

House Bill 457

By: Representatives Stephens of the 164th, Cooper of the 41st, Channell of the 116th, Parrish of the 156th, and Randall of the 138th

A BILL TO BE ENTITLED
AN ACT

1 To amend Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to
2 controlled substances, so as to authorize the use of remote automated medication systems;
3 to provide for legislative findings; to provide for definitions; to provide for requirements; to
4 provide for the establishment of rules and regulations by the State Board of Pharmacy; to
5 amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
6 pharmacists and pharmacies, so as to authorize pharmacists to dispense prescriptions through
7 a remote automated medication system; to provide that a remote automated medication
8 system shall not be considered a vending machine for certain purposes; to provide for related
9 matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

10 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

11 style="text-align:center">**SECTION 1.**

12 The General Assembly finds that:

- 13 (1) The cost of health care services is increasing at a rate that requires constant review and
14 adoption of better and more efficient delivery systems;
- 15 (2) Technology is constantly improving the efficiency of the delivery of health care
16 services;
- 17 (3) Georgia law must be revised from time to time to permit the adoption of new
18 technology to enable that increase in efficiency;
- 19 (4) There is a national pharmacist shortage and current pharmaceutical practices utilizing
20 remote automated medication systems have demonstrated reduction of human error,
21 improvements to patient safety, and the effective provision of pharmacist care services to
22 patients from a distance;
- 23 (5) Those systems permit the remote dispensing of prescriptions in a way that is safe,
24 accurate, effective, and efficient, and permits the control necessary to avoid improper
25 dispensing, while substantially reducing the cost of getting those prescriptions to the patient
26 and reducing the amount of unused medications needing return or other disposition;

27 (6) Such systems have been endorsed by the Centers for Medicare and Medicaid Services
 28 ("CMS"), the federal agency which administers medicare, Medicaid, and the Children's
 29 Health Insurance Program, and are in use in other states;

30 (7) The ability of the State Board of Pharmacy to regulate the dispensing, pre-packaging,
 31 and repackaging of medications to residents in this state is of vital importance;

32 (8) There is a need for the State Board of Pharmacy to regulate remote automated
 33 medication systems for residents in this state while being flexible enough to adapt future
 34 technologies and the economic and efficiency benefits such technologies provide in the
 35 health care setting;

36 (9) Additional structure and guidance will improve pharmaceutical services for residents
 37 in health care facilities utilizing remote automated medication systems; and

38 (10) This Act will enable the use of such systems subject to the provisions of this Act and
 39 rules and regulations of the State Board of Pharmacy adopted pursuant to this Act.

40

SECTION 2.

41 Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled
 42 substances, is amended in Code Section 16-13-21, relating to definitions relative to
 43 regulation of controlled substances, by adding a new paragraph to read as follows:

44 "(26.1) 'Remote automated medication system' means an automated mechanical system
 45 that is located in an institution, as defined in paragraph (18.1) of Code Section 26-4-5,
 46 that does not have an on-site pharmacy and in which medication may be dispensed in a
 47 manner that may be specific to a patient."

48

SECTION 3.

49 Said chapter is further amended in Code Section 16-13-41, relating to prescriptions, by
 50 adding a new subsection to read as follows:

51 "(i)(1) Pharmacists may dispense prescriptions from a remote location for the benefit of
 52 an institution that uses a remote automated medication system in accordance with the
 53 requirements set forth in this subsection and rules and regulations adopted by the State
 54 Board of Pharmacy pursuant to paragraph (8) of this subsection. As used in this
 55 subsection, the term 'institution' means any licensed hospital, nursing home, personal care
 56 home, hospice, health clinic, or prison clinic.

57 (2)(A) A pharmacist shall be responsible for the safe and efficient dispensing,
 58 repackaging, delivery, control, bar coding, transaction records, dispensation records,
 59 labeling, and accountability for all medications in a remote automated medication
 60 system located in an institution that does not have a pharmacy present on site.

61 (B) If a pharmacist is not physically present where the remote automated medication
62 system is located in an institution, the pharmacist shall have access to the system by
63 electronic and visual means in order to ensure the safe and efficient dispensing,
64 repackaging, delivery, control, bar coding, transaction records, labeling, and
65 accountability for all medications in the system.

66 (3) If an institution uses a remote automated medication system, a pharmacist shall
67 review for accuracy, completeness, and appropriateness all medication orders after
68 being entered in the system.

69 (4)(A) If an institution uses a remote automated medication system, the pharmacy
70 license holder that manages the system and the institution where the system is located
71 shall meet the following requirements:

72 (i) An institution that uses a system does not need to have a pharmacist physically
73 present to review the selection, packaging, or repackaging of medications by the
74 system; and

75 (ii) A remote automated medication system may allow simultaneous access to
76 multiple drug strengths, dosage forms, or drug entities if contained within a
77 patient-specific package.

78 (B) A remote automated medication system shall at a minimum:

79 (i) Use bar code technology to ensure accuracy in loading and selection of
80 medications in the system;

81 (ii) Have electronic reporting capability regarding the identity of all persons with
82 access to the system and regarding all medications removed from the system; and

83 (iii) Before administration of a medication to a patient by an individual authorized
84 to administer medication in this state, provide:

85 (I) A picture of the medication if available; or

86 (II) If a picture is not available, either a written report that describes the medication
87 or a description of the medication on a label affixed to the patient-specific pouch
88 containing the medication.

89 (C) The institution where the remote automated medication system is located shall
90 have at a minimum:

91 (i) A pharmacist available for consultation by telephone or other appropriate
92 communications technology 24 hours per day;

93 (ii) Technical assistance regarding operation of the system available by telephone or
94 other appropriate communications technology 24 hours per day; and

95 (iii) A quality assurance program as described under paragraph (5) of this subsection.

96 (D) The pharmacy license holder that manages a remote automated medication system
97 shall provide a comprehensive training program to all persons with access to the
98 system.

99 (5)(A) A pharmacist that operates a remote automated medication system, in
100 consultation with the institution where the system is located, shall develop and
101 implement a quality assurance program in accordance with rules and regulations
102 adopted by the State Board of Pharmacy.

103 (B) The quality assurance program developed pursuant to this paragraph shall include:

104 (i) Policies and procedures at both the pharmacy where the system receives an order
105 and the institution where the system administers the medication regarding operation
106 of the system;

107 (ii) Daily inspection of the integrity of the system;

108 (iii) A plan for addressing medication errors;

109 (iv) A plan for reviewing incidents regarding inappropriate use and access to the
110 system;

111 (v) Proper labeling procedures that comply with applicable state and federal laws;

112 (vi) Policies and procedures for the safe handling and return of unused medications;
113 and

114 (vii) Any other requirements determined by the State Board of Pharmacy and set
115 forth in rules and regulations.

116 (6)(A) A pharmacist that operates a remote automated medication system shall limit
117 access to the system to individuals authorized to access the system by requiring
118 individual security codes for all functions.

119 (B) A record shall be kept of each transaction containing user identification
120 information.

121 (7)(A) A pharmacist who operates a remote automated medication system shall
122 maintain maintenance logs and repair records for the system.

123 (B) In a power outage or otherwise unforeseen situation, a pharmacist shall ensure that:

124 (i) A backup power source for the system is available by a connection with the
125 institution's generator; and

126 (ii) Only a registered professional nurse or a licensed practical nurse has access to the
127 medications contained within the system.

128 (8) No later than December 31, 2011, the State Board of Pharmacy shall establish rules
129 and regulations to implement the requirements of this subsection. Such rules and
130 regulations may be periodically revised and updated as appropriate."

131 **SECTION 4.**

132 Said chapter is further amended in Code Section 16-13-75, relating to drugs to be kept in the
133 original container, as follows:

134 "16-13-75.

135 (a) Possession and control of controlled substances or dangerous drugs by anyone other
136 than the individuals specified in Code Section 16-13-35 or 16-13-72 shall be legal only if
137 such drugs are in the original container in which they were dispensed by the pharmacist or
138 the practitioner of the healing arts and are labeled according to Code Section 26-3-8.

139 (b) The possession, filling, and use of canisters for remote automated medication systems
140 pursuant to subsection (i) of Code Section 16-13-41 shall not be considered a violation of
141 this Code section."

142 **SECTION 5.**

143 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and
144 pharmacies, is amended in Code Section 26-4-5, relating to definitions, by adding a new
145 paragraph to read as follows:

146 "(37.1) 'Remote automated medication system' means an automated mechanical system
147 that is located in an institution that does not have an on-site pharmacy and in which
148 medication may be dispensed in a manner that may be specific to a patient."

149 **SECTION 6.**

150 Said chapter is further amended in Code Section 26-4-80, relating to dispensing prescription
151 drugs, by adding a new subsection to read as follows:

152 "(p) Pharmacists dispensing prescriptions from a remote location for the benefit of an
153 institution that uses a remote automated medication system in accordance with the
154 requirements of subsection (i) of Code Section 16-13-41 and in rules and regulations
155 adopted by the State Board of Pharmacy pursuant to such subsection shall be considered
156 in compliance with this Code section."

157 **SECTION 7.**

158 Said chapter is further amended in Code Section 26-4-89, relating to the prohibition on
159 selling drugs in vending machines, as follows:

160 "26-4-89.

161 (a) Any person who shall sell or dispense drugs by the use of vending machines shall be
162 guilty of a misdemeanor.

163 (b) A remote automated medication system shall not be considered a vending machine for
164 purposes of this Code section."

165 **SECTION 8.**

166 This Act shall become effective upon its approval by the Governor or upon its becoming law
167 without such approval.

168 **SECTION 9.**

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