

House Bill 132 (AS PASSED HOUSE AND SENATE)

By: Representatives Hawkins of the 27th, Rogers of the 29th, Watson of the 166th, Channell of the 120th, Lindsey of the 54th, and others

A BILL TO BE ENTITLED
AN ACT

1 To amend Chapter 4 of Title 26 and Chapter 11 of Title 43 of the Official Code of Georgia
2 Annotated, relating to pharmacists and pharmacies and dentists, dental hygienists, and dental
3 assistants, respectively, so as to provide that the Georgia State Board of Pharmacy and the
4 Georgia Board of Dentistry are transferred from being administratively attached to the
5 Secretary of State to being divisions of the Department of Community Health; to provide for
6 the powers and duties of each board; to authorize each board to employ an executive director;
7 to provide for the powers and duties of such executive directors; to provide that the Georgia
8 Drugs and Narcotics Agency may employ personnel who are not special agents and may
9 contract with licensing boards for purposes of conducting investigations; to provide for a
10 census of dentists and dental hygienists; to revise provisions relating to qualifications of
11 applicants to practice dentistry; to provide for notice of felonies by licensees; to revise
12 provisions for purposes of conformity; to provide for related matters; to repeal conflicting
13 laws; and for other purposes.

14 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

PART I

SECTION 1-1.

17 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and
18 pharmacies, is amended in Code Section 26-4-5, relating to definitions, by revising paragraph
19 (11.1) and by adding new paragraphs to read as follows:

20 "(3.1) 'Cognizant member' means that member of the Georgia State Board of Pharmacy
21 who is charged with conducting investigative interviews relating to investigations
22 involving licensees, registrants, and permit holders."

23 "(11.1) 'Division director' means the division director of the professional licensing boards
24 division, as provided in Chapter 1 of Title 43."

25 "(15.1) 'Executive director' means the executive director appointed by the Georgia State
26 Board of Pharmacy pursuant to Code Section 26-4-20."

27 **SECTION 1-2.**

28 Said chapter is further amended by revising Code Section 26-4-20, relating to the
29 continuation of the State Board of Pharmacy and enforcement of provisions of chapter vested
30 in board, as follows:

31 "26-4-20.

32 (a) The Georgia State Board of Pharmacy existing immediately preceding July 1, ~~1998~~
33 2013, is continued in existence, and members serving on the board immediately preceding
34 that date shall continue to serve out their terms of office and until their respective
35 successors are appointed and qualified.

36 (b) The responsibility for enforcement of the provisions of this chapter shall be vested in
37 the Georgia State Board of Pharmacy. The board shall have all of the duties, powers, and
38 authority specifically granted by or necessary for the enforcement of this chapter, as well
39 as such other duties, powers, and authority as it may be granted from time to time by
40 applicable law.

41 (c) On and after July 1, 2013, the board shall not be under the jurisdiction of the Secretary
42 of State but shall be a division of the Department of Community Health; provided,
43 however, that except as otherwise specifically provided, the board shall be autonomous
44 from the Board of Community Health and the commissioner of community health and shall
45 exercise its quasi-judicial, rule-making, licensing, or policy-making functions
46 independently of the department and without approval or control of the department and
47 prepare its budget and submit its budgetary requests, if any, through the department. Such
48 transfer shall in no way affect any existing obligations, liabilities, or rights of the board, as
49 such existed on June 30, 2013. The board shall have with respect to all matters within the
50 jurisdiction of the board as provided under this chapter the powers, duties, and functions
51 of professional licensing boards as provided in Chapter 1 of Title 43.

52 (d) The board shall appoint and fix the compensation, which shall be approved by the
53 Board of Community Health, of an executive director of such board who shall serve at the
54 pleasure of the board.

55 (e) The venue of any action involving members of the board shall be the county in which
56 is found the primary office of the board. The executive director of the board shall not be
57 considered a member of the board in determining the venue of any such action, and no
58 court shall have jurisdiction over any such action solely by virtue of the executive director
59 residing or maintaining a residence within its jurisdiction."

60 **SECTION 1-3.**

61 Said chapter is further amended in Code Section 26-4-21, relating to eligibility requirements
62 for board members, by revising subsection (c) as follows:

63 "(c) Appointees to the board shall immediately after their appointment take and subscribe
 64 to an oath or affirmation before a qualified officer that they will faithfully and impartially
 65 perform the duties of the office, ~~which~~ and the oath shall be filed with the ~~Secretary of~~
 66 ~~State Office of the Governor~~, whereupon the ~~Secretary of State Office of the Governor~~
 67 shall issue to each appointee a certificate of appointment."

68 **SECTION 1-4.**

69 Said chapter is further amended in Code Section 26-4-22, relating to the number and terms
 70 of members, appointment, and vacancies, by revising subsection (a) as follows:

71 "(a) The board shall consist of seven members possessing the qualification specified in
 72 subsection (a) of Code Section 26-4-21 and one additional member possessing the
 73 qualifications specified in subsection (b) of Code Section 26-4-21 who shall be appointed
 74 by the Governor and confirmed by the Senate for a term of five years or until their
 75 successors are appointed and qualified. Pharmacist members shall represent a diversity of
 76 practice settings and geographic dispersion of practitioners across ~~the~~ this state."

77 **SECTION 1-5.**

78 Said chapter is further amended by revising Code Section 26-4-23, relating to removal of
 79 board members, as follows:

80 "26-4-23.

81 Any member who has failed to attend three consecutive regular monthly meetings of the
 82 board for any reason other than illness of such member shall be subject to removal by the
 83 Governor upon request of the board. The president of the board shall notify the Governor
 84 in writing when any such member has failed to attend three consecutive regular monthly
 85 meetings. Any member of the board may be removed by the Governor in the same manner
 86 as provided in Code Section 43-1-17."

87 **SECTION 1-6.**

88 Said chapter is further amended by revising Code Section 26-4-24, relating to meetings and
 89 organization, appeals, and serving of notices and legal process, as follows:

90 "26-4-24.

91 The board shall meet at least annually to organize and elect a president and a ~~vice-president~~
 92 vice president from its members. ~~The division director shall be the secretary of the board~~
 93 ~~and shall have all the power, duties, and authority with reference to such board as shall be~~
 94 ~~prescribed by Chapter 1 of Title 43 and shall perform such other duties as may be~~
 95 ~~prescribed by the board.~~ The vice president shall serve as the cognizant member of the
 96 board. All appeals from the decision of the board, all documents or applications required

97 by law to be filed with the board, and any notice or legal process to be served upon the
 98 board may be filed with or served upon the ~~division director~~ executive director at his or her
 99 office in the county of domicile of the ~~professional licensing boards division~~ board."

100 **SECTION 1-7.**

101 Said chapter is further amended by revising Code Section 26-4-25, relating to compensation
 102 of board members, as follows:

103 "26-4-25.

104 Each member of the board ~~shall be reimbursed as provided for in subsection (f) of Code~~
 105 ~~Section 43-1-2~~ may receive the expense allowance as provided by subsection (b) of Code
 106 Section 45-7-21 and the same mileage allowance for the use of a personal car as that
 107 received by other state officials and employees or a travel allowance of actual
 108 transportation costs if traveling by public carrier within this state. Each board member
 109 shall also be reimbursed for any conference or meeting registration fee incurred in the
 110 performance of his or her duties as a board member. For each day's service outside of this
 111 state as a board member, such member shall receive actual expenses as an expense
 112 allowance as well as the mileage allowance for the use of a personal car equal to that
 113 received by other state officials and employees or a travel allowance of actual
 114 transportation costs if traveling by public carrier or by rental motor vehicle. Expense
 115 vouchers submitted by board members shall be subject to approval of the president and
 116 executive director. Out-of-state travel by board members shall be approved by the board
 117 president and the executive director."

118 **SECTION 1-8.**

119 Said chapter is further amended by revising Code Section 26-4-26, relating to meetings,
 120 notice, quorum, and open meetings, as follows:

121 "26-4-26.

122 (a) ~~The~~ To transact its business, the board shall meet on a regular basis to transact its
 123 business hold regular meetings at least once each month unless, in the discretion of the
 124 president, it is deemed unnecessary for a particular month. The board shall meet at such
 125 additional times as it may determine. Such additional meetings may be called by the
 126 president of the board or by at least two-thirds of the members of the board.

127 (b) Notice of all meetings of the board shall be given in the manner and pursuant to
 128 requirements prescribed by Chapter 14 of Title 50 relating to open meetings.

129 (c) A majority of the members of the board shall constitute a quorum for the conduct of
 130 a board meeting and, except where a greater number is required by this chapter or by any
 131 rule of the board, all actions of the board shall be by a majority of a quorum.

132 (d) Meetings and hearings of the board shall be held at the site of the office of the board
 133 or at such other site as may be specified by the president of the board.
 134 ~~(d)~~(e) All board meetings and hearings shall be open to the public. The board may, in its
 135 discretion and according to law, conduct any portion of its meeting in executive session
 136 closed to the public.
 137 (f) Proceedings before the board wherein a licensee's or permit holder's right to practice
 138 pursuant to this chapter in this state is terminated, suspended, or limited or wherein a public
 139 reprimand is administered shall require prior notice to the licensee and an opportunity for
 140 hearing; and such proceedings shall be considered contested cases within the meaning of
 141 Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act.' Neither refusal of a
 142 license or permit nor a private reprimand nor a letter of concern shall be considered a
 143 contested case within the meaning of Chapter 13 of Title 50; provided, however, that the
 144 applicant shall be allowed to appear before the board, if the applicant so requests, prior to
 145 the board making a final decision regarding the issuance of the license or permit. The
 146 power to subpoena as set forth in Chapter 13 of Title 50 shall include the power to
 147 subpoena any relevant book, writing, paper, or document. If any licensee or permit holder
 148 fails to appear at any hearing after reasonable notice, the board may proceed to hear the
 149 evidence against such licensee or permit holder and take action as if such licensee or permit
 150 holder had been present."

151 **SECTION 1-9.**

152 Said chapter is further amended in Code Section 26-4-28, relating to the powers, duties, and
 153 authority of the State Board of Pharmacy, by revising paragraphs (20) and (21) of subsection
 154 (a), by adding new paragraphs to subsection (a), and by revising subsection (b) as follows:

155 "(20) The requiring of background checks, including, but not limited to, criminal history
 156 record checks, on any persons or firms applying for licensure or registration pursuant to
 157 this chapter; ~~and~~

158 (21) Serving as the sole governmental or other authority which shall have the authority
 159 to approve or recognize accreditation or certification programs for specialty pharmacy
 160 practice or to determine the acceptability of entities which may accredit pharmacies or
 161 certify pharmacists in a specialty of pharmacy practice, and the board may require such
 162 accreditation or certification as a prerequisite for specialty or advanced pharmacy
 163 practice. Such accreditation and certification standards for specialties shall be set forth
 164 in rules promulgated by the board with such rules to contain the required qualifications
 165 or limitations. Any accreditation or certification for specialty pharmacy practice
 166 approved or recognized by the board shall be deemed sufficient to meet any and all
 167 standards, licensure, or requirements, or any combination thereof, otherwise set forth by

168 any private entity or other government agency to satisfy its stated goals and standards for
 169 such accreditation or certification. Nothing in this paragraph shall prohibit private
 170 entities, government agencies, professional organizations, or educational institutions from
 171 submitting accreditation or certification programs for the review and potential approval
 172 or recognition by the board. Accreditation and certification for specialty pharmacy
 173 practice under this paragraph shall be subject to the following conditions:

174 (A) Applications shall be submitted as set forth in rules promulgated or approved by
 175 the board for accreditation or certification;

176 (B) Only a pharmacist registered by this state and maintaining an active license in good
 177 standing is eligible for certification in a specialty pharmacy practice by the board;

178 (C) Only a pharmacy registered by this state and maintaining an active license in good
 179 standing is eligible for accreditation for specialty pharmacy practice by the board;

180 (D) Any board approved or recognized accreditation for a specialty pharmacy practice
 181 of a pharmacy is to be deemed sufficient and shall satisfy any standards or
 182 qualifications required for payment of services rendered as set forth by any insurance
 183 company, carrier, or similar third-party payor plan in any policy or contract issued,
 184 issued for delivery, delivered, or renewed on or after July 1, 1999;

185 (E) Any board approved or recognized specialty certification issued to a pharmacist is
 186 deemed sufficient and shall satisfy any standards or qualifications required for payment
 187 of services rendered as set forth by any insurance company, carrier, or similar
 188 third-party payor plan in any policy or contract issued, issued for delivery, delivered,
 189 or renewed on or after July 1, 1999; and

190 (F) The board may deny, revoke, limit, suspend, probate, or fail to renew the
 191 accreditation or specialty certification of a pharmacy, pharmacist, or both for cause as
 192 set forth in Code Section 26-4-60 or for a violation of Chapter 13 of Title 16 or if the
 193 board determines that a pharmacy, pharmacist, or both; no longer meet the accreditation
 194 or certification requirements of the board. Before such action, the board shall serve
 195 upon the pharmacist in charge of a pharmacy or pharmacist an order to show cause why
 196 accreditation or certification should not be denied, revoked, limited, suspended, or
 197 probated or why the renewal should not be refused. The order to show cause shall
 198 contain a statement for the basis therefor and shall call upon the pharmacist in charge
 199 of a pharmacy, the pharmacist, or both; to appear before the board at a time and place
 200 not more than 60 days after the date of the service of the order;:

201 (22) To adopt a seal by which the board shall authenticate the acts of the board;

202 (23) To keep a docket of public proceedings, actions, and filings;

203 (24) To set its office hours;

- 204 (25) To require licensees and permit holders to report a change of business address or
205 personal address within ten days of the change in either address;
- 206 (26) To adopt necessary rules concerning proceedings, hearings, review hearings,
207 actions, filings, depositions, and motions related to uncontested cases;
- 208 (27)(A) To authorize the Georgia Drugs and Narcotics Agency to conduct inspections
209 and initiate investigations on its behalf for the purpose of discovering violations of this
210 chapter, Chapter 3 of this title, and Chapter 13 of Title 16.
- 211 (B) When conducting investigations and inspections on behalf of the board, the
212 Georgia Drugs and Narcotics Agency shall have the same access to and may examine
213 any relevant writing, document, or other material relating to any licensee, registrant,
214 permittee, or applicant as the board. The executive director may issue subpoenas to
215 compel access to any writing, document, or other material upon a determination that
216 reasonable grounds exist for the belief that a violation of this chapter, Chapter 3 of this
217 title, Chapter 13 of Title 16, or any other law relating to the practice of pharmacy may
218 have taken place. The results of all investigations and inspections initiated by the
219 Georgia Drugs and Narcotics Agency which relate to an individual licensed or
220 permitted by the board shall be reported by the Georgia Drugs and Narcotics Agency
221 to the board, and the records of such investigations shall be kept for the board by the
222 director of the Georgia Drugs and Narcotics Agency, and the board shall retain the right
223 to have access to such records at any time. Notwithstanding the provisions of this
224 subparagraph, Code Section 16-13-60 shall control the access to or release of
225 information.
- 226 (C) Nothing in this chapter shall be construed to prohibit or limit the authority of the
227 executive director or the director of the Georgia Drugs and Narcotics Agency to
228 conduct inspections and initiate investigations on its own initiative for the purpose of
229 discovering violations of this chapter, Chapter 3 of this title, and Chapter 13 of Title 16
230 and disclose such information to any law enforcement agency or prosecuting attorney.
231 Notwithstanding the provisions of this subparagraph, Code Section 16-13-60 shall
232 control the access to or release of information.
- 233 (D) The executive director or the director of the Georgia Drugs and Narcotics Agency
234 may also disclose to any person or entity information concerning the existence of any
235 investigation for unlicensed practice being conducted against any person who is neither
236 licensed nor an applicant for licensure by the board;
- 237 (28) To administer oaths, subpoena witnesses and documentary evidence, including
238 relevant medical records, and take testimony in all matters relating to its duties;
- 239 (29) To conduct hearings, reviews, and other proceedings according to Chapter 13 of
240 Title 50;

241 (30) To have the cognizant member of the board conduct investigative interviews in
 242 conjunction with the Georgia Drugs and Narcotics Agency and thereafter to report his or
 243 her findings, with recommendations, to the board. In order to obtain a nonprejudicial
 244 decision, such report and recommendations shall not disclose the identity of the subject
 245 of the investigation. The cognizant member shall not vote on matters which he or she has
 246 presented to the board as the cognizant member;

247 (31) To issue cease and desist orders to stop the unlicensed practice of pharmacy or other
 248 professions licensed, certified, or permitted under this chapter and impose penalties for
 249 such violations;

250 (32) To refer cases for criminal prosecution or injunctive relief to appropriate
 251 prosecuting attorneys or other law enforcement authorities of this state, another state, or
 252 the United States;

253 (33) To release investigative or applicant files to another enforcement agency or lawful
 254 licensing authority in another state;

255 (34) To sue and be sued in a court of competent jurisdiction;

256 (35) To enter into contracts;

257 (36) To assess fines for violations of this chapter or board rules; and

258 (37) To set all reasonable fees by adoption of a schedule of fees approved by the board.
 259 The board shall set such fees sufficient to cover costs of operation.

260 (b) Proceedings by the board in the exercise of its authority to cancel, suspend, or revoke
 261 any license issued under the terms of this chapter shall be conducted in accordance with
 262 Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act.' In all such proceedings,
 263 the board shall have authority to compel the attendance of witnesses and the production of
 264 any book, writing, or document upon the issuance of a subpoena therefor signed by the
 265 secretary of the board. In any hearing in which the fitness of a licensee or applicant to
 266 practice pharmacy or another business or profession licensed by the board under this
 267 chapter is in question, the board may exclude all persons from its deliberation of the
 268 appropriate action to be taken and may, when it deems it necessary, speak to a licensee or
 269 applicant and his or her legal counsel in private."

270 **SECTION 1-10.**

271 Said chapter is further amended by adding new Code sections to read as follows:

272 "26-4-28.1.

273 (a) The executive director:

274 (1) Shall be a full-time employee of the board and shall serve as the chief executive
 275 officer and secretary of the board. Any person, in order to qualify for appointment as the
 276 executive director, shall be of good moral character and shall possess such qualifications

277 as the board may require. The executive director shall have, with respect to the board,
278 the same powers, duties, and functions granted to the division director with respect to
279 professional licensing boards under Chapter 1 of Title 43 but shall not be subject to any
280 approval or other powers exercised by the Secretary of State;

281 (2) With the approval of the board, may employ or contract with and fix the
282 compensation of administrative assistants, secretaries, and any other such staff as deemed
283 necessary to assist in the duties of the board. The director of the Georgia Drugs and
284 Narcotics Agency shall serve as the assistant executive director, who shall act on behalf
285 of the executive director in his or her absence. The executive director and other board
286 staff shall be allowed reimbursement for travel and other expenses necessarily incurred
287 in the performance of their duties in the same manner as other state officers and
288 employees, and shall receive payment of the same in the manner provided for the board;

289 (3) Shall take an oath to discharge faithfully the duties of the office; and

290 (4) Shall be charged with the duties and powers as prescribed by the board.

291 (b) The executive director shall prepare and maintain a public roster containing the names
292 and business addresses of all current licensees, registration holders, and permit holders for
293 each of the various registrants regulated by the board. A copy of the roster shall be
294 available to any person upon request at a fee prescribed by the board sufficient to cover the
295 cost of printing and distribution. The following shall be treated as confidential, not subject
296 to Article 4 of Chapter 18 of Title 50, relating to open records, and shall not be disclosed
297 without the approval of the board:

298 (1) Applications and other personal information submitted by applicants, except to the
299 applicant, the staff, and the board;

300 (2) Information, favorable or unfavorable, submitted by a reference source concerning
301 an applicant, except to the staff and the board;

302 (3) Examination questions and other examination materials, except to the staff and the
303 board; and

304 (4) The deliberations of the board with respect to an application, an examination, a
305 complaint, an investigation, or a disciplinary proceeding, except as may be contained in
306 official board minutes; provided, however, that such deliberations may be released to a
307 law enforcement agency or prosecuting attorney of this state or to another state or federal
308 enforcement agency or lawful licensing authority. Releasing the documents pursuant to
309 this paragraph shall not subject any otherwise privileged documents to the provisions of
310 Code Section 50-18-70.

311 26-4-28.2.
 312 Any licensee, registration holder, or permit holder who is convicted under the laws of this
 313 state, the United States, or any other state, territory, or country of a felony shall be required
 314 to notify the board of the conviction within ten days of the conviction. The failure to notify
 315 the board of a conviction shall be considered grounds for revocation of his or her license,
 316 registration, permit, or other authorization to engage in the practice of pharmacy or another
 317 profession regulated under this chapter."

318 **SECTION 1-11.**

319 Said chapter is further amended by revising Code Section 26-4-29, relating to the Georgia
 320 Drugs and Narcotics Agency, continuance, appointment, requirements, and duties of director,
 321 power to make arrests, report of violations of drug laws, and dangerous drug list, as follows:
 322 "26-4-29.

323 (a) The agency created in 1908 as the Office of the Chief Drug Inspector and known as the
 324 Georgia Drugs and Narcotics Agency since 1976 is continued in existence as the Georgia
 325 Drugs and Narcotics Agency. This agency shall be a budget unit as defined under Code
 326 Section 45-12-71; provided, however, that the agency shall be assigned for administrative
 327 purposes only, as defined in Code Section 50-4-3, to the ~~office of the Secretary of State~~
 328 Department of Community Health, except that such department shall prepare and submit
 329 the budget for the Georgia Drugs and Narcotics Agency. The Georgia Drugs and Narcotics
 330 Agency is authorized by this Code section to enforce the drug laws of this state. The board
 331 shall appoint a director who shall be charged with supervision and control of such agency.
 332 The Georgia Drugs and Narcotics Agency ~~agency~~ shall employ the number of personnel
 333 deemed necessary to properly protect the health, safety, and welfare of the citizens of this
 334 state. Such personnel shall be pharmacists registered in this state when employed as either
 335 special agents or the deputy director.

336 (b) The director shall hold office at the pleasure of the board, and should any vacancy
 337 occur in ~~said~~ such office for any cause whatsoever, ~~said~~ the board shall appoint a successor
 338 at a regular or called meeting. The director shall be a pharmacist registered in this state.
 339 The director shall serve as the assistant executive director for the board and act on behalf
 340 of the executive director during his or her absence. The salary of the director shall be fixed
 341 by the board. The whole time of the director shall be at the disposal of the board. The
 342 director, or Georgia Drugs and Narcotics Agency ~~agency~~ personnel acting on behalf of the
 343 director, shall have the duty and the power to:

344 (1) Visit and inspect factories, warehouses, wholesaling establishments, retailing
 345 establishments, chemical laboratories, and such other establishments in which any drugs,
 346 devices, cosmetics, and such articles known as family remedies, grocer's drugs, and toilet

347 articles are manufactured, processed, packaged, sold at wholesale, sold at retail, or
 348 otherwise held for introduction into commerce;

349 (2) Enter and inspect any vehicle used to transport or hold any drugs, devices, cosmetics,
 350 or any of the articles listed in paragraph (1) of this subsection;

351 (3) Investigate alleged violations of laws and regulations regarding drugs, devices,
 352 cosmetics, or any of the articles listed in paragraph (1) of this subsection;

353 (4) Take up samples of the articles listed in paragraph (1) of this subsection from any of
 354 ~~the said~~ such establishments for examination and analysis by the state chemist, or under
 355 such person's direction and supervision, as provided by Code Section 26-4-131;

356 (5) Seize and take possession of all articles which are declared to be contraband under
 357 Chapter 13 of Title 16 and Chapter 3 of this title and this chapter and deliver such articles
 358 to the agency;

359 (6) Compel the attendance of witnesses and the production of evidence on behalf of the
 360 board via a subpoena issued by the director, when there is reason to believe any violations
 361 of laws or regulations concerning drugs, devices, cosmetics, or any of the articles listed
 362 in paragraph (1) of this subsection have occurred; and

363 (7) Perform such other duties as may be directed by the board.

364 (c)(1) The director, deputy director, and special agents of the Georgia Drugs and
 365 Narcotics Agency shall have the authority and power that sheriffs possess to make arrests
 366 of any persons violating or charged with violating Chapter 13 of Title 16 and Chapter 3
 367 of this title and this chapter. The deputy director and special agents shall be required to
 368 be P.O.S.T. certified peace officers under Chapter 8 of Title 35, the 'Georgia Peace
 369 Officer Standards and Training Act.'

370 (2) In case of such arrest, the director, deputy director, or any of the special agents shall
 371 immediately deliver the person so arrested to the custody of the sheriff of the county
 372 wherein the offense is alleged to have been committed. The duty of the sheriff in regard
 373 to the person delivered to the sheriff by any such person arrested under power of this
 374 Code section shall be the same as if the sheriff had made the original arrest.

375 ~~(c.1)~~(d) When the deputy director or a special agent employed by the Georgia Drugs and
 376 Narcotics Agency leaves the agency under honorable conditions after accumulating 25
 377 years of service in the agency, as a result of a disability arising in the line of duty, or
 378 pursuant to approval by the State Board of Pharmacy, such director or agent shall be
 379 entitled to retain his or her weapon and badge pursuant to approval by the State Board of
 380 Pharmacy, and, upon leaving the agency, the director of the Georgia Drugs and Narcotics
 381 Agency shall retain his or her weapon and badge pursuant to approval by the State Board
 382 of Pharmacy.

383 (e) The Georgia Drugs and Narcotics Agency may employ personnel who are not special
 384 agents to conduct and assist with inspections.

385 ~~(d)~~(f) Except as otherwise provided in this chapter, upon receiving a summary report from
 386 agency personnel, the director shall report to the board what have been determined to be
 387 violations of the drug laws and rules over which the board has authority. After such reports
 388 have been made to the board, the board ~~can~~ may instruct the director to:

389 (1) Cite any such person or establishment to appear before the cognizant member of the
 390 board for an investigative interview;

391 (2) Forward such reports to the Attorney General's office for action decided on by the
 392 board; or

393 (3) Take whatever other action the board deems necessary.

394 (g) The Georgia Drugs and Narcotics Agency may contract with and submit invoices for
 395 payment of services rendered to other professional licensing boards for the purposes of
 396 conducting investigations on their behalf and under the authority of such other professional
 397 licensing boards. Such investigations and subsequent reports and summaries shall be
 398 subject to the same confidentiality restrictions and disclosure as required for investigations
 399 and reports for the requesting professional licensing board. Any such payment of services
 400 received by the agency shall be deposited into the general fund of the state treasury.

401 ~~(e)~~(h) The Georgia Drugs and Narcotics Agency shall compile and submit to the General
 402 Assembly during each annual legislative session a list of known dangerous drugs as defined
 403 in subsection (a) of Code Section 16-13-71 and any other drugs or devices which the board
 404 has determined may be dangerous or detrimental to the public health and safety and should
 405 require a prescription, and the Georgia Drugs and Narcotics Agency shall assist the State
 406 Board of Pharmacy during each annual legislative session by compiling and submitting a
 407 list of substances to add to or reschedule substances enumerated in the schedules in Code
 408 Sections 16-13-25 through 16-13-29 by using the guidelines set forth in Code Section
 409 16-13-22.

410 ~~(f)~~(i) The State Board of Pharmacy is authorized and directed to publish in print or
 411 electronically and distribute the 'Dangerous Drug List' as prepared by the Georgia Drugs
 412 and Narcotics Agency and the 'Georgia Controlled Substances Act' as enacted by law.

413 ~~(z)~~(j) The Georgia State Board of Pharmacy shall provide for a fee as deemed reasonable,
 414 or at no cost, such number of copies of the 'Dangerous Drug List' and 'Georgia Controlled
 415 Substances Act' to law enforcement officials, school officials, parents, and other interested
 416 citizens as are required."

417 **SECTION 1-12.**

418 Said chapter is further amended by revising Code Section 26-4-43, relating to temporary
419 licenses, as follows:

420 "26-4-43.

421 A temporary license may be issued by the ~~division director~~ executive director upon the
422 approval of the president of the board if an applicant produces satisfactory evidence of
423 fulfilling the requirements for licensure under this article, except the examination
424 requirement, and evidence of an emergency situation justifying such temporary license.
425 All temporary licenses shall expire at the end of the month during which the first board
426 meeting is conducted following the issuance of such license and may not be reissued or
427 renewed."

428 **SECTION 1-13.**

429 Said chapter is further amended in Code Section 26-4-44, relating to renewal of licenses, by
430 revising subsection (a) as follows:

431 "(a) Each pharmacist shall apply for renewal of his or her license biennially pursuant to the
432 rules and regulations promulgated by the board. A pharmacist who desires to continue in
433 the practice of pharmacy in this state shall file with the board an application in such form
434 and containing such data as the board may require for renewal of the license. Notice of any
435 change of employment or change of business address shall be filed with the ~~division~~
436 ~~director~~ executive director within ten days after such change. If the board finds that the
437 applicant has been licensed and that such license has not been revoked or placed under
438 suspension and that the applicant has paid the renewal fee, has continued his or her
439 pharmacy education in accordance with Code Section 26-4-45 and the rules and regulations
440 of the board, and is entitled to continue in the practice of pharmacy, then the board shall
441 issue a license to the applicant."

442 **SECTION 1-14.**

443 Said chapter is further amended by revising Code Section 26-4-45, relating to continuing
444 professional pharmaceutical education requirements, as follows:

445 "26-4-45.

446 The board shall establish a program of continuing professional pharmaceutical education
447 for the renewal of pharmacist licenses. Notwithstanding any other provision of this
448 chapter, no pharmacist license shall be renewed by the board or the ~~division director~~
449 executive director until the pharmacist submits to the board satisfactory proof of his or her
450 participation, during the biennium preceding his or her application for renewal, in a
451 minimum of 30 hours of approved programs of continuing professional pharmacy

452 education as defined in this Code section. Continuing professional pharmacy education
 453 shall consist of educational programs providing training pertinent to the practice of
 454 pharmacy and approved by the board under this Code section. The board shall approve
 455 educational programs for persons practicing pharmacy in this state on a reasonable
 456 nondiscriminatory fee basis and may contract with institutions of higher learning,
 457 professional organizations, or qualified individuals for the providing of approved programs.
 458 In addition to such programs, the board shall allow the continuing professional pharmacy
 459 education requirement to be fulfilled by the completion of approved correspondence
 460 courses which provide the required hours of approved programs of continuing professional
 461 pharmaceutical education or to be fulfilled by a combination of approved correspondence
 462 courses and other approved educational programs. The board may, consistent with the
 463 requirements of this Code section, promulgate rules and regulations to implement and
 464 administer this Code section, including the establishment of a committee to prescribe
 465 standards, approve and contract for educational programs, and set the required minimum
 466 number of hours per year."

467 **SECTION 1-15.**

468 Said chapter is further amended in Code Section 26-4-49, relating to drug researcher permits,
 469 application for registration, fees, suspension or revocation, and penalty for violations, by
 470 revising subsection (b) as follows:

471 "(b) The board may require that the application for registration as a drug researcher be
 472 accompanied by a fee in an amount established under rules promulgated by the board, and
 473 the board may establish conditions for exemptions from such fees. Such registration shall
 474 not be transferable and shall expire on the expiration date established by the ~~division~~
 475 ~~director~~ executive director and may be renewed pursuant to rules and regulations
 476 promulgated by the board. If not renewed, the registration shall lapse and become null and
 477 void."

478 **SECTION 1-16.**

479 Said chapter is further amended by revising Code Section 26-4-60, relating to grounds for
 480 suspension, revocation, or refusal to grant licenses, as follows:

481 "26-4-60.

482 (a) The board of pharmacy may refuse to issue or renew, or may suspend, revoke, or
 483 restrict the licenses of, or fine any person pursuant to the procedures set forth in this Code
 484 section, upon one or more of the following grounds:

485 (1) ~~Unprofessional conduct as that term is defined by the rules of the board~~ Engaging in
 486 any unprofessional, immoral, unethical, deceptive, or deleterious conduct or practice

487 harmful to the public, which conduct or practice materially affects the fitness of the
 488 licensee or applicant to practice pharmacy or another business or profession licensed
 489 under this chapter, or of a nature likely to jeopardize the interest of the public, which
 490 conduct or practice need not have resulted in actual injury to any person or be directly
 491 related to the practice of pharmacy or another licensed business or profession but shows
 492 that the licensee or applicant has committed any act or omission which is indicative of
 493 bad moral character or untrustworthiness; unprofessional conduct shall also include any
 494 departure from, or the failure to conform to, the minimal reasonable standards of
 495 acceptable and prevailing practices of the business or profession licensed under this
 496 chapter;

497 (2) Incapacity that prevents a licensee from engaging in the practice of pharmacy or
 498 another business or profession licensed under this chapter with reasonable skill,
 499 competence, and safety to the public;

500 (3) ~~Being guilty of one or more of the following:~~

501 (A) ~~A~~ Convicted of a felony;

502 (B) ~~Any act~~ Convicted of any crime involving moral turpitude in this state or any other
 503 state, territory, or country or in the courts of the United States; or

504 (C) ~~Violations~~ Convicted or guilty of violations of the pharmacy or drug laws of this
 505 state, or rules and regulations pertaining thereto, or of laws, rules, and regulations of
 506 any other state, or of the federal government;

507 (4) ~~Misrepresentation of a material fact by a licensee in securing the issuance or renewal~~
 508 ~~of a license~~ Knowingly making misleading, deceptive, untrue, or fraudulent
 509 representations in the practice of a business or profession licensed under this chapter or
 510 on any document connected therewith; practicing fraud or deceit or intentionally making
 511 any false statement in obtaining a license to practice the licensed business or profession;
 512 or making a false statement or deceptive registration with the board;

513 (5) Engaging or aiding and abetting an individual to engage in the practice of pharmacy
 514 without a license falsely using the title of 'pharmacist' or 'pharmacy intern,' or falsely
 515 using the term 'pharmacy' in any manner;

516 (6) Failing to pay the costs assessed in a disciplinary hearing pursuant to subsection (c)
 517 of Code Section 26-4-28;

518 (7)(A) Becoming unfit or incompetent to practice pharmacy by reason of:

519 (i) Intemperance in the use of alcoholic beverages, narcotics, or habit-forming drugs
 520 or stimulants; or

521 (ii) Any abnormal physical or mental condition which threatens the safety of persons
 522 to whom such person may compound or dispense prescriptions, drugs, or devices or

523 for whom he or she might manufacture, prepare, or package or supervise the
524 manufacturing, preparation, or packaging of prescriptions, drugs, or devices.

525 (B) In enforcing this paragraph, the board may, upon reasonable grounds, require a
526 licensee or applicant to submit to a mental or physical examination by licensed health
527 care providers designated by the board. The results of such examination shall be
528 admissible in any hearing before the board, notwithstanding any claim of privilege
529 under a contrary rule of law or statute, including, but not limited to, Code Section
530 ~~24-9-21~~ 24-5-501. Every person who ~~shall accept~~ accepts the privilege of practicing
531 pharmacy in this state or who ~~shall file~~ files an application for a license to practice
532 pharmacy in this state shall be deemed to have given his or her consent to submit to
533 such mental or physical examination and to have waived all objections to the
534 admissibility of the results in any hearing before the board, upon the grounds that the
535 same constitutes a privileged communication. If a licensee or applicant fails to submit
536 to such an examination when properly directed to do so by the board, unless such
537 failure was due to circumstances beyond his or her control, the board may enter a final
538 order upon proper notice, hearing, and proof of such refusal. Any licensee or applicant
539 who is prohibited from practicing pharmacy under this paragraph shall at reasonable
540 intervals be afforded an opportunity to demonstrate to the board that he or she can
541 resume or begin the practice of pharmacy with reasonable skill and safety to patients.

542 (C) For the purposes of this paragraph, the board may, upon reasonable grounds, obtain
543 any and all records relating to the mental or physical condition of a licensee or
544 applicant, including psychiatric records; and such records shall be admissible in any
545 hearing before the board, notwithstanding any claim of privilege under a contrary rule
546 of law or statute, including, but not limited to, Code Section ~~24-9-21~~ 24-5-501. Every
547 person who ~~shall accept~~ accepts the privilege of practicing pharmacy in this state or
548 who ~~shall file~~ files an application for a license to practice pharmacy in this state shall
549 be deemed to have given his or her consent to the board's obtaining any such records
550 and to have waived all objections to the admissibility of such records in any hearing
551 before the board, upon the grounds that the same constitutes a privileged
552 communication.

553 (D) If any licensee or applicant could, in the absence of this paragraph, invoke a
554 privilege to prevent the disclosure of the results of the examination provided for in
555 subparagraph (B) of this paragraph or the records relating to the mental or physical
556 condition of such licensee or applicant obtained pursuant to subparagraph (C) of this
557 paragraph, all such information shall be received by the board in camera and shall not
558 be disclosed to the public, nor shall any part of the record containing such information
559 be used against any licensee or applicant in any other type of proceeding;

560 (8) Being ~~adjudicated to be mentally ill or insane~~ adjudged mentally incompetent by a
 561 court of competent jurisdiction within or outside this state; any such adjudication shall
 562 automatically suspend the license of any such person and shall prevent the reissuance or
 563 renewal of any license so suspended for as long as the adjudication of incompetence is
 564 in effect;

565 (9) Violating any rules and regulations promulgated by the board;

566 (10) Promoting to the public in any manner a drug which may be dispensed only
 567 pursuant to prescription;

568 (11) Regularly employing the mails or other common carriers to sell, distribute, and
 569 deliver a drug which requires a prescription directly to a patient; provided, however, that
 570 this provision shall not prohibit the use of the mails or other common carriers to sell,
 571 distribute, and deliver a prescription drug directly to:

572 (A) A patient or directly to a patient's guardian or caregiver or a physician or physician
 573 acting as the patient's agent for whom the prescription drug was prescribed if:

574 (i) Such prescription drugs are prescribed for complex chronic, terminal, or rare
 575 conditions;

576 (ii) Such prescription drugs require special administration, comprehensive patient
 577 training, or the provision of supplies and medical devices or have unique patient
 578 compliance and safety monitoring requirements;

579 (iii) Due to the prescription drug's high monetary cost, short shelf life, special
 580 manufacturer specified packaging and shipping requirements or instructions which
 581 require temperature sensitive storage and handling, limited availability or distribution,
 582 or other factors, the drugs are not carried in the regular inventories of retail
 583 pharmacies such that the drugs could be immediately dispensed to multiple retail
 584 walk-in patients;

585 (iv) Such prescription drug has an annual retail value to the patient of more than
 586 \$10,000.00;

587 (v) The patient receiving the prescription drug consents to the delivery of the
 588 prescription drug via expedited overnight common carrier and designates the specialty
 589 pharmacy to receive the prescription drug on his or her behalf;

590 (vi) The specialty pharmacy utilizes, as appropriate and in accordance with standards
 591 of the manufacturer, United States Pharmacopeia, and Federal Drug Administration
 592 and other standards adopted by the State Board of Pharmacy, temperature tags, time
 593 temperature strips, insulated packaging, or a combination of these; and

594 (vii) The specialty pharmacy establishes and notifies the enrollee of its policies and
 595 procedures to address instances in which medications do not arrive in a timely manner

596 or in which they have been compromised during shipment and to assure that the
597 pharmacy replaces or makes provisions to replace such drugs;

598 (B) An institution or to sell, distribute, or deliver prescription drugs, upon his or her
599 request, to an enrollee in a health benefits plan of a group model health maintenance
600 organization or its affiliates by a pharmacy which is operated by that same group model
601 health maintenance organization and licensed under Code Section 26-4-110 or to a
602 patient on behalf of a pharmacy. Any pharmacy using the mails or other common
603 carriers to dispense prescriptions pursuant to this paragraph shall comply with the
604 following conditions:

605 (i) The pharmacy shall provide an electronic, telephonic, or written communications
606 mechanism which reasonably determines whether the medications distributed by the
607 mails or other common carriers have been received by the enrollee and through which
608 a pharmacist employed by the group model health maintenance organization or a
609 pharmacy intern under his or her direct supervision is enabled to offer counseling to
610 the enrollee as authorized by and in accordance with his or her obligations under Code
611 Section 26-4-85, unless the enrollee refuses such consultation or counseling pursuant
612 to subsection (e) of such Code section. In addition, the enrollee shall receive
613 information indicating what he or she should do if the integrity of the packaging or
614 medication has been compromised during shipment;

615 (ii) In accordance with clinical and professional standards, the State Board of
616 Pharmacy shall promulgate a list of medications which may not be delivered by the
617 mails or other common carriers. However, until such list is promulgated, the group
618 model health maintenance organization shall not deliver by use of the mails or other
619 common carriers Class II controlled substance medications, medications which
620 require refrigeration, chemotherapy medications deemed by the federal
621 Environmental Protection Agency as dangerous, medications in suppository form, and
622 other medications which, in the professional opinion of the dispensing pharmacist,
623 may be clinically compromised by distribution through the mail or other common
624 carriers;

625 (iii) The pharmacy shall utilize, as appropriate and in accordance with standards of
626 the manufacturer, United States Pharmacopeia, and Federal Drug Administration and
627 other standards adopted by the State Board of Pharmacy, temperature tags, time
628 temperature strips, insulated packaging, or a combination of these; and

629 (iv) The pharmacy shall establish and notify the enrollee of its policies and
630 procedures to address instances in which medications do not arrive in a timely manner
631 or in which they have been compromised during shipment and to assure that the
632 pharmacy replaces or makes provisions to replace such drugs.

633 For purposes of this subparagraph ~~(B) of this paragraph~~, the term 'group model health
 634 maintenance organization' means a health maintenance organization that has an
 635 exclusive contract with a medical group practice to provide or arrange for the provision
 636 of substantially all physician services to enrollees in health benefits plans of the health
 637 maintenance organization; or

638 (C) A pharmacist or pharmacy to dispense a prescription and deliver it to another
 639 pharmacist or pharmacy to make available for a patient to receive the prescription and
 640 patient counseling according to Code Section 26-4-85. The State Board of Pharmacy
 641 shall adopt any rules and regulations necessary to implement this subparagraph;

642 (12) Unless otherwise authorized by law, dispensing or causing to be dispensed a
 643 different drug or brand of drug in place of the drug or brand of drug ordered or prescribed
 644 without the prior authorization of the practitioner ordering or prescribing the same;

645 (13) Violating or attempting to violate a statute, law, or any lawfully promulgated rule
 646 or regulation of this state, any other state, the board, the United States, or any other lawful
 647 authority without regard to whether the violation is criminally punishable, ~~which~~ when
 648 such statute, law, rule, or regulation relates to or in part regulates the practice of
 649 pharmacy or another business or profession licensed under this chapter, when the licensee
 650 or applicant knows or should know that such action ~~is violative of~~ violates such statute,
 651 law, or rule; or violating either a public or confidential lawful order of the board
 652 previously entered by the board in a disciplinary hearing, consent decree, or license
 653 reinstatement; ~~or~~

654 (14) Having his or her license to practice pharmacy or another business or profession
 655 licensed under this chapter revoked, suspended, or annulled by any lawful licensing
 656 authority of this or any other state, having disciplinary action taken against him or her by
 657 any lawful licensing authority of this or any other state, or being denied a license or
 658 renewal by any lawful licensing authority of this or any other state;

659 (15) Failure to demonstrate the qualifications or standards for a license contained in this
 660 Code section or under the laws, rules, or regulations under which licensure is sought or
 661 held; it shall be incumbent upon the applicant to demonstrate to the satisfaction of the
 662 board that he or she meets all the requirements for the issuance of a license, and if the
 663 board is not satisfied as to the applicant's qualifications, it may deny a license without a
 664 prior hearing; provided, however, that the applicant shall be allowed to appear before the
 665 board if he or she so desires; or

666 (16) Knowingly performing any act which in any way aids, assists, procures, advises, or
 667 encourages any unlicensed person or any licensee whose license has been suspended or
 668 revoked by the board to practice pharmacy or another business or profession licensed

669 under this chapter or to practice outside the scope of any disciplinary limitation placed
670 upon the licensee by the board.

671 (b) The board shall have the power to suspend or revoke the license of the pharmacist in
672 charge when a complete and accurate record of all controlled substances on hand, received,
673 manufactured, sold, dispensed, or otherwise disposed of has not been kept by the pharmacy
674 in conformance with the record-keeping and inventory requirements of federal law and the
675 rules of the board.

676 (c) Any person whose license to practice pharmacy in this state has been suspended,
677 revoked, or restricted pursuant to this chapter, whether voluntarily or by action of the
678 board, shall have the right, at reasonable intervals, to petition the board for reinstatement
679 of such license pursuant to rules and regulations promulgated by the board. Such petition
680 shall be made in writing and in the form prescribed by the board. The board may, in its
681 discretion, grant or deny such petition, or it may modify its original finding to reflect any
682 circumstances which have changed sufficiently to warrant such modifications.

683 (d) Nothing in this Code section shall be construed as barring criminal prosecutions for
684 violations of this chapter.

685 (e) All final decisions by the board shall be subject to judicial review pursuant to Chapter
686 13 of Title 50, the 'Georgia Administrative Procedure Act.'

687 (f) Any individual or entity whose license to practice pharmacy is revoked, suspended, or
688 not renewed shall return his or her license to the offices of the board within ten days after
689 receipt of notice of such action.

690 (g) For purposes of this Code section, a conviction shall include a finding or verdict of
691 guilty; or a plea of guilty, or a plea of nolo contendere, or no contest in a criminal
692 proceeding, regardless of whether the adjudication of guilt or sentence is withheld or not
693 entered thereon.

694 (h) Nothing in this Code section shall be construed as barring or prohibiting pharmacists
695 from providing or distributing health or drug product information or materials to patients
696 which are intended to improve the health care of patients.

697 (i) The board shall have the power to suspend any license issued under Article 3 of this
698 chapter when such holder is not in compliance with a court order for child support as
699 provided in Code Section 19-6-28.1 or 19-11-9.3. The board shall also have the power to
700 deny the application for issuance or renewal of a license under Article 3 of this chapter
701 when such applicant is not in compliance with a court order for child support as provided
702 in either of such Code sections. The hearings and appeals procedures provided for in such
703 Code sections shall be the only such procedures required to suspend or deny any license
704 issued under Article 3 of this chapter.

705 (j) Nothing in this chapter shall prohibit any person from assisting any duly licensed
706 pharmacist or practitioner in the measuring of quantities of medication and the typing of
707 labels therefor, but excluding the dispensing, compounding, or mixing of drugs, provided
708 that such duly licensed pharmacist or practitioner shall be physically present in the
709 dispensing area and actually observing the actions of such person in doing such measuring
710 and typing, and provided, further, that no prescription shall be given to the person
711 requesting the same unless the contents and the label thereof shall have been verified by
712 a licensed pharmacist or practitioner.

713 (k) The board shall have the power to suspend any license issued under Article 3 of this
714 chapter when such holder is a borrower in default who is not in satisfactory repayment
715 status as provided in Code Section 20-3-295. The board shall also have the power to deny
716 the application for issuance or renewal of a license under Article 3 of this chapter when
717 such applicant is a borrower in default who is not in satisfactory repayment status as
718 provided in Code Section 20-3-295. The hearings and appeals procedures provided for in
719 Code Section 20-3-295 shall be the only such procedures required to suspend or deny any
720 license issued under Article 3 of this chapter.

721 (l)(1) The executive director is vested with the power and authority to make or cause to
722 be made through employees or agents of the board or the Georgia Drugs and Narcotics
723 Agency such investigations as he or she or the board may deem necessary or proper for
724 the enforcement of the provisions of this Code section and the laws relating to the
725 practice of pharmacy and other businesses and professions licensed by the board. Any
726 person properly conducting an investigation on behalf of the board shall have access to
727 and may examine any writing, document, or other material relating to the fitness of any
728 licensee or applicant. The executive director or his or her appointed representative may
729 issue subpoenas to compel access to any writing, document, or other material upon a
730 determination that reasonable grounds exist for the belief that a violation of this Code
731 section or any other law relating to the practice of pharmacy or other business or
732 profession subject to regulation or licensing by the board may have taken place.
733 Notwithstanding the provisions of this paragraph, Code Section 16-13-60 shall control
734 the access to or release of information.

735 (2) If a licensee is the subject of a board inquiry, all records relating to any person who
736 receives services rendered by that licensee in his or her capacity as licensee shall be
737 admissible at any hearing held to determine whether a violation of this chapter has taken
738 place, regardless of any statutory privilege; provided, however, that any documentary
739 evidence relating to a person who received those services shall be reviewed in camera and
740 shall not be disclosed to the public.

741 (m) A person, firm, corporation, association, authority, or other entity shall be immune
742 from civil and criminal liability for reporting or investigating the acts or omissions of a
743 licensee or applicant which violate the provisions of subsection (a) of this Code section or
744 any other provision of law relating to a licensee's or applicant's fitness to practice a
745 business or profession licensed under this chapter, or for initiating or conducting
746 proceedings against such licensee or applicant, if such report is made or action is taken in
747 good faith, without fraud or malice. Any person who testifies or who makes a
748 recommendation to the board in the nature of peer review, in good faith, without fraud or
749 malice, before the board in any proceeding involving the provisions of subsection (a) of
750 this Code section or any other law relating to a licensee's or applicant's fitness to practice
751 the business or profession licensed by the board shall be immune from civil and criminal
752 liability for so testifying.

753 (n) Neither the issuance of a private reprimand nor the denial of a license by reciprocity
754 nor the denial of a request for reinstatement of a revoked license nor the refusal to issue a
755 previously denied license shall be considered to be a contested case within the meaning of
756 Chapter 13 of Title 50, the 'Georgia Administrative Procedure Act'; notice and hearing
757 within the meaning of such chapter shall not be required, but the applicant or licensee shall
758 be allowed to appear before the board if he or she so requests. The board may resolve a
759 pending action by the issuance of a letter of concern. Such letter shall not be considered
760 a disciplinary action or a contested case under Chapter 13 of Title 50 and shall not be
761 disclosed to any person except the licensee or applicant.

762 (o) If any licensee or applicant after reasonable notice fails to appear at any hearing of the
763 board for that licensee or applicant, the board may proceed to hear the evidence against
764 such licensee or applicant and take action as if such licensee or applicant had been present.
765 A notice of hearing, initial or recommended decision, or final decision of the board in a
766 disciplinary proceeding shall be served personally upon the licensee or applicant or served
767 by certified mail or statutory overnight delivery, return receipt requested, to the last known
768 address of record with the board. If such material is served by certified mail or statutory
769 overnight delivery and is returned marked 'unclaimed' or 'refused' or is otherwise
770 undeliverable and if the licensee or applicant cannot, after diligent effort, be located, the
771 executive director, or his or her designee, shall be deemed to be the agent for service for
772 such licensee or applicant for purposes of this Code section, and service upon the executive
773 director, or his or her designee, shall be deemed to be service upon the licensee or
774 applicant.

775 (p) Board proceedings that result in the voluntary surrender of a license or the failure to
776 renew a license by the end of an established penalty period shall have the same effect as
777 a revocation of such license, subject to reinstatement in the discretion of the board. The

778 board may restore and reissue a license to practice under this chapter and, as a condition
 779 thereof, may impose any disciplinary sanction provided by this Code section or the
 780 provisions of this chapter.

781 (q) This Code section shall apply equally to all licensees or applicants whether individuals,
 782 partners, or members of any other incorporated or unincorporated associations,
 783 corporations, limited liability companies, or other associations of any kind whatsoever."

784 **SECTION 1-17.**

785 Said chapter is further amended by revising subsection (a) of Code Section 26-4-115, relating
 786 to wholesale drug distributors, registration, fees, reports of excessive purchases, and penalty
 787 for violations, as follows:

788 "(a) All persons, firms, or corporations, whether located in this state or in any other state,
 789 engaged in the business of selling or distributing drugs at wholesale in this state, in the
 790 business of supplying drugs to manufacturers, compounders, and processors in this state,
 791 or in the business of a reverse drug distributor shall biennially register with the board as a
 792 drug wholesaler, distributor, reverse drug distributor, or supplier. The application for
 793 registration shall be made on a form to be prescribed and furnished by ~~said the~~ board and
 794 shall show each place of business of the applicant for registration, together with such other
 795 information as may be required by the board. The application shall be accompanied by a
 796 fee in an amount established by the board for each place of business registered by the
 797 applicant. Such registration shall not be transferable and shall expire on the expiration date
 798 established by the ~~division director~~ executive director. Registration shall be renewed
 799 pursuant to the rules and regulations of the board, and a renewal fee prescribed by the
 800 board shall be required. If not renewed, the registration shall lapse and become null and
 801 void. Registrants shall be subject to such rules and regulations with respect to sanitation
 802 or equipment as the board may, from time to time, adopt for the protection of the public
 803 health and safety. Such registration may be suspended or revoked or the registrant may be
 804 reprimanded, fined, or placed on probation by the board if the registrant fails to comply
 805 with any law of this state, the United States, or any other state having to do with the control
 806 of pharmacists, pharmacies, wholesale distribution, or reverse drug distribution of
 807 controlled substances or dangerous drugs as defined in Chapter 13 of Title 16; if the
 808 registrant fails to comply with any rule or regulation promulgated by the board; or if any
 809 registration or license issued to the registrant under the federal act is suspended or
 810 revoked."

811

PART II

812

SECTION 2-1.

813 Chapter 11 of Title 43 of the Official Code of Georgia Annotated, relating to dentists, dental
 814 hygienists, and dental assistants, is amended in Code Section 43-11-1, relating to definitions,
 815 so as to add a new paragraph to read as follows:

816 "(6.1) 'Executive director' means the executive director appointed by the board pursuant
 817 to Code Section 43-11-2.1."

818

SECTION 2-2.

819 Said chapter is further amended by adding a new Code section to read as follows:

820 "43-11-2.1

821 (a) On and after July 1, 2013, the board shall not be under the jurisdiction of the Secretary
 822 of State but shall be a division of the Department of Community Health; provided,
 823 however, that except as otherwise specifically provided, the board shall be autonomous
 824 from the Board of Community Health and the commissioner of community health and shall
 825 exercise its quasi-judicial, rule-making, licensing, or policy-making functions
 826 independently of the department and without approval or control of the department and
 827 prepare its budget and submit its budgetary requests, if any, through the department. Such
 828 transfer shall in no way affect any existing obligations, liabilities, or rights of the board, as
 829 such existed on June 30, 2013. The board shall have with respect to all matters within the
 830 jurisdiction of the board as provided under this chapter the powers, duties, and functions
 831 of professional licensing boards as provided in Chapter 1 of this title.

832 (b) The board shall appoint and fix the compensation, which shall be approved by the
 833 Board of Community Health, of an executive director of such board who shall serve at the
 834 pleasure of the board. Any reference in this chapter to the executive director shall mean the
 835 executive director appointed pursuant to this subsection. The executive director shall have
 836 those duties and powers prescribed by the board and any power, duty, and functions
 837 granted to the division director with respect to professional licensing boards under Chapter
 838 1 of Title 43 but shall not be subject to any approval or other powers exercised by the
 839 Secretary of State.

840 (c) Meetings and hearings of the board shall be held at the site of the office of the board
 841 or at such other site as may be specified by the president of the board. A majority of the
 842 members of the board shall constitute a quorum for the transaction of business of the board.

843 (d) The board, through the executive director, may hire investigators for the purpose of
 844 conducting investigations. Any person so employed, if a P.O.S.T. certified peace officer
 845 under Chapter 8 of Title 35, shall be considered to be a peace officer and shall have all
 846 powers, duties, and status of a peace officer of this state; provided, however, that such

847 investigators shall only be authorized, upon written approval of the executive director,
 848 notwithstanding Code Sections 16-11-126 and 16-11-129, to carry firearms in the
 849 performance of their duties and exercise the powers of arrest in the performance of their
 850 duties.

851 (e) The venue of any action involving members of the board shall be the county in which
 852 is found the primary office of the governmental entity of which the defendant is an officer.
 853 The executive director of the board shall not be considered a member of the board in
 854 determining the venue of any such action and no court shall have jurisdiction of any such
 855 action solely by virtue of the executive director residing or maintaining a residence within
 856 its jurisdiction.

857 (f) The board shall give point credit to veterans in the same manner as required under Code
 858 Sections 43-1-9 through 43-1-13.

859 (g) Initial judicial review of a final decision of the board shall be held solely in the
 860 superior court of the county of domicile of the board.

861 (h) The executive director shall make a report no later than December 31 of each year
 862 covering the activities of the board for that calendar year, which shall be made available
 863 to any member of the General Assembly upon request.

864 (i) The executive director shall prepare and maintain a roster containing the names and
 865 addresses of all current dental and dental hygiene licensees. A copy of this roster shall be
 866 available to any person upon request at a fee prescribed by the executive director sufficient
 867 to cover the cost of printing and distribution.

868 (j) The executive director, with the approval of the board, notwithstanding any other
 869 provisions of law to the contrary, shall enter into such contracts as are deemed necessary
 870 to carry out this chapter to provide for all services required of the board.

871 (k) It shall be the duty of the executive director to keep minutes and a record of all acts of
 872 the board and such other books and records as may be necessary to show the acts of the
 873 board."

874 **SECTION 2-3.**

875 Said chapter is further amended in Code Section 43-11-5, relating to the duty of members to
 876 notify the division director of address, as follows:

877 "43-11-5.

878 Each member of the board, upon the receipt of his or her commission, shall file with the
 879 ~~division director~~ executive director his or her post office address and thereafter a notice of
 880 any change ~~therein~~ thereof. Any notice mailed to such address by the ~~division director~~
 881 executive director shall be deemed to comply with the requirements of this chapter as
 882 notice to him or her."

883 **SECTION 2-4.**

884 Said chapter is further amended in Code Section 43-11-6, relating to reimbursement of
885 members, as follows:

886 "43-11-6.

887 Each member of the board shall ~~be reimbursed as provided for in subsection (f) of Code~~
888 ~~Section 43-1-2~~ receive the expense allowance as provided by subsection (b) of Code
889 Section 45-7-21 and the same mileage allowance for the use of a personal car as that
890 received by other state officials and employees or a travel allowance of actual
891 transportation cost if traveling by public carrier within this state. Each board member shall
892 also be reimbursed for any conference or meeting registration fee incurred in the
893 performance of his or her duties as a board member. For each day's service outside of the
894 state as a board member, such member shall receive actual expenses as an expense
895 allowance as well as the mileage allowance for the use of a personal car equal to that
896 received by other state officials and employees or a travel allowance of actual
897 transportation cost if traveling by public carrier or by rental motor vehicle. Expense
898 vouchers submitted by board members are subject to approval of the president and
899 executive director. Out-of-state travel by board members must be approved by the board
900 president and the executive director."

901 **SECTION 2-5.**

902 Said chapter is further amended in Code Section 43-11-7, relating to powers and duties of
903 the board, as follows:

904 "43-11-7.

905 The board shall perform such duties and possess and exercise such powers, relative to the
906 protection of the public health and the control and regulation of the practice of dentistry as
907 this chapter prescribes and confers upon it. The board shall also have ~~the power and~~
908 ~~authority to promulgate~~ the following powers and duties:

909 (1) To adopt, amend, and repeal rules and regulations to carry out the performance of its
910 duties as set forth in this chapter;

911 (2) To examine all applicants for licenses to practice dentistry who are entitled under this
912 chapter to be so examined and issue licenses to practice dentistry according to this
913 chapter;

914 (3) To make all necessary bylaws and rules for the governance of the board and the
915 performance of its duties;

916 (4) To have and use a common seal bearing the name 'Georgia Board of Dentistry' by
917 which the board shall authenticate the acts of the board;

- 918 (5) To establish rules regarding licensure including, but not limited to, inactive status as
919 the board deems appropriate;
- 920 (6) To issue, deny, or reinstate the licenses or permits of duly qualified applicants for
921 licensure or permits under this chapter;
- 922 (7) To revoke, suspend, issue terms and conditions, place on probation, limit practice,
923 fine, require additional dental training, require dental community service, or otherwise
924 sanction licensees, permit holders or others over whom the board has jurisdiction under
925 this chapter;
- 926 (8) To employ an executive director and such other staff as the board may deem
927 necessary and appropriate to implement this chapter and provide support and who shall
928 be subject to the same confidentiality requirements of the board;
- 929 (9) To keep a docket of public proceedings, actions, and filings;
- 930 (10) To set its office hours;
- 931 (11) To set all reasonable fees by adoption of a schedule of fees approved by the board.
932 The board shall set such fees sufficient to cover costs of operation;
- 933 (12) To adopt necessary rules concerning proceedings, hearings, review hearings,
934 actions, filings, depositions, and motions related to uncontested cases;
- 935 (13) To initiate investigations for purposes of discovering violations of this chapter;
- 936 (14) To administer oaths, subpoena witnesses and documentary evidence including
937 dental records, and take testimony in all matters relating to its duties;
- 938 (15) To conduct hearings, reviews, and other proceedings according to Chapter 13 of
939 Title 50;
- 940 (16) To conduct investigative interviews;
- 941 (17) To issue cease and desist orders to stop the unlicensed practice of dentistry or other
942 professions licensed or permitted under this chapter and impose penalties for such
943 violations;
- 944 (18) To refer cases for criminal prosecution or injunctive relief to appropriate
945 prosecuting attorneys or other law enforcement authorities of this state, another state, or
946 the United States;
- 947 (19) To release investigative or applicant files to another enforcement agency or lawful
948 licensing authority in another state;
- 949 (20) To sue and be sued in a court of competent jurisdiction;
- 950 (21) To enter into contracts; and
- 951 (22) To accept donations, contributions, grants, or bequests of funds or property."

952 **SECTION 2-6.**

953 Said chapter is further amended in Code Section 43-11-8, relating to the board examining
 954 applicants, issuing licenses, and making bylaws and rules, as follows:

955 "43-11-8.

956 ~~(a) The board shall exercise the following powers and duties:~~

957 ~~(1) Examine all applicants for licenses to practice dentistry who are entitled under this~~
 958 ~~chapter to be so examined and issue licenses to practice dentistry according to this~~
 959 ~~chapter;~~

960 ~~(2) Make all necessary bylaws and rules for the governance of the board and the~~
 961 ~~performance of its duties; and~~

962 ~~(3) Have and use a common seal bearing the name 'Georgia Board of Dentistry.'~~

963 ~~(b) It shall be the duty of the division director to keep minutes and a record of all the acts~~
 964 ~~of the board and such other books and records as may be necessary to show the acts of the~~
 965 ~~board. Reserved."~~

966 **SECTION 2-7.**

967 Said chapter is further amended in Code Section 43-11-11, relating to a census of practicing
 968 dentists and dental hygienists and publication of names, as follows:

969 "43-11-11.

970 ~~The board may, from time to time, through its members or other suitable persons, take a~~
 971 ~~census of all practicing dentists and dental hygienists of any locality, city, or county in the~~
 972 ~~state when it may consider it necessary for the purpose of carrying out this chapter; the~~
 973 ~~board may at any time cause the names of all licensed dentists and dental hygienists in any~~
 974 ~~locality, city, or county to be posted or published; and the board is authorized to pay for~~
 975 ~~taking such census and posting or publishing such names.~~

976 (a) The board shall gather census data on each dentist and dental hygienist in this state.
 977 Such census data shall be obtained from each dentist and dental hygienist as part of the
 978 license renewal process on a biennial basis. Renewal of a license shall be contingent on
 979 completion and provision of a census questionnaire to the board. Failure by a licensee to
 980 submit the census questionnaire shall authorize the board to refuse to grant a license
 981 renewal, revoke a license, or discipline a licensee under Code Section 43-11-47.

982 (b) The board shall by regulation establish a standard form for the collection of census
 983 data. Such form and the census data obtained shall be available for dissemination to any
 984 member of the public.

985 (c) The standard form shall at a minimum request the following information from dentists
 986 renewing their license:

987 (1) The dentist's age and gender;

988 (2) Each location identified by ZIP Code in which the dentist operates a private dental
 989 practice or practices dentistry;

990 (3) Whether the dentist is a specialist and the specialty in which the dentist is engaged;
 991 and

992 (4) Whether the dentist practices dentistry full time, which shall mean 30 or more hours
 993 per week, or part time, which shall mean less than 30 hours per week.

994 (d) The standard form shall at a minimum request the following information from dental
 995 hygienists renewing their license:

996 (1) The dental hygienist's age and gender;

997 (2) Each location identified by ZIP Code in which the dental hygienist provides
 998 treatment services; and

999 (3) Whether the dental hygienist provides treatment full time, which shall mean 30 or
 1000 more hours per week, or part time, which shall mean less than 30 hours per week."

1001 **SECTION 2-8.**

1002 Said chapter is further amended in Code Section 43-11-12, relating to public inspection of
 1003 board records, as follows:

1004 "43-11-12.

1005 It shall be the duty of the ~~division director~~ executive director to keep at his or her office the
 1006 minutes of the board, together with all the books and records of the board, which ~~books and~~
 1007 ~~records shall, except as provided in subsection (k) of Code Section 43-1-2, be public~~
 1008 records open to inspection by the public except on Sundays and legal holidays. The
 1009 following shall be treated as confidential and need not be disclosed without prior approval
 1010 of the board:

1011 (1) Applications and other personal information submitted by applicants, except to the
 1012 applicant, staff, and the board;

1013 (2) Information, favorable or unfavorable, submitted by a reference source concerning
 1014 an applicant, except to the staff and board;

1015 (3) Examination questions and other examination materials, except to the staff and the
 1016 board; and

1017 (4) The deliberations of the board with respect to an application, an examination, a
 1018 complaint, an investigation, or a disciplinary proceeding, except as may be contained in
 1019 the official board minutes."

1020 **SECTION 2-9.**

1021 Said chapter is further amended in Code Section 43-11-13, relating to service of orders and
 1022 subpoenas of the board, as follows:

1023 "43-11-13.

1024 (a) It shall be the duty of the several sheriffs, their deputies, and the constables to serve
 1025 any and all lawful orders and subpoenas of the board. The board may also appoint any
 1026 other person to serve any decision, order, or subpoena of the board, ~~which~~ and it shall be
 1027 that person's duty ~~it shall be~~ to execute the same.

1028 (b) All orders and processes of the board shall be signed and attested by the ~~division~~
 1029 ~~director~~ executive director or the president of the board in the name of the board with its
 1030 seal attached; and any notice or legal process necessary to be served upon the board may
 1031 be served upon the ~~division director~~ executive director."

1032 **SECTION 2-10.**

1033 Said chapter is further amended in Code Section 43-11-40, relating to qualification of
 1034 applicants for licenses to practice dentistry and criminal background check, as follows:

1035 "43-11-40.

1036 (a)(1) Applicants for a license to practice dentistry must have received a doctor of dental
 1037 surgery (D.D.S.) degree or a doctor of dental medicine (D.M.D.) degree from a dental
 1038 school approved by the board and accredited by the Commission on Dental Accreditation
 1039 of the American Dental Association (ADA) or its successor agency, if any. Those
 1040 applicants who have received a doctoral degree in dentistry from a dental school not so
 1041 accredited must comply with the following requirements in order to submit an application
 1042 for licensure:

1043 (A) Successful completion at an accredited dental school approved by the board of the
 1044 last two years of a pre-doctoral program and receipt of the doctor of dental surgery
 1045 (D.D.S.) or doctor of dental medicine (D.M.D.) degree; and

1046 (B) Certification by the dean of the accredited dental school where such supplementary
 1047 program was taken that the candidate has achieved the same level of didactic and
 1048 clinical competency as expected of a graduate of the school receiving a doctor of dental
 1049 surgery (D.D.S.) or doctor of dental medicine (D.M.D.) degree.

1050 (2) The board may establish by rule or regulation the requirements for documentation of
 1051 an applicant's educational and personal qualifications for licensure.

1052 (3) In order to be granted a license under this Code section, all applicants must pass a
 1053 clinical examination approved by the board and a jurisprudence examination on the laws
 1054 of this state and rules and regulations as they relate to the practice of dentistry as
 1055 established or approved by the board, which shall be administered in the English
 1056 language.

1057 (b) All applications to the board for a license shall be made through the ~~division director~~
 1058 executive director, who shall then submit all such applications to the board.

1059 (c) Subject to the provisions of subsection (a) of Code Section 43-11-47, applicants who
 1060 have met the requirements of this Code section shall be granted licenses to practice
 1061 dentistry.

1062 (d) Application for a license under this Code section shall constitute consent for
 1063 performance of a criminal background check. Each applicant who submits an application
 1064 to the board for licensure agrees to provide the board with any and all information
 1065 necessary to run a criminal background check, including but not limited to classifiable sets
 1066 of fingerprints. The applicant shall be responsible for all fees associated with the
 1067 performance of a background check."

1068 SECTION 2-11.

1069 Said chapter is further amended in Code Section 43-11-41, relating to applications for
 1070 provisional licenses to practice dentistry by credentials, as follows:

1071 "43-11-41.

1072 (a)(1) Applicants for a provisional license to practice dentistry by credentials must have
 1073 received a doctor of dental surgery (D.D.S.) degree or a doctor of dental medicine
 1074 (D.M.D.) degree from a dental school approved by the board and accredited by the
 1075 Commission on Dental Accreditation of the American Dental Association (ADA) or its
 1076 successor agency, if any. Applicants must have been in full-time clinical practice, as
 1077 defined by rules and regulations established by the board; full-time faculty, as defined by
 1078 board rule and regulation; or a combination of both for the five years immediately
 1079 preceding the date of the application and must hold an active dental license in good
 1080 standing from another state. Those applicants who have received a doctoral degree in
 1081 dentistry from a dental school not so accredited must comply with the following
 1082 requirements in order to submit an application for provisional licensure by credentials:

1083 (A) Successful completion at an accredited dental school approved by the board of the
 1084 last two years of a pre-doctoral program ~~leading to~~ and receipt of the doctor of dental
 1085 surgery (D.D.S.) or doctor of dental medicine (D.M.D.) degree; and

1086 (B) Certification by the dean of the accredited dental school where such supplementary
 1087 program was taken that the candidate has achieved the same level of didactic and
 1088 clinical competency as expected of a graduate of the school.

1089 (2) The board may establish by rule or regulation the requirements for documentation of
 1090 an applicant's educational and personal qualifications for provisional licensure.

1091 (3) In order to be granted a provisional license under this Code section, all applicants
 1092 must have passed a clinical examination given by a state or regional testing agency
 1093 approved by the board and a jurisprudence examination on the laws of this state and rules
 1094 and regulations as they relate to the practice of dentistry as established or approved by

1095 the board, which shall be administered in the English language.

1096 (4) The board may establish additional licensure requirements by rule and regulation.

1097 (b) All applications to the board for a provisional license by credentials shall be made
1098 through the ~~division director~~ executive director, who shall then submit all such applications
1099 to the board. The fee for provisional licensure by credentials shall be paid to the ~~division~~
1100 ~~director~~ executive director and shall be in an amount established by the board.

1101 (c) Subject to the provisions of subsection (a) of Code Section 43-11-47, an applicant who
1102 has met the requirements of this Code section shall be granted a provisional license to
1103 practice dentistry, which shall be valid for two years from the date it is issued and may be
1104 renewed subject to the approval of the board.

1105 (d) Application for a provisional license under this Code section shall constitute consent
1106 for performance of a criminal background check. Each applicant who submits an
1107 application to the board for provisional licensure agrees to provide the board with any and
1108 all information necessary to run a criminal background check, including but not limited to
1109 classifiable sets of fingerprints. The applicant shall be responsible for all fees associated
1110 with the performance of a background check.

1111 (e) Upon receipt of license, the applicant by credentials must establish active practice, as
1112 defined by rules and regulations of the board, in this state within two years of receiving
1113 such license under this Code section or the license shall be automatically revoked."

1114 **SECTION 2-12.**

1115 Said chapter is further amended in Code Section 43-11-43, relating to fees, as follows:

1116 "43-11-43.

1117 Each person applying for examination for a license to practice dentistry shall, at the time
1118 of making his or her application, pay to the ~~division director~~ executive director a fee to be
1119 set by the board. Each person applying for the renewal of a license or authority to practice
1120 dentistry or for the establishment of a license or authority that has been lost shall, at the
1121 time of making his or her application, pay to the ~~division director~~ executive director a fee
1122 to be set by the board. Such fee shall cover the entire service for granting or issuing
1123 licenses to practice dentistry."

1124 **SECTION 2-13.**

1125 Said chapter is further amended in Code Section 43-11-46, relating to renewal of registration,
1126 by revising subsection (a) as follows:

1127 "(a) Every person licensed by the board to practice dentistry shall register biennially on the

1128 renewal date set by the ~~division director~~ board and shall pay to the ~~division director~~
 1129 executive director a registration fee which shall be set by the board. The board shall
 1130 provide for penalty fees for late registration."

1131 **SECTION 2-14.**

1132 Said chapter is further amended in Code Section 43-11-47, relating to the refusal to grant,
 1133 or revocation of, licenses, by revising paragraph (3) of subsection (a) and subsections (h) and
 1134 (k) as follows:

1135 "(3) Been convicted of any felony or of any crime involving moral turpitude in the courts
 1136 of this state or any other state, territory, or country or in the courts of the United States;
 1137 as used in this subsection, the term 'felony' shall include any offense which, if committed
 1138 in this state, would be deemed a felony without regard to its designation elsewhere; and,
 1139 as used in this subsection, the term 'conviction' shall include a finding or verdict of guilty
 1140 or a plea of guilty, regardless of whether an appeal of the conviction has been sought.
 1141 Any licensee who is convicted under the laws of this state, the United States, or any other
 1142 state, territory, or country of a felony shall be required to notify the board of conviction
 1143 within ten days of the conviction. The failure to notify the board of a conviction shall be
 1144 considered grounds for revocation of his or her license;"

1145 "(h)(1) The ~~division director~~ executive director is vested with the power and authority to
 1146 make, or cause to be made through employees or agents of the board, such investigations
 1147 as he or she or the board or any district attorney may deem necessary or proper for the
 1148 enforcement of the provisions of this chapter. Any person properly conducting an
 1149 investigation on behalf of the board shall have access to and may examine any writing,
 1150 document, or other material relating to the fitness of any licensee or applicant. The
 1151 ~~division director~~ executive director, the president of the board, or his or her the appointed
 1152 representative of either may issue subpoenas to compel such access upon a determination
 1153 that reasonable grounds exist for the belief that a violation of this chapter or any other law
 1154 relating to the practice of dentistry may have taken place. Upon approval of the board, any
 1155 person properly conducting an investigation on behalf of the board shall have access to and
 1156 shall have the right to examine the physical premises of a dental practice.

1157 (2) The results of all investigations initiated by the board shall be reported solely to the
 1158 board, and the records of such investigations shall be kept for the board by the ~~division~~
 1159 ~~director~~ executive director, with the board retaining the right to have access at any time
 1160 to such records. No part of any such records shall be released, except to the board, for
 1161 any purpose other than a hearing before the board, nor shall such records be subject to
 1162 subpoena; provided, however, that the board shall be authorized to release such records
 1163 to any law enforcement agency or prosecuting attorney or to another enforcement agency

1164 or lawful licensing authority.

1165 (3) All records relating to any patient of a licensee who is the subject of a board inquiry
 1166 shall be admissible at any hearing held to determine whether a violation of this chapter
 1167 has taken place, regardless of any statutory privilege; provided, however, that any
 1168 documentary evidence relating to a patient shall be reviewed in camera and shall not be
 1169 disclosed to the public.

1170 (4) The board shall have the authority to exclude all persons during its deliberations on
 1171 disciplinary proceedings and to discuss any disciplinary matter in private with a licensee
 1172 or applicant and the legal counsel of that licensee or applicant."

1173 "(k) If any licensee or applicant fails to appear at any hearing after reasonable notice, the
 1174 board may proceed to hear the evidence against such licensee or applicant and take action
 1175 as if such licensee or applicant had been present. A notice of hearing, initial or
 1176 recommended decision, or final decision of the board in a disciplinary proceeding shall be
 1177 served upon the licensee or applicant by certified mail or statutory overnight delivery,
 1178 return receipt requested, to the last known address of record with the board. If such
 1179 material is returned marked 'unclaimed' or 'refused' or is otherwise undeliverable and if the
 1180 licensee or applicant cannot, after diligent effort, be located, the ~~division director~~ executive
 1181 director shall be deemed to be the agent for service for such licensee or applicant for
 1182 purposes of this Code section, and service upon the ~~division director~~ executive director
 1183 shall be deemed to be service upon the licensee or applicant."

1184 **SECTION 2-15.**

1185 Said chapter is further amended in Code Section 43-11-48, relating to the initiation of
 1186 proceedings for violation of chapter, by revising subsection (b) as follows:

1187 "(b) A record of all hearings, decisions, and orders shall be kept for the board by the
 1188 ~~division director~~ executive director."

1189 **SECTION 2-16.**

1190 Said chapter is further amended in Code Section 43-11-70, relating to an examination
 1191 requirement, as follows:

1192 "43-11-70.

1193 No person shall practice as a dental hygienist in this state until such person has passed a
 1194 written and a clinical examination conducted or approved by the board. The fee for such
 1195 examination shall be paid to the ~~division director~~ executive director and shall be in an
 1196 amount established by the board. The board shall issue licenses and license certificates as
 1197 dental hygienists to those persons who have passed the examination in a manner
 1198 satisfactory to the board, ~~which~~ and the license certificate shall be posted and displayed in

1199 the place in which the hygienist is employed."

1200 **SECTION 2-17.**

1201 Said chapter is further amended in Code Section 43-11-71.1, relating to applications for
1202 licenses to practice dental hygiene by credentials, by revising subsection (b) as follows:

1203 "(b) All applications to the board for a license by credentials shall be made through the
1204 ~~division director~~ executive director, who shall then submit all such applications to the
1205 board. The fee for licensure by credentials shall be paid to the ~~division director~~ executive
1206 director and shall be in an amount established by the board."

1207 **SECTION 2-18.**

1208 Said chapter is further amended in Code Section 43-11-73, relating to renewals, by revising
1209 subsection (a) as follows:

1210 "(a) Every person licensed by the board to practice dental hygiene shall register biennially
1211 on the renewal date set by the ~~division director~~ executive director and shall pay to the
1212 ~~division director~~ executive director a registration fee which shall be set by the board. The
1213 board shall provide for penalty fees for late registration."

1214 **PART III**

1215 **SECTION 3-1.**

1216 All laws and parts of laws in conflict with this Act are repealed.

1 Resolution #55 (15) –2015 Annual Leadership Forum

2

3 TITLE: Improve Safety of Mail-Ordered Medication

4

5 SPONSORED BY: District VIII

6

7 DATE: July 7, 2014

8

9 DISPOSITION:

10

11 Whereas, brick and mortar pharmacies are required to keep logs of ambient
12 temperature, as well as freezer and refrigerator temperatures, for
13 their medications; and

14

15 Whereas, some mail-order medications lose potency due to extreme
16 temperature changes during shipment, which can lead to
17 overdosing or under dosing of medications with risks of morbidity
18 and mortality; and

19

20 Whereas, other industries have standards for monitoring and/or controlling
21 temperature of shipments; and

22

23 Whereas, technology exists (eg, color-changing temperature strips) that
24 indicate to a patient whether their medication was exposed to
25 inappropriate temperatures, therefore be it

26

27 RESOLVED, that the Academy advocate for the use of visual temperature
28 indicators on each box or vial of medication shipped in the mail,
29 and be it further

30

31 RESOLVED, that the Academy advocate for replacement of medication if
32 potency is affected during shipment by extreme temperature
33 changes.

34

35 FISCAL NOTE:

36

37 REFER TO: 2015 Annual Leadership Forum

38

39 LEAD AUTHOR: Jennifer Brinton, MD, FAAP

40

41 Telephone:

42 Email: _____

43

44 BACKGROUND

45 INFORMATION: Background Information from the Author
Reference Committee
B – Practice

Consent

46 Resolution #55 (15) –2015 Annual Leadership Forum

47 Page Two

48

49 The resolution pertaining to mail-order pharmaceuticals relates to
50 getting some control/oversight in a part of health care that currently
51 has almost no control. In mail-order drugs, every drug is at risk of
52 freezing, or overheating. Any drug may be changed. And, while the
53 same technology to monitor temperature could solve both
54 issues,(meaning vaccines and medications delivered to homes,)
55 separate entities monitor of these medications and thus necessitate
56 a separate resolution for mail-ordered medications.

57

58 Background Information from the Committee on Drugs and the
59 Section on Clinical Pharmacology and Therapeutics

60 At this time, the Committee on Drugs is not addressing the issue(s)
61 raised in the resolved portion(s) of this resolution. However, the
62 following is current information related to the topic.

63

64 State Boards of Pharmacy regulate the practice of pharmacy and
65 require pharmacists, pharmacies and pharmacy technicians to be
66 licensed. The National Association of Boards of Pharmacy
67 (NABP) is the impartial professional organization that supports the
68 state boards of pharmacy in protecting public health. NABP aims
69 to ensure the public's health and safety through its pharmacist

70 license transfer and pharmacist competence assessment programs,
71 as well as through various accreditation programs. One of its
72 programs is called VIPPS-Verified Internet Pharmacy Practice
73 Sites, a program to assess an online pharmacy compliance with
74 state and federal laws, regulations and NABP's criteria. Online
75 pharmacies, internet pharmacies, or mail order pharmacies function
76 in much the same manner as traditional pharmacies and are subject
77 to the same rules, regulations, and patient care requirements as
78 brick-and-mortar pharmacies. VIPPS accreditation requires an
79 Internet pharmacy to comply with the licensing and survey
80 requirements of its state and each state to which it dispenses
81 pharmaceuticals. VIPPS-accredited pharmacies meet nationally
82 endorsed standards of pharmacy practice, demonstrate compliance
83 with standards of privacy and authentication, security of
84 prescriptions, adherence to quality assurance policies, and provide

85 meaningful consultation between patients and pharmacists. Other
86 pharmacy verification organizations exist such as LegitScript
87 which maintains standards endorsed by the NABP.

88

89 The United States Pharmacopeia (USP) is an independent science
90 based public health organization that sets quality standards for
91 Resolution #55 (15) –2015 Annual Leadership Forum

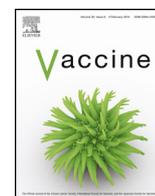
92 Page Three

93

94 prescription and OTC drugs and dietary supplements manufactured
95 and sold in the United States. USP General Chapter<1079> Good
96 Storage and Shipping Practices provides information to ensure
97 product stability within the supply chain. The information
98 includes: proper handling and storage, distribution from a
99 pharmacy to a patient/customer, returns of drug products, training
100 of personnel, and storage of samples. Other Chapters cover
101 Pharmaceutical Stability <1150>, Stability Considerations in
102 Dispensing Practice <1191>, and Monitoring Devices-Time,
103 temperature, and humidity <1118>. This chapter describes devices
104 that measure temperature and humidity either at a point in time or
105 during a specific interval. These include mercury thermometers,
106 chemical, infrared, thermocouple, and thermo mechanical devices.
107

108 Some Boards of Pharmacy (eg, Missouri Board of Pharmacy) have
109 adopted laws which establish new requirements for prescription
110 delivery. Under the Missouri rule (20 CSR 2220-2.013)
111 pharmacies are required to “develop and implement written

112 policies and procedures to ensure the safe and appropriate delivery
113 of prescription drugs within the temperature requirements
114 recommended by the manufacturer or the United States
115 Pharmacopeia (USP). The rule applies to all Missouri-licensed
116 pharmacies delivering filled prescriptions regardless of delivery
117 method (eg, employee delivery, common carrier, or mail).



Conference report

From refrigerator to arm: Issues in vaccination delivery

ARTICLE INFO

Keywords:

Vaccine
Delivery
Process
Improvement
Issues

ABSTRACT

This report summarizes the first meeting of a panel of immunization experts who met in Washington, DC, on May 4–5, 2012. The panel consisted of experts from national immunization policy organizations; state, regional, and local immunization programs; and vaccinating health care practices. The primary objective of this meeting was to identify issues in the vaccine delivery process as a critical first step in the determination of where and how improvements can be made. Vaccines are one of the greatest achievements in public health. However, in order to maintain the integrity of vaccines and the success of vaccination programs, proper handling of vaccines from the receipt of shipment through administration to the patient is critical. Continuous improvement of the vaccine delivery process is important to ensure appropriate vaccine handling by all vaccine providers. The overarching consensus of the participants of this meeting was that the major challenge in vaccine delivery is the complexity throughout all areas of the vaccine delivery process, which is often underestimated, particularly in the areas of vaccine preparation and administration. The lack of detailed, consistent standards encompassing all areas of the vaccine delivery process, and the gaps in oversight, education, and training of vaccine providers, particularly providers of adult vaccines, were also identified as major issues. The next step for this panel is to reconvene to explore potential solutions to address the identified issues.

1. Background

Vaccines are one of the greatest achievements in public health. Vaccination of one birth cohort with the current immunization schedule is estimated to prevent approximately 20 million cases of disease and 42,000 deaths [1]. In the United States, the recommended universal use of vaccines has led to reductions ranging from 96% to 100% in the morbidity of each of 9 vaccine-preventable diseases (smallpox, diphtheria, pertussis, tetanus, poliomyelitis, measles, mumps, rubella, and *Haemophilus influenzae* type b) (Table 1) [2]. This demonstrates the success of vaccines and further emphasizes the need for and impact of vaccination programs like Vaccines for Children (VFC). Further, vaccination has resulted in the global eradication of smallpox and eradication of polio in all but 3 countries [2–4].

If vaccines are not handled properly, vaccine effectiveness may be compromised, which can potentially erode the reputation and trust of the public in vaccination, thereby putting the health of the entire population at risk in the long term. In order to maintain the integrity of vaccines and success of vaccination programs, proper handling of vaccines from the receipt of shipment through administration to the patient is critical. Therefore, a panel of immunization experts, including experts from national immunization policy organizations; state, regional, and local immunization programs; and vaccinating health care practices, met recently to identify issues in vaccine delivery. Their goal was to evaluate the current immunization landscape and identify issues impacting proper vaccine delivery, from storage and handling to post-injection documenta-

tion. Identification of the issues that occur with vaccine delivery is a critical first step in the determination of where and how improvements can be made. A subsequent second step will focus on identifying solutions to address the issues identified in this paper.

2. Complexity

The panel reached a general consensus that the process of storing, handling, preparing, and administering vaccines is far more complex than many participants realized, and efforts should focus on simplifying the overall process and greatly enhancing education and training. The specific issues identified in each area of vaccine delivery are described and collated in Table 2.

A major challenge with vaccine delivery is its complexity in each area of the process—from vaccine acquisition, storage, and handling to preparation and administration—requiring many specific steps to ensure that the cold chain is maintained and the vaccine is delivered properly. In addition, there is a lack of detailed, consistent standards for each of these processes that ensure proper vaccine delivery. A number of organizations (e.g., the Centers for Disease Control and Prevention [CDC], the VFC program, manufacturers, state public health immunization programs, World Health Organization [WHO], state health departments) have their own best practice recommendations, but there is no consensus, making it challenging for providers to adhere to a best practice standard. Moreover, while storage and handling have been the focus of efforts to improve vaccine delivery, the complexity of steps required to

Table 1
Decrease from baseline 20th century annual morbidity from 9 diseases with vaccines recommended before 1990 for universal use in children in the United States [2].

Disease	% Decrease
Smallpox	100
Diphtheria	100
Pertussis	95.7
Tetanus	97.4
Poliomyelitis (paralytic)	100
Measles	100
Mumps	99.6
Rubella	99.3
<i>Haemophilus influenzae</i> type b	99.7

properly prepare and administer a vaccine is often underestimated by health care workers, and simplification of this part of the vaccine delivery chain remains an underappreciated issue. Hence, simplification and standardization of all aspects of vaccine delivery will help reduce the potential for errors.

3. Training

The complexity of vaccine delivery, combined with a lack of consistent standards and training, often results in the failure of providers to meet requirements for vaccine storage, handling, and administration, which can compromise vaccine effectiveness and potentially lead to preventable adverse consequences. There is a gap in the availability of training programs for vaccine delivery across the spectrum of health care providers, although some professional organizations, such as the American Pharmacists Association, do offer national standardized training programs. Consequently, the level of expertise of health care professionals who administer vaccines varies greatly, and providers are not always aware of sources for guidance and recommendations. Standardizing education and training for vaccine storage, handling, and administration is important for all providers and is especially important for adult

Table 2
Identified issues with vaccine delivery.

	Issues
Overall	Need to simplify process and improve training
Storage	Complexity of requirements Lack of training and consistent standards Failure to maintain cold/cool chain Inadequate storage unit Inadequate storage unit setup Improper vaccine transport Inadequate temperature monitoring Inadequate temperature monitoring equipment Inadequate or lacking safeguards
Handling	Complexity of requirements Lack of training and consistent standards Lack of dedicated vaccine manager and/or backup manager Lack of vaccine management plans (routine and/or emergency) Inadequate response to temperature excursions Compromised or expired vaccine stored with regular vaccine supply
Administration	Complexity of process often underestimated Lack of training and consistent standards Inadequate vaccine preparation (not reconstituting properly, not adding diluents) Inappropriate needle gauge or length Improper placement of injection Unsafe injection practices Injection of wrong medicine Lack of system checks (for accuracy, properly prepared vaccine, uncompromised vaccine) Lack of or inaccurate documentation

immunizers, because these providers generally have less experience in vaccine delivery than their pediatric counterparts, but are becoming increasingly important in vaccine delivery due to the expanding recommendations for adult immunization and implementation of the Affordable Care Act.

4. Storage

Failure to maintain the cold chain is a major issue in vaccine storage that can compromise vaccine effectiveness. According to the Advisory Committee on Immunization Practices (ACIP), vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated. Clinicians should consult with state or local health departments in these situations [5]. Refrigerated vaccines must be maintained between 35 °F and 46 °F [2 °C and 8 °C],¹ and frozen vaccines must be maintained between –58 °F and +5 °F [–50 °C and –15 °C] to ensure maximum vaccine potency [5,6]. However, in the OIG study of VFC vaccines, it was found that vaccines stored by 76% (34/45) of selected VFC providers were exposed to inappropriate temperatures for at least 5 cumulative hours during a 2-week period [7]. Six of the providers' refrigerated and 11 of the providers' frozen vaccines were exposed to temperatures outside the required range for more than 120 h during the 2-week period [7].² Exactly how such temperature variation can affect vaccine potency will vary among vaccines. Although the impact on a particular vaccine exposed to temperature variation would have to be addressed by the manufacturer, it is demonstrated that any deviations from recommended storage temperatures have the potential to compromise vaccine efficacy.

5. Cold chain

The integrity of the cold chain can be impacted at several points. The use of inadequate storage units is an issue. Stand-alone units, meaning the use of separate refrigerator and freezer units, are strongly recommended by most organizations (e.g., the CDC and many state health departments) [6]. Dormitory units or a compact combination refrigerator/freezer unit with one exterior door and an evaporator plate or cooling coil that is typically located inside the freezer compartment are NOT recommended, even for temporary storage [6]. Research has shown that these units provide poor long-term temperature stability, are sensitive to loading density, and are prone to large temperature non-uniformity or pockets of hot and cold air [8].

Another common problem is inadequate placement of vaccines within the storage units. Vaccines may be improperly stored against the walls, in the door of the unit, or near cold air vents instead of being centrally placed (away from any freezer vent) in a location where the temperature is the most stable. There is also a risk of temperature excursions, or a fluctuation above or below the temperature range recommended for product storage by the manufacturer, when vaccines are transported improperly (e.g., without a thermometer or packed improperly with ice or dry ice). This risk is increased because there is a lack of standards on the appropriate transport of vaccines by providers, even though they often need to transport vaccines to different locations in certain situations (e.g., emergency power outages, use in off-site clinics, when another

¹ When conversation was held with the panel, CDC Vaccine Storage and Handling Toolkit not yet published or released, so references are to CDC Pink Book. Since that time, the toolkit has been made available for use.

² Temperatures were measured with thermometers tracking ambient air temperatures in storage units rather than using biosafe glycol-encased probes, which tend to provide more accurate measurements than ambient air temperatures.

clinic has a specific need or can use a vaccine that would otherwise expire unused in its current location).

Inadequate temperature monitoring or the use of inadequate equipment can also place vaccines at risk for prolonged temperature excursions that are likely to compromise vaccine integrity. Providers may use thermometers that are not high quality or not accurately calibrated, or may fail to place thermometers in the center of the unit with the vaccine to ensure accurate temperature readings [6]. Also, temperatures are often not checked and documented regularly (a minimum of twice daily at the beginning and end of the day is recommended by the CDC), and there often is a failure to document temperatures and keep logs for the required time (3 years) [6]. Alarm systems, which can alert providers to temperature excursions during off hours, may be lacking. These systems can help prevent the loss of vaccine and ensure the integrity of the cold chain [6].

6. Handling

In a study of VFC vaccine providers by the Office of the Inspector General (OIG), no providers met all vaccine management requirements in 10 categories (vaccine storage equipment, vaccine storage practices, temperature monitoring, vaccine storage and handling plans, vaccine personnel, vaccine waste, vaccine security and equipment maintenance, vaccine ordering and inventory management, receiving vaccine shipments, and vaccine preparation). The study included a sample of 45 VFC providers from the 5 grantees with the highest volume of vaccines ordered in 2010 [7]. This raises concerns because handling of vaccines by VFC providers probably reflects the best case scenario; state public health departments regulate and directly oversee the practices of VFC providers and provide training and education not offered to immunization providers outside the program. Although private pediatric immunization handling practices are not audited, many pediatric offices provide both private and VFC vaccines and use similar or the same procedure for managing both types of vaccine. However, the pediatric private practice vaccine supply does not necessarily enjoy the same oversight relative to adherence with accepted storage, handling, and administration standards compared with the VFC vaccine supply. In addition, adult vaccination is not subject to the same level of scrutiny.

Problems with vaccine handling also include the failure to identify and train a designated vaccine manager (and a backup person), a lack of vaccine management plans (routine and/or emergency), and an inadequate response to temperature excursions. Without designated, trained vaccine managers and management plans, handlers of vaccines are often unaware of proper procedures, which can lead to unsafe practices, compromising vaccine effectiveness [6]. Routine management plans are required to provide guidelines for how to accept vaccine, manage inventory, and handle compromised vaccine [6]. Emergency plans are required to ensure that all personnel are aware of the emergency backup storage location, contact information, and how to transport vaccine properly [6]. A lack of plans could also leave personnel unaware that immediate action is required to correct out-of-range temperatures [6]. Failure to respond appropriately to restore recommended temperatures as soon as out-of-range temperatures are noted can prolong temperature excursions and compromise vaccines.

There are no readily accessible data on the effect of temperature excursions on vaccine potency, so although the state health department and the manufacturer should be contacted regarding the effect of temperature excursions in order to provide individualized guidance, providers who do not consult manufacturers are unsure of the steps required in response to temperature excursions (e.g., dispose of or return vaccine, change expiration date,

or no action required). There are also differences among health departments regarding who should contact the manufacturer to report excursions to solicit their guidance. The absence of national standards and published guidance leaves private providers (not enrolled in the VFC program) unsure of how the process should be handled and who should take ownership of reporting and preventing recurrence.

Compromised vaccine that is not labeled as such and is stored with the regular vaccine supply is a problem because this practice could lead to the inadvertent administration of compromised vaccine to patients, leaving them inadequately protected against disease. Similarly, expired vaccine stored with the regular vaccine supply increases the risk for administration of expired vaccines, which have decreased potency. Despite recommendations that expired or compromised vaccine be immediately separated from the vaccine supply and clearly marked [6], in the study by the OIG, 36% of providers had expired and nonexpired vaccines stored together [7].

7. Preparation and administration

Vaccine preparation and administration is an area of vaccine delivery that has not been considered as problematic as other areas in the process. In fact, it has not been critically evaluated. However, issues in preparation and administration are important to consider. Unlike other areas in the vaccine delivery process, there is no oversight such as certification, auditing procedures, or detailed standards. In addition, information provided in education and training programs for people delivering vaccines may vary greatly, demonstrating a need for standardization. An evaluation of vaccine preparation and administration is needed to define and clarify best practices.

Many health care workers may not be aware of the degree of complexity of the administration process or how differing vaccine presentation methods can affect complexity. The number of steps required for vaccine preparation and administration varies greatly depending on vaccine presentation (i.e., liquid or lyophilized in a vial, or manufacturer prefilled syringe), with some presentations requiring as many as 30 steps and others having as few as 8 steps [9], (Fig. 1). Indeed, preparing vaccine in multidose presentations for administration comes with more potential points for the introduction of error. As such, providers have to be made more aware of this and provided guidance to improve the practice of preparing vaccines dispensed from multidose vials.

Inappropriately used terminology further impacts the complexity of vaccine preparation and accepted practices. For example, the terms *predrawn syringe* and *prefilled syringe* sometimes are used interchangeably. This usage is not correct as the terms refer to different methods of preparing syringes prior to administration.

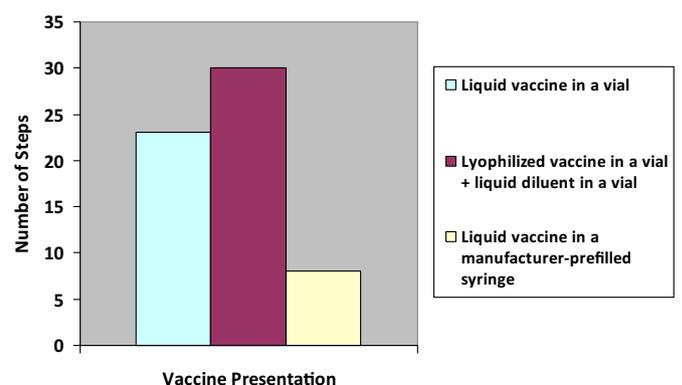


Fig. 1. Steps required for vaccine preparation and administration [9].

Predrawn syringes refer to those prepared by a health care worker by drawing vaccine from a vial into the syringe prior to the time it will be needed. This practice is not recommended, but providers often predraw vaccine doses from vials to save time [6]. Predrawing can increase the risk for administration errors and can lead to misidentification, resulting in the wrong patient receiving the wrong medication [6]. Predrawn syringes also increase the risk for contamination because conventional syringes are not meant for storage, and bacterial growth can occur when vaccines that do not contain a preservative are stored inappropriately or for any substantial length of time [6]. Additionally, certain vaccines may be compromised when exposed to light for extended periods [5]. In contrast, prefilled syringes refer to manufacturer-filled and supplied, unit-dose, ready-to-administer vaccines in syringes that are individually labeled, designed for long-term storage, and ready for use at point of care. This vaccine preparation is available for many but not all vaccines. These unit-dose, ready-to-administer vaccines provide a means to eliminate inappropriate preparation. Because prefilled syringes require fewer steps for preparation, they simplify this part of the process, save time, minimize the use of materials required for vaccine preparation, and can help reduce opportunities for error and potential contamination because they require fewer steps to prepare [10]. For these reasons, the CDC discourages predrawing and encourages the use of unit-dose, ready-to-administer vaccines as an alternative to predrawn vaccines, particularly for large vaccination events [6].

Problems that occur with other vaccine presentations, including administration of incorrect vaccine, incorrect dosage, and inadequate preparation of lyophilized vaccine (e.g., not reconstituting properly, not adding diluents properly, using an incorrect diluent), may also be addressed by vaccine presentation selection in addition to training [6]. Correct preparation and administration of vaccine may be a greater issue particularly for providers of adult vaccines since traditionally they administer vaccines less frequently, which could increase the chance for error. Ensuring that vaccines are administered at the right time for each patient can be a challenge for these providers. Further, guidelines do not always provide detailed recommendations on the specifics of vaccine administration. Gray areas include determination of appropriate route of injection and needle gauge and length (particularly for obese patients) and best practices for ensuring that recommended injection sites are used.

Despite the availability of best practice guidance for injection from the CDC and other groups (e.g., use aseptic technique, use syringes and needles only once, use single-dose vials for one patient only) [5,11], there is a lack of awareness and implementation of these recommendations by many providers. Better data and research are needed regarding frequency of vaccine administration errors. However, one study evaluating injection practices among US clinicians who administer parenteral medications, including vaccines, in a variety of health care settings, demonstrated that many providers use unsafe injection practices [12]. Although literature specifically regarding vaccines is lacking, multiple case studies and anecdotal evidence indicate inappropriate practices in this area, potentially placing patients at risk for iatrogenic adverse events.

8. Documentation

Lack of system checks is also an issue with vaccine administration. System checks can ensure that vaccines are prepared correctly, the correct vaccine is administered, and the vaccine is not expired or otherwise compromised. Mistakes can sometimes be made because of inconsistent packaging of vaccines across manufacturers, lot numbers and expiration dates that are unclear or hard to read, and vaccines and medicines that have similar names. Careful documentation can help prevent some of these problems, but there is

often inadequate documentation before and after the actual vaccine injection, which can potentially result in inaccurate records and inventory. Currently, the use of technology is not employed as a system check or to mitigate documentation errors, although a recent Canadian feasibility study demonstrated the utility of bar code scanning to improve data quality [13].

9. Conclusions and next steps

Vaccines are a great public health achievement; therefore, it is important that they be delivered properly to ensure maximum protection. There are issues that can occur with vaccine delivery during vaccine storage, handling, preparation, and administration that can compromise the effectiveness of vaccines and result in preventable errors. Due to the complexity of the vaccine delivery process combined with a lack of training and awareness of best practice standards, vaccine providers, particularly providers to adults, may struggle to follow best practices for vaccine delivery. The importance of appropriate vaccine storage and handling has been the focus of many educational programs; however, issues in vaccine administration are often overlooked. The area of vaccine administration should be evaluated to determine how the process can be simplified and to define best practices. Failure to adhere to best practices in all areas of vaccine delivery can result in wasted vaccine or necessitate revaccination. It may also cause patients unnecessary pain, potentially increase the risk for an iatrogenic adverse event, and leave patients with less protection against the disease than is anticipated.

The goal of this publication is to raise provider awareness about the current complexity of vaccine storage, handling, preparation, and administration, and the importance of strict adherence to vaccine delivery guidelines. We also seek to identify where issues occur in the vaccine delivery process that can negatively affect outcomes. Identification of these issues is the first step in the process of improving vaccine delivery. The next step for this panel toward continuous process improvement will be to reconvene to develop specific recommendations for the practical steps that can be taken to address the issues identified within each area of the vaccine delivery process.

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