

By: Representative Howell

To: Public Health and Human Services

HOUSE BILL NO. 7

1 AN ACT TO CREATE NEW SECTION 73-21-129, MISSISSIPPI CODE OF
 2 1972, TO REQUIRE DRUG MANUFACTURERS THAT ARE REQUIRED TO REGISTER
 3 WITH THE STATE BOARD OF PHARMACY TO MAKE ADEQUATE PROVISION FOR
 4 THE RETURN OF OUTDATED DRUGS FROM PHARMACIES FOR UP TO SIX MONTHS
 5 AFTER THE LABELED EXPIRATION DATE FOR PROMPT CREDIT OR
 6 REPLACEMENT; TO REQUIRE DRUG WHOLESALE DISTRIBUTORS AND REVERSE
 7 DISTRIBUTORS THAT ARE REQUIRED TO REGISTER WITH THE BOARD TO
 8 IMPLEMENT AND ADMINISTER THE RETURN POLICIES ESTABLISHED BY THE
 9 MANUFACTURER; TO AMEND SECTION 73-21-73, MISSISSIPPI CODE OF 1972,
 10 TO DEFINE THE TERM "REVERSE DISTRIBUTOR"; TO AMEND SECTION
 11 73-21-105, MISSISSIPPI CODE OF 1972, TO REQUIRE REVERSE
 12 DISTRIBUTORS LOCATED IN OR OUTSIDE OF THIS STATE THAT CONDUCT
 13 BUSINESS WITH PHARMACIES IN THIS STATE TO REGISTER WITH THE BOARD;
 14 AND FOR RELATED PURPOSES.

15 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

16 **SECTION 1.** The following shall be codified as Section
 17 73-21-129, Mississippi Code of 1972:

18 73-21-129. Each manufacturer that is required to register
 19 with the board and have a permit under Section 73-21-105 shall
 20 make adequate provision for the return of outdated drugs from
 21 pharmacies, both full and partial containers, excluding
 22 biological, infused or intravenously injected drugs and drugs that
 23 are inhaled during surgery, for up to six (6) months after the
 24 labeled expiration date, for prompt credit or replacement.
 25 Wholesale distributors and reverse distributors that are required
 26 to register with the board and have a permit under Section
 27 73-21-105 shall implement and administer the return policies
 28 established by the manufacturer.

29 **SECTION 2.** Section 73-21-73, Mississippi Code of 1972, is
 30 amended as follows:

31 73-21-73. As used in this chapter, unless the context
 32 requires otherwise:



33 (a) "Administer" * * * meansu the direct application of
34 a prescription drug pursuant to a lawful order of a practitioner
35 to the body of a patient by injection, inhalation, ingestion or
36 any other means.

37 (b) "Board of Pharmacy," "Pharmacy Board," "MSBP" or
38 "board" * * * meansu the State Board of Pharmacy.

39 (c) "Compounding" means (i) the production,
40 preparation, propagation, conversion or processing of a sterile or
41 nonsterile drug or device either directly or indirectly by
42 extraction from substances of natural origin or independently by
43 means of chemical or biological synthesis or from bulk chemicals
44 or the preparation, mixing, measuring, assembling, packaging or
45 labeling of a drug or device as a result of a practitioner's
46 prescription drug order or initiative based on the
47 practitioner/patient/pharmacist relationship in the course of
48 professional practice, or (ii) for the purpose of, as an incident
49 to, research, teaching or chemical analysis and not for sale or
50 dispensing. Compounding also includes the preparation of drugs or
51 devices in anticipation of prescription drug orders based on
52 routine regularly observed prescribing patterns.

53 (d) "Continuing education unit" * * * meansu ten (10)
54 clock hours of study or other such activity as may be approved by
55 the board, including, but not limited to, all programs which have
56 been approved by the American Council on Pharmaceutical Education.

57 (e) "Deliver" or "delivery" * * * meansu the actual,
58 constructive or attempted transfer of a drug or device from one
59 person to another, whether or not for a consideration.

60 (f) "Device" * * * meansu an instrument, apparatus,
61 implement, machine, contrivance, implant, in vitro reagent or
62 other similar or related article, including any component part or
63 accessory which is required under federal or state law to be
64 prescribed by a practitioner and dispensed by a pharmacist.



65 (g) "Dispense" or "dispensing" * * * meansu the
66 interpretation of a valid prescription, order of a practitioner by
67 a pharmacist and the subsequent preparation of the drug or device
68 for administration to or use by a patient or other individual
69 entitled to receive the drug.

70 (h) "Distribute" * * * meansu the delivery of a drug or
71 device other than by administering or dispensing to persons other
72 than the ultimate consumer.

73 (i) "Drug" * * * meansu:

74 (i) Articles recognized as drugs in the official
75 United States Pharmacopeia, official National Formulary, official
76 Homeopathic Pharmacopeia, other drug compendium or any supplement
77 to any of them;

78 (ii) Articles intended for use in the diagnosis,
79 cure, mitigation, treatment or prevention of disease in man or
80 other animals;

81 (iii) Articles other than food intended to affect
82 the structure or any function of the body of man or other animals;
83 and

84 (iv) Articles intended for use as a component of
85 any articles specified in subparagraph (i), (ii) or (iii) of this
86 paragraph.

87 (j) "Drugroom" * * * meansu a business, which does not
88 require the services of a pharmacist, where prescription drugs or
89 prescription devices are bought, sold, maintained or provided to
90 consumers.

91 (k) "Extern" * * * meansu a student in the professional
92 program of a school of pharmacy accredited by the American Council
93 on Pharmaceutical Education who is making normal progress toward
94 completion of a professional degree in pharmacy.

95 (l) "Foreign pharmacy graduate" * * * meansu a person
96 whose undergraduate pharmacy degree was conferred by a recognized
97 school of pharmacy outside of the United States, the District of



98 Columbia and Puerto Rico. Recognized schools of pharmacy are
99 those colleges and universities listed in the World Health
100 Organization's World Directory of Schools of Pharmacy, or
101 otherwise approved by the Foreign Pharmacy Graduate Examination
102 Committee (FPGEC) certification program as established by the
103 National Association of Boards of Pharmacy.

104 (m) "Generic equivalent drug product" * * * means a
105 drug product which (i) contains the identical active chemical
106 ingredient of the same strength, quantity and dosage form; (ii) is
107 of the same generic drug name as determined by the United States
108 Adoptive Names and accepted by the United States Food and Drug
109 Administration; and (iii) conforms to such rules and regulations
110 as may be adopted by the board for the protection of the public to
111 assure that such drug product is therapeutically equivalent.

112 (n) "Interested directly" * * * means being employed
113 by, having full or partial ownership of, or control of, any
114 facility permitted or licensed by the Mississippi State Board of
115 Pharmacy.

116 (o) "Interested indirectly" * * * means having a spouse
117 who is employed by any facility permitted or licensed by the
118 Mississippi State Board of Pharmacy.

119 (p) "Intern" * * * means a person who has graduated
120 from a school of pharmacy but has not yet become licensed as a
121 pharmacist.

122 (q) "Manufacturer" * * * means a person, business or
123 other entity engaged in the production, preparation, propagation,
124 conversion or processing of a prescription drug or device, if such
125 actions are associated with promotion and marketing of such drugs
126 or devices.

127 (r) "Manufacturer's distributor" * * * means any person
128 or business who is not an employee of a manufacturer, but who
129 distributes sample drugs or devices, as defined under subsection



130 (i) of this section, under contract or business arrangement for a
131 manufacturer to practitioners.

132 (s) "Manufacturing" of prescription products * * *
133 means the production, preparation, propagation, conversion or
134 processing of a drug or device, either directly or indirectly, by
135 extraction from substances from natural origin or independently by
136 means of chemical or biological synthesis, or from bulk chemicals
137 and includes any packaging or repackaging of the substance(s) or
138 labeling or relabeling of its container, if such actions are
139 associated with promotion and marketing of such drug or devices.

140 (t) "Misappropriation of a prescription drug" * * *
141 means to illegally or unlawfully convert a drug, as defined in
142 subsection (i) of this section, to one's own use or to the use of
143 another.

144 (u) "Nonprescription drugs" * * * means non narcotic
145 medicines or drugs that may be sold without a prescription and are
146 prepackaged and labeled for use by the consumer in accordance with
147 the requirements of the statutes and regulations of this state and
148 the federal government.

149 (v) "Person" * * * means an individual, corporation,
150 partnership, association or any other legal entity.

151 (w) "Pharmacist" * * * means an individual health care
152 provider licensed by this state to engage in the practice of
153 pharmacy. This recognizes a pharmacist as a learned professional
154 who is authorized to provide patient services.

155 (x) "Pharmacy" * * * means any location for which a
156 pharmacy permit is required and in which prescription drugs are
157 maintained, compounded and dispensed for patients by a pharmacist.
158 This definition includes any location where pharmacy-related
159 services are provided by a pharmacist.

160 (y) "Prepackaging" * * * means the act of placing small
161 precounted quantities of drug products in containers suitable for



162 dispensing or administering in anticipation of prescriptions or
163 orders.

164 (z) Unlawful or unauthorized "possession" * * * means
165 physical holding or control by a pharmacist of a controlled
166 substance outside the usual and lawful course of employment.

167 (aa) "Practice of pharmacy" * * * means a health care
168 service that includes, but is not limited to, the compounding,
169 dispensing, and labeling of drugs or devices; interpreting and
170 evaluating prescriptions; administering and distributing drugs and
171 devices; the compounding, dispensing and labeling of drugs and
172 devices; maintaining prescription drug records; advising and
173 consulting concerning therapeutic values, content, hazards and
174 uses of drugs and devices; initiating or modifying of drug therapy
175 in accordance with written guidelines or protocols previously
176 established and approved by the board; selecting drugs;
177 participating in drug utilization reviews; storing prescription
178 drugs and devices; ordering lab work in accordance with written
179 guidelines or protocols as defined by paragraph (kk) of this
180 section; providing pharmacotherapeutic consultations; supervising
181 supportive personnel and such other acts, services, operations or
182 transactions necessary or incidental to the conduct of the
183 foregoing.

184 (bb) "Practitioner" * * * means a physician, dentist,
185 veterinarian, or other health care provider authorized by law to
186 diagnose and prescribe drugs.

187 (cc) "Prescription" * * * means a written, verbal or
188 electronically transmitted order issued by a practitioner for a
189 drug or device to be dispensed for a patient by a pharmacist.

190 (dd) "Prescription drug" or "legend drug" * * * means a
191 drug which is required under federal law to be labeled with either
192 of the following statements prior to being dispensed or delivered:

193 (i) "Caution: Federal law prohibits dispensing
194 without prescription," or



195 (ii) "Caution: Federal law restricts this drug to
196 use by or on the order of a licensed veterinarian"; or a drug
197 which is required by any applicable federal or state law or
198 regulation to be dispensed on prescription only or is restricted
199 to use by practitioners only.

200 (ee) "Product selection" * * * means the dispensing of
201 a generic equivalent drug product in lieu of the drug product
202 ordered by the prescriber.

203 (ff) "Provider" or "primary health care provider" * * *
204 includes a pharmacist who provides health care services within his
205 or her scope of practice pursuant to state law and regulation.

206 (gg) "Registrant" * * * means a pharmacy or other
207 entity which is registered with the Mississippi State Board of
208 Pharmacy to buy, sell or maintain controlled substances.

209 (hh) "Repackager" means a person registered by the
210 Federal Food and Drug Administration as a repackager who removes a
211 prescription drug product from its marketed container and places
212 it into another, usually of smaller size, to be distributed to
213 persons other than the consumer.

214 (ii) "Reverse distributor" means a business operator
215 that is responsible for the receipt and appropriate disposal of
216 unwanted, unneeded or outdated stocks of controlled or
217 uncontrolled drugs from a pharmacy.

218 (jj) "Supportive personnel" or "pharmacist
219 technician" * * * means those individuals utilized in pharmacies
220 whose responsibilities are to provide nonjudgmental technical
221 services concerned with the preparation and distribution of drugs
222 under the direct supervision and responsibility of a pharmacist.

223 (kk) "Written guideline or protocol" * * * means an
224 agreement in which any practitioner authorized to prescribe drugs
225 delegates to a pharmacist authority to conduct specific
226 prescribing functions in an institutional setting, or with
227 individual patients, provided that a specific protocol agreement



228 is signed on each patient and is filed as required by law or by
229 rule or regulation of the board.

230 (11) "Wholesaler" * * * means a person who buys or
231 otherwise acquires prescription drugs or prescription devices for
232 resale or distribution, or for repackaging for resale or
233 distribution, to persons other than consumers.

234 **SECTION 3.** Section 73-21-105, Mississippi Code of 1972, is
235 amended as follows:

236 73-21-105. (1) Every facility/business that * * * engages
237 in the wholesale distribution of prescription drugs, to include
238 without limitation, manufacturing in this state, distribution into
239 this state, or selling or offering to sell in this state, or
240 distribution from or within this state, and every reverse
241 distributor located in or outside of this state that conducts
242 business with pharmacies in this state, shall register biennially
243 with the Mississippi State Board of Pharmacy by applying for a
244 permit on a form supplied by the board and accompanied by a fee as
245 set by subsection (4) of this section. The Pharmacy Board shall
246 by regulation determine the classification of permit(s) that shall
247 be required.

248 (2) Every business/facility/pharmacy located in this state
249 that engages in or proposes to engage in the dispensing and
250 delivery of prescription drugs to consumers shall register with
251 the Mississippi State Board of Pharmacy by applying for a permit
252 on a form supplied by the board and accompanied by a fee as set by
253 subsection (4) of this section. The Pharmacy Board shall by
254 regulation determine the classification of permit(s) that shall be
255 required.

256 (3) The board shall establish by rule or regulation the
257 criteria which each business shall meet to qualify for a permit in
258 each classification. The board shall issue a permit to any
259 applicant who meets the criteria as established. The board may
260 issue various types of permits with varying restrictions to



261 businesses where the board deems it necessary by reason of the
262 type of activities conducted by the business requesting a permit.

263 (4) The board shall specify by rule or regulation the
264 registration procedures to be followed, including, but not limited
265 to, specification of forms for use in applying for such permits
266 and times, places and fees for filing such applications. However,
267 the biennial fee for an original or renewal permit shall not
268 exceed Three Hundred Dollars (\$300.00).

269 (5) Applications for permits shall include the following
270 information about the proposed business:

271 (a) Ownership;

272 (b) Location;

273 (c) Identity of the responsible person or pharmacist
274 licensed to practice in the state, who shall be the pharmacist in
275 charge of the pharmacy, where one is required by this chapter, and
276 such further information as the board may deem necessary.

277 (6) Permits issued by the board pursuant to this section
278 shall not be transferable or assignable.

279 (7) The board shall specify by rule or regulation minimum
280 standards for the responsibility in the conduct of any
281 business/facility and/or pharmacy that has been issued a permit.
282 The board is specifically authorized to require that the portion
283 of the facility located in this state to which a pharmacy permit
284 applies be operated only under the direct supervision of no less
285 than one (1) pharmacist licensed to practice in this state, and to
286 provide such other special requirements as deemed necessary.
287 Nothing in this subsection shall be construed to prevent any
288 person from owning a pharmacy.

289 (8) All businesses permitted by the board shall report to
290 the board the occurrence of any of the following changes:

291 (a) Permanent closing;

292 (b) Change of ownership, management, location or
293 pharmacist in charge;



294 (c) Any and all other matters and occurrences as the
295 board may require by rule or regulation.

296 (9) Disasters, accidents and emergencies which may affect
297 the strength, purity or labeling of drugs, medications, devices or
298 other materials used in the diagnosis or the treatment of injury,
299 illness and disease shall be immediately reported to the board.

300 (10) No business that is required to obtain a permit shall
301 be operated until a permit has been issued for such business by
302 the board. Any person, firm or corporation violating any of the
303 provisions of this section shall be guilty of a misdemeanor and,
304 upon conviction thereof, shall be punished by a fine of not less
305 than One Hundred Dollars (\$100.00) nor more than One Thousand
306 Dollars (\$1,000.00), or imprisonment in the county jail for not
307 less than thirty (30) days nor more than ninety (90) days, or by
308 both such fine and imprisonment. However, the provisions of this
309 chapter shall not apply to physicians, dentists, veterinarians,
310 osteopaths or other practitioners of the healing arts who are
311 licensed under the laws of the State of Mississippi and are
312 authorized to dispense and administer prescription drugs in the
313 course of their professional practice.

314 **SECTION 4.** This act shall take effect and be in force from
315 and after July 1, 2007.

