



MISSOURI BOARD OF PHARMACY

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TO: ALL LICENSEES

FROM: THE MISSOURI BOARD OF PHARMACY

RE: IMPLEMENTATION OF SB 754 (ELECTRONIC RECORDS)

DATE: AUGUST 27, 2010

During its recent legislative session, the Missouri General Assembly enacted SB 754 which amended § 338.100, RSMo, to expand Missouri's requirements for electronic prescription recordkeeping. The amended § 338.100, RSMo, became effective on August 28, 2010, and is attached below.

Please be advised the Board is in the process of reviewing its rules to incorporate the recent legislative changes. In the interim, the following guidance notes are being provided to assist with statutory compliance:

SB 754 governs electronic recordkeeping and not electronic prescribing. The Board will conduct further review of its electronic prescription regulations to ensure consistency with the recently promulgated Drug Enforcement Administration's electronic prescribing Interim Final Rule.

- Under the amended § 338.100, pharmacy prescription records can be maintained electronically, including, original prescription orders. Thus, pharmacies operating a compliant electronic recordkeeping system will no longer be required to maintain hard copy prescriptions if the prescription order is maintained electronically. However, original written and faxed controlled substance prescription records must still be physically maintained on file at the pharmacy, as required by state and federal controlled substance laws. For investigation purposes, the Board recommends that the pharmacy also maintain a record of the electronic data received from the prescriber in its electronic system.
- The electronic recordkeeping provisions are optional. Pharmacies electing to maintain an electronic system must comply with all applicable statutory and regulatory requirements.
- An "electronic recordkeeping system" is defined by § 338.100.3, RSMo, as "a system, including machines, methods of organization, and procedures, that provides input, storage, processing, communications, output, and control functions for digitized images of original prescriptions."
- Records maintained in an electronic recordkeeping system must "contain all information otherwise required in a manual recordkeeping system." This includes, but is not necessarily limited, to:
 1. All prescription information required to be maintained by 20 CSR 2220-2.018;
 2. All refill information required to be maintained by 20 CSR 2220-2.085(4), and;

3. A clear audit trail of any changes or alterations to a prescription record, as required by § 338.100.1, RSMo, and 20 CSR 2220-2.085(4), and;
- Electronic prescription records must be “readily retrievable.” Under 20 CSR 2220-2.010(4), electronic recordkeeping systems must also be maintained to allow separate identification/retrieval of Schedule I and II controlled substances, separate identification/retrieval of Schedule III, IV and V controlled substances and separate identification/retrieval of other noncontrolled drugs.

Please monitor the Board's website at <http://pr.mo.gov/pharmacists.asp> for future rule review dates and information. For additional compliance questions, please e-mail us at lawquestions@pr.mo.gov, or call (573) 751-9056.

(This statement reflects the Board of Pharmacy's current interpretation of Missouri's law and regulations and does not constitute a legal opinion or other binding legal statement. The Board reserves the right to modify its interpretation as necessary or appropriate. Licensees should independently review all statutes and rules cited herein to ensure compliance with Missouri law.)

Advisory notes from the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD):

- *Under the federal rules, electronic prescribing of controlled substances is not allowed until the software used and its application have been audited and approved by the DEA;*
- *The DEA rules for electronic prescribing mandate that what starts out electronic, must stay electronic. A pharmacy cannot receive a prescription electronically, and then print it out via a fax machine and turn it into paper. If the prescription is received electronically via computer, it must be archived in the pharmacy via computer file.*

SECOND REGULAR SESSION
[TRULY AGREED TO AND FINALLY PASSED]
CONFERENCE COMMITTEE SUBSTITUTE NO. 2 FOR
HOUSE COMMITTEE SUBSTITUTE FOR
SENATE COMMITTEE SUBSTITUTE FOR
SENATE BILL NO. 754
95TH GENERAL ASSEMBLY
2010

3900S.09T

AN ACT

To repeal sections 193.145, 193.265, 195.080, 208.010, 214.160, 214.270, 214.276, 214.277, 214.283, 214.290, 214.300, 214.310, 214.320, 214.325, 214.330, 214.335, 214.340, 214.345, 214.360, 214.363, 214.365, 214.367, 214.387, 214.392, 214.400, 214.410, 214.500, 214.504, 214.508, 214.512, 214.516, 214.550, 301.142, 334.735, 337.528, 338.100, 339.010, 339.020, 339.030, 339.040, 339.080, 339.110, 339.160, 339.170, 339.710, 344.010, and 344.020, RSMo, and to enact in lieu thereof fifty-two new sections relating to the licensing of certain professions, with penalty provisions.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 193.145, 193.265, 195.080, 208.010, 214.160, 214.270, 214.276, 214.277, 214.283, 214.290, 214.300, 214.310, 214.320, 214.325, 214.330, 214.335, 214.340, 214.345, 214.360, 214.363, 214.365, 214.367, 214.387, 214.392, 214.400, 214.410, 214.500, 214.504, 214.508, 214.512, 214.516, 214.550, 301.142, 334.735, 337.528, 338.100, 339.010, 339.020, 339.030, 339.040, 339.080, 339.110, 339.160, 339.170, 339.710, 344.010, and 344.020, are repealed and fifty-two new sections enacted in lieu thereof, to be known as sections 193.145, 193.265, 195.080, 208.010, 208.198, 214.160, 214.270, 214.276, 214.277, 214.282, 214.283, 214.300, 214.310, 214.320, 214.325, 214.330, 214.335, 214.340, 214.345, 214.360, 214.363, 214.365, 214.367, 214.387, 214.389, 214.392, 214.400, 214.410, 214.500, 214.504, 214.508, 214.512, 214.516, 214.550, 301.142, 334.735, 337.528, 338.100, 339.010, 339.020, 339.030, 339.040, 339.080, 339.110, 339.160, 339.170, 339.710,

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

22 registry regarding the committee's actions if they have been previously notified
23 of the complaint; and

24 (3) Send a letter to the licensee that clearly states that the committee
25 found the complaint to be unsubstantiated, that the committee has taken the
26 requested action, and notify the licensee of the provisions of subsection 3 of this
27 section.

28 3. Any person who has been the subject of an unsubstantiated complaint
29 as provided in subsection 1 or 2 of this section shall not be required to disclose
30 the existence of such complaint in subsequent applications or representations
31 relating to their counseling professions.

338.100. 1. Every permit holder of a licensed pharmacy shall cause to be
2 kept in a uniform fashion consistent with this section a suitable **book, file, or**
3 **electronic recordkeeping system** in which shall be preserved, for a period of
4 not less than five years, the original or order of each drug which has been
5 compounded or dispensed at such pharmacy, according to and in compliance with
6 standards provided by the board, and shall produce the same in court or before
7 any grand jury whenever lawfully required. A licensed pharmacy may maintain
8 its prescription file on readable microfilm for records maintained over three
9 years. After September, 1999, a licensed pharmacy may preserve prescription
10 files on microfilm or by electronic media storage for records maintained over three
11 years. The pharmacist in charge shall be responsible for complying with the
12 permit holder's record-keeping system in compliance with this section. Records
13 maintained by a pharmacy that contain medical or drug information on patients
14 or their care shall be considered as confidential and shall only be released
15 according to standards provided by the board. Upon request, the pharmacist in
16 charge of such pharmacy shall furnish to the [prescribe] **prescriber**, and may
17 furnish to the person for whom such prescription was compounded or dispensed,
18 a true and correct copy of the original prescription. The file of original
19 prescriptions **kept in any format in compliance with this section**, and other
20 confidential records, as defined by law, shall at all times be open for inspection
21 by board of pharmacy representatives. **Records maintained in an electronic**
22 **recordkeeping system shall contain all information otherwise required**
23 **in a manual recordkeeping system. Electronic records shall be readily**
24 **retrievable. Pharmacies may electronically maintain the original**
25 **prescription or prescription order for each drug and may electronically**
26 **annotate any change or alteration to a prescription record in the**

27 **electronic recordkeeping system as authorized by law; provided**
28 **however, original written and faxed prescriptions shall be physically**
29 **maintained on file at the pharmacy under state and federal controlled**
30 **substance laws.**

31 2. An institutional pharmacy located in a hospital shall be responsible for
32 maintaining records of the transactions of the pharmacy as required by federal
33 and state laws and as necessary to maintain adequate control and accountability
34 of all drugs. This shall include a system of controls and records for the
35 requisitioning and dispensing of pharmaceutical supplies where applicable to
36 patients, nursing care units and to other departments or services of the
37 institution. Inspection performed pursuant to this subsection shall be consistent
38 with the provisions of section 197.100, RSMo.

39 3. **"Electronic recordkeeping system", as used in this section,**
40 **shall mean a system, including machines, methods of organization, and**
41 **procedures, that provides input, storage, processing, communications,**
42 **output, and control functions for digitized images of original**
43 **prescriptions.**