and rules adopted under those sections, except for

- pedigree papers, invoices, or shipping documents related to legend drugs;
 - The possession of any drug in violation of ss. 499.001-499.081, except if the violation relates to a deficiency in pedigree papers.
 - Punishable under ss. 775.082, 775.083, and 775.084. Listing appears at end of this document.
- Any person who violates any of the following provisions commits a felony of the third degree:
- The refusal or constructive refusal to allow:
 - The department to enter or inspect an establishment in which drugs are manufactured, processed, repackaged, sold, brokered, or held;
 - Inspection of any record of that establishment;
 - The department to enter and inspect any vehicle that is being used to transport drugs; or
 - The department to take samples of any drug.
 - The sale, purchase, or trade, or the offer to sell, purchase, or trade a drug sample, the distribution of a drug sample in violation of s. 499.028, or the failure to otherwise comply with s. 499.028;
 - Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this chapter related to a drug;
 - The failure to receive, maintain, or provide invoices and shipping documents, other than pedigree papers, if applicable, related to the distribution of a legend drug;
 - The importation of a legend drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act;
 - The wholesale distribution of any prescription drug that was:
 - Purchased by a public or private hospital or other health care entity; or
 - Donated or supplied at a reduced price to a charitable organization.
 - The failure to obtain a permit as a prescription drug wholesaler when a permit is required by ss. 499.001-499.081 for that activity;
 - Knowingly possessing any adulterated or misbranded legend drug outside of a designated quarantine area;
 - The purchase or sale of prescription drugs for wholesale distribution in exchange for currency, as defined in s. 560.103(6);
 - Punishable under ss. 775.082, 775.083, and 775.084. Listing appears at end of this document.
- Any person who violates any of the following provisions commits a felony of the second degree:
- Knowingly manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use;

- Knowingly adulterating a drug that is intended for further distribution;
- Knowingly receiving a drug that is adulterated and delivering or proffering delivery of such drug for pay or otherwise;
- Committing any act that causes a drug to be a counterfeit drug, or selling, dispensing, or knowingly holding for sale a counterfeit drug;
- Forging, counterfeiting, simulating, or falsely representing any drug, or without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under ss. 499.001-499.081;
- Knowingly obtaining or attempting to obtain a prescription drug for wholesale distribution by fraud, deceit, misrepresentation, or subterfuge, or engaging in misrepresentation of fraud in the distribution of a drug;
- Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug;
- Knowingly distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in Chapter 465 or the rules adopted under Chapter 465;
- A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesaler, or seller of the article to which a false advertisement relates, is not liable under this section by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, repackager, wholesaler, seller, or advertising agency that asked him or her to disseminate such advertisement.
- Punishable under ss. 775.082, 775.083, and 775.084. Listing appears at end of this document.

Felony Provisions of Sections 775.082, 775.083, 775.084

The following is a brief synopsis of the key provisions provided in ss. 775.082, 775.083, 775.084. It is not a summary of all provisions included in these sections.

Section 775.082 – Penalties; Applicability of Sentencing Structures; Mandatory Minimum sentences for Certain Reoffenders Previously Released from Prison

- For a felony of the first degree, by a term of imprisonment not exceeding 30 years or, when specifically provided by statute, by imprisonment for a term of years not exceeding life imprisonment.
- For a felony of the second degree, by a term of imprisonment not exceeding 15 years.
- For a felony of the third degree, by a term of imprisonment not exceeding 5 years.
- A person who has been convicted of a designated misdemeanor may be sentenced as follows:
 - For a misdemeanor of the first degree, by a definite term of imprisonment not exceeding one (1) year;
 - For a misdemeanor of the second degree, by a definite term of imprisonment not exceeding 60 days.

Section 775.083 – Fines

A person who has been convicted of an offense other than a capital felony may be sentenced to pay a fine in addition to any punishment described in s. 775.082; when specifically authorized by statute, he or she may be sentenced to pay a fine in lieu of any punishment described in s. 775.082. A person who has been convicted of a noncriminal violation may be sentenced to pay a fine. Fines for designated crimes and for noncriminal violations shall not exceed:

- \$15,000, when the conviction is of a life felony;
- \$10,000, when the conviction is of a felony of the first or second degree;
- \$5,000, when the conviction is of a felony of the third degree;
- \$1,000, when the conviction is of a misdemeanor of the first degree;
- \$500, when the conviction is of a misdemeanor of the second degree or a noncriminal violation;
- Any higher amount equal to double the pecuniary gain derived from the offense by the offender or double the pecuniary loss suffered by the victim;
- Any higher amount specifically authorized by statute.

Section 775.084 – Violent career criminals; habitual felony offenders and habitual violent felony offenders; three-time violent felony offenders; definitions; procedure; enhanced penalties or mandatory minimum prison terms

- The court, in conformity with the procedures established under this section, may sentence an habitual felony offender as follows:
 - Life in the case of a life felony or a felony of the first degree;
 - A term of years not exceeding 30 in the case of a felony of the second degree;
 - A term of years not exceeding 10 in the case of a felony of the third degree.

- The court, in conformity with the procedures established, may sentence the habitual violent felony offender as follows:
 - In the case of a life felony or a felony of the first degree, for life, and such offender shall not be eligible for release for 15 years;
 - In the case of a felony of the second degree, for a term of years not exceeding 30, and such offender shall not be eligible for release for 10 years;
 - In the case of a felony of the third degree, for a term of years not exceeding 10, and such offender shall not be eligible for release for 5 years.

- The court, in conformity with the procedures established, must sentence a three-time violent felony offender to a mandatory minimum term of imprisonment, as follows:
 - In the case of a felony punishable by life, to term of imprisonment for life;
 - In the case of a felony of the first degree, to a term of imprisonment of 30 years;
 - In the case of a felony of the second degree, to a term of imprisonment of 15 years; or
 - In the case of a felony of the third degree, to a term of imprisonment of 5 years.

- The court, in conformity with the procedures established, must sentence the violent career criminal, as follows:
 - Life, in the case of a life felony or a felony of the first degree;
 - A term of years not exceeding 40, with a mandatory minimum term of 30 years imprisonment, in the case of a felony of the second degree;
 - A term of years not exceeding 15, with a mandatory minimum term of 10 years imprisonment, in the case of a felony of the third degree.

Affiliated Group as Defined by U.S. Internal Revenue Code

Sec. 1504. - Definitions

(a) Affiliated group defined

For purposes of this subtitle -

(1) In general

The term "affiliated group" means -

(A) 1 or more chains of includible corporations connected through stock ownership with a common parent corporation which is an includible corporation, but only if -

(B) (i) the common parent owns directly stock meeting the requirements of paragraph (2) in at least 1 of the other includible corporations, and

(ii) stock meeting the requirements of paragraph (2) in each of the includible corporations (except the common parent) is owned directly by 1 or more of the other includible corporations.

(2) 80-percent voting and value test

The ownership of stock of any corporation meets the requirements of this paragraph if it -

(A) possesses at least 80 percent of the total voting power of the stock of such corporation, and

(B) has a value equal to at least 80 percent of the total value of the stock of such corporation.

(3) 5 years must elapse before reconsolidation

(A) In general

If -

(i) a corporation is included (or required to be included) in a consolidated return filed by an affiliated group for a taxable year which includes any period after December 31, 1984, and

(ii) such corporation ceases to be a member of such group in a taxable year beginning after December 31, 1984, with respect to periods after such cessation, such corporation (and any successor of such corporation) may not be included in any consolidated return filed by the affiliated group (or by another affiliated group with the same common parent or a successor of such common parent) before the 61st month beginning after its first taxable year in which it ceased to be a member of such affiliated group.

(B) Secretary may waive application of subparagraph (A)

The Secretary may waive the application of subparagraph (A) to any corporation for any period subject to such conditions as the Secretary may prescribe.

(4) Stock not to include certain preferred stock

For purposes of this subsection, the term "stock" does not include any stock which -

(A) is not entitled to vote,

(B) is limited and preferred as to dividends and does not participate in corporate growth to any significant extent,

(C) has redemption and liquidation rights which do not exceed the issue price of such stock (except for a reasonable redemption or liquidation premium), and

(D) is not convertible into another class of stock.

(5) Regulations

The Secretary shall prescribe such regulations as may be necessary or appropriate to carry out the purposes of this subsection, including (but not limited to) regulations -

(A) which treat warrants, obligations convertible into stock, and other similar interests as stock, and stock as not stock,

(B) which treat options to acquire or sell stock as having been exercised,

(C) which provide that the requirements of paragraph (2)(B) shall be treated as met if the affiliated group, in reliance on a good faith determination of value, treated such requirements as met,

(D) which disregard an inadvertent ceasing to meet the requirements of paragraph (2)(B) by reason of changes in relative values of different classes of stock,

(E) which provide that transfers of stock within the group shall not be taken into account in determining whether a corporation ceases to be a member of an affiliated group, and

(F) which disregard changes in voting power to the extent such changes are disproportionate to related changes in value.

(b) Definition of "includible corporation"

As used in this chapter, the term "includible corporation" means any corporation except -

(1) Corporations exempt from taxation under section 501.

(2) Insurance companies subject to taxation under section 801.

- (3) Foreign corporations.
- (4) Corporations with respect to which an election under section 936 (relating to possession tax credit) is in effect for the taxable year.
- (5) Repealed. [Pub. L. 94-455](#), title X, **Sec.** 1053(d)(2), Oct. 4, 1976, 90 Stat. 1649.)
- (6) Regulated investment companies and real estate investment trusts subject to tax under subchapter M of chapter 1.
- (7) A DISC (as defined in section 992(a)(1)).
- (8) An S corporation.

(c) Includible insurance companies

Notwithstanding the provisions of paragraph (2) of subsection (b) -

(1) Two or more domestic insurance companies each of which is subject to tax under section 801 shall be treated as includible corporations for purposes of applying subsection (a) to such insurance companies alone.

(2)

(A) If an affiliated group (determined without regard to subsection (b)(2)) includes one or more domestic insurance companies taxed under section 801, the common parent of such group may elect (pursuant to regulations prescribed by the Secretary) to treat all such companies as includible corporations for purposes of applying subsection (a) except that no such company shall be so treated until it has been a member of the affiliated group for the 5 taxable years immediately preceding the taxable year for which the consolidated return is filed.

(B) If an election under this paragraph is in effect for a taxable year –

(i) section 243(b)(3) and the exception provided under section 243(b)(2) with respect to subsections (b)(2) and (c) of this section,

(ii) section 542(b)(5), and **(iii)** subsection (a)(4) and (b)(2)(D) of section 1563, and the reference to section 1563(b)(2)(D) contained in section 1563(b)(3)(C), shall not be effective for such taxable year.

(d) Subsidiary formed to comply with foreign law

In the case of a domestic corporation owning or controlling, directly or indirectly, 100 percent of the capital stock (exclusive of directors' qualifying shares) of a corporation organized under the laws of a contiguous foreign country and maintained solely for the purpose of complying with the laws of such country as to title and operation of property, such foreign corporation may, at the option of the domestic corporation, be treated for the purpose of this subtitle as a domestic corporation.

(e) Includible tax-exempt organizations

Despite the provisions of paragraph (1) of subsection (b), two or more organizations exempt from taxation under section 501, one or more of which is described in section 501(c)(2) and the others of which derive income from such 501(c)(2) organizations, shall be considered as includible corporations for the purpose of the application of subsection (a) to such organizations alone.

(f) Special rule for certain amounts derived from a corporation previously treated as a DISC

In determining the consolidated taxable income of an affiliated group for any taxable year beginning after December 31, 1984, a corporation which had been a DISC and which would otherwise be a member of such group shall not be treated as such a member with respect to -

(1) any distribution (or deemed distribution) of accumulated DISC income which was not treated as previously taxed income under section 805(b)(2)(A) of the Tax Reform Act of 1984, and

(2) any amount treated as received under section 805(b)(3) of such Act

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