SENATE DOCKET, NO. 00245 FILED ON: 01/19/2011

SENATE . . . . . No. 00483

The Commonwealth of Massachusetts

PRESENTED BY:

Stephen M. Brewer

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

An Act relative to electronic prescribing.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Stephen M. Brewer	*Worcester, Hampden, Hampshire, Franklin*

SENATE . . . . . No. 00483

By Mr. Brewer, petition (accompanied by bill, Senate, No. 483) of Brewer for legislation relative to electronic prescribing [Joint Committee on Health Care Financing].

The Commonwealth of Massachusetts

In the Year Two Thousand Eleven

An Act relative to electronic prescribing.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. The General Laws are hereby amended by inserting after chapter 111 the following chapter:-

CHAPTER 111O.

Massachusetts Electronic Prescribing Act

Section 1. Definitions.

A. Dispenser means a registered pharmacist or other legal entity licensed, registered or otherwise permitted by the jurisdiction in which the person practices or in which the entity is located to dispense drugs for human use by prescriptions.

B. Electronic Health Record (EHR) means the aggregate electronic record of health-related information on an individual that is created and gathered cumulatively across more than one

health care organization and is managed and consulted by licensed clinicians and staff involved in the individual's health and care. By these definitions, an EHR is an EMR with extramural interoperability, for example, ability to gather health information from other health systems.

C. Electronic Prescribing or Electronic Prescription (eRx) means the transfer of prescription information from the prescriber to the pharmacy by electronic means, instead of by paper, phone, or fax.

D. Electronic Transmission means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

E. Electronic Transmission Device means any mechanism used to facilitate the electronic transmission of a prescription by any individual authorized to prescribe in this state.

F. Patient means the individual for whom the prescriber makes a treatment decision.

G. Prescriber means an individual authorized under existing Massachusetts regulation to write a prescription for a patient under his or her direct care

H. Prescription Drug means a drug that may not be dispensed for human use without a prescription under the laws of the United States and of this State.

I. Prescription Drug Order means a prescription for a prescription drug in the state of Massachusetts as defined under

J. Prior Authorization means the process of obtaining prior approval from a health plan, pharmacy benefits manager or other entity for coverage of a prescription drug or other medical product or procedure.

Section 2. Electronic Prescribing Transmission Standards

A. The electronic transmission devices shall transmit information to prescribers and dispensers in accordance with Section 1860D-4(e)(2) of the Social Security Act, applied without regard to whether the patient is eligible for benefits under Title XVIII of the Social Security Act or whether the drug is a "covered Part D drug" within the meaning of the Social Security Act, as amended or any other covered drug.

Section 3. Federal Alignment

A. Electronic prescribing devices, software and hardware shall be designed in a manner to support meaningful use of electronic health records as required as part of the ARRA.

B. The state shall provide financial incentives to Medicaid providers as described in Section 4201 of the ARRA and pursue available Federal Financial Participation for these incentives and the state's administrative costs associated with the program.

C. The state board of pharmacy shall promulgate regulations aligning the state rules for the electronic transmission of prescriptions with the most recent regulations for such transmissions with the federal Drug Enforcement Administration [21 CFR Parts 1300, 1304, 1306 and 1311].

Section 4. Standards for Electronic Transmission of Prescriptions

A. All Prescription Drug Orders communicated by way of Electronic Transmission shall:

a. Be transmitted directly to a Pharmacist or Registered Pharmacy Technician in a licensed Pharmacy of the patient's choice with no intervening person having access to the Prescription Drug Order.

b. Identify the transmitter's phone number or any other suitable means to contact the transmitter for verbal and/or written confirmation, the time and date of transmission, and the identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or state law;

c. Be transmitted by a prescriber or the designated agent of the prescriber as allowed under existing state law; and

d. Be deemed the original Prescription Drug Order, provided it meets the requirements of this subsection.

B. All Electronic Transmission Devices used to communicate a prescription to a Pharmacist or Registered Pharmacy Technician in a licensed pharmacy shall:

a. Allow any legal Prescription Drug Order to be written and entered into the device without limitations or interference, including a limited medication list from which a prescriber can select a medication on the device or non-clinical multiple messaging, prior to submission to a Pharmacist or Registered Pharmacy Technician in a licensed pharmacy;

b. Allow the prescription to be written through a neutral and open platform that does not use any means, program, or device, including, but not limited to, advertising, instant messaging, and pop up messaging, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision (as defined in clause (f) of the Definitions) of a health care professional at the point of care (as defined in clause (e) of the Definitions (i) Clause (b) shall apply if such means, program, or device is triggered by, initiated by, or is in specific response to, the input, selection, and/or act of a prescriber or his or her designated agent prescribing a covered

outpatient drug or indicating which pharmacy a patient will visit to pick up the prescription or from which pharmacy the medication is preferred to be delivered.

c. In the event that the pharmacy a patient wishes to use is unable to receive the intended prescription, provide a system for printing the prescription for the patient to bring to the pharmacy that would prevent a duplicate prescription to be printed or transmitted once the prescription is final.

d. Allow for a written reminder to be provided to the patient at the time of the office visit pertaining to what prescription has been ordered electronically and to which pharmacy the prescription was sent.

e. Notwithstanding clause (b), electronic transmission devices may show information regarding a plan's formulary so long as— (i) All covered outpatient drugs and all pharmacies with a National Council for Prescription Drug Programs identification number (NCPDP #; in and out of network) available are readily disclosed to the prescriber; (ii) Nothing is designed to preclude or make more difficult the prescriber's or patient's selection of any particular pharmacy or covered outpatient drug; and (iii) An electronic prior authorization process for allowing approval of an exception to the plan formulary or other restriction is available on the device as described in Section 8 of this Act, providing real-time adjudication.

f. Allow a final review of the complete prescription before it is sent to the pharmacy.

g. As set forth in clause (b) above, be limited to messages to the prescriber and his or her staff that are consistent with the pharmaceutical label, substantially supported by scientific evidence, accurate, up to date, and fact-based, including a fair and balanced presentation of risks and benefits, and support for better clinical decision-making, such as, alerts to adverse events

and access to formulary information. This information must be consistent with the U.S. Food and Drug Administration regulations for advertising pharmaceutical products and not be selectively or competitively pushed to the prescriber. The distribution of such information must not diminish the patient's right to appeal.

h. The prescriber may authorize his or her designated agent to communicate a Prescription Drug Order orally or by way of Electronic Transmission to a Pharmacist or Registered Pharmacy Technician in a licensed Pharmacy, provided that the identity of the transmitting agent is included in the order as allowed under existing federal and state laws.

i. All electronic equipment for receipt of Prescription Drug Orders communicated by way of Electronic Transmission shall be maintained against unauthorized access as required by the HITECH Act.

j. Persons other than those bound by a confidentiality agreement or Business Associate Agreement pertaining to a patient's protected health information shall not have access to Pharmacy records containing Protected Health Information concerning the Pharmacy's patients as required by the Health Insurance Portability and Accountability Act.

Section 5. Alerts and Notifications

A. Alerts and messages provided to a prescriber must be meaningful to the appropriate delivery of care to a patient. Acceptable alerts and communications shall:

a. Be categorized or prioritized based on their clinical importance, including severity and likelihood of any adverse events;

b. Be individually suppressible by the prescriber, if they relate to either rare or minor adverse events;

c. Be able to be overridden by the prescriber so that the prescriber can prescribe his or her prescription drug of choice for the patient;

d. Display the date that the decision support rules underlying each alert or message were last updated, as well as a link to a general description of the decision support rules and the source of any financial support received in connection with the development of those rules; or

e. Clearly indicate whether the alert or other message relates to the prescription drug's safety or efficacy for the patient.

B. Information provided to a prescriber through an e-prescribing device shall not contain any material false statements or omissions. For purposes of this Act, a material false statement or omission is defined as an untrue statement of a material fact or an omission to state a material fact necessary in order to make the statements made under the circumstances in which they are made not misleading.

C. Any information provided to a prescriber through an e-prescribing device relating to the safety or efficacy of any drug (including any alerts or other messages) shall include a readily-accessible citation to any sources that support the accuracy of the information and link directly to FDA source information.

Section 6. Standards for Prior Authorization

A. Requests for prior authorization must utilize a standard format for such requests as defined by the Bureau of Insurance that is consistent with the Medicare Part D Coverage Determination Request Form.

B. Pursuant to paragraph A, key elements to be captured in prior authorization request form, whether electronic or paper, shall include:

a. Patient information data fields, including:

i. Patient name, date of birth, address, phone and gender;

ii. Patient health plan or prescription drug plan name; and

iii. Patient authorizing plan name and identification number.

b. Prescriber data fields, including:

i. Prescriber name, phone number and National Provider Identifier (NPI);

ii. Point of Contact (POC) name and phone number, if different than the prescriber; and

iii. Prescriber business address and fax number.

c. Pharmacy information data fields, if transmitting the prescription electronically:

i. Pharmacy name, phone number and Pharmacy National Provider Identifier;

ii. Pharmacy address.

d. Prescription drug information data fields, including:

i. Name, strength, quantity, dosing schedule of requested drug, day supply and refills authorized by prescriber;

ii. Other medications tried and explanation of results;

iii. Drug allergies; and

iv. Current clinical findings and management.

C. Specific information shall be provided to the prescriber pertaining to acceptable reasons for a prior authorization approval upon the request of the prescriber and information shall be provided to the prescriber if the prior authorization is rejected.

D. At a minimum, prior authorization shall be granted if the preferred drug:

a. Has been ineffective in the treatment of the patient's disease or medical condition, or

b. Based on both sound clinical or medical and scientific evidence another drug would result in better patient outcomes; or

c. Is expected to be ineffective based on the known relevant physical, genetic or mental characteristics of the patient and known characteristics of the prescription drug regimen, is likely to be ineffective or adversely affect the prescription drug's effectiveness or patient compliance; or

d. Has caused, or based on sound clinical evidence and medical and scientific evidence is likely to cause, an adverse reaction or other harm to the patient.

Section 7. Electronic Prior Authorization

A. Pursuant to Section 7 of this Act, an electronic prior authorization system shall:

a. Be aligned with the SCRIPT standard as set forth by the National Council for Prescription Drug Programs.

b. Be required as a part of devices, software and hardware systems that facilitate electronic submission of prescription drug orders;

c. Utilize a universal format for prior authorization requests to be developed by the Bureau of Insurance pursuant to Section 7 of this Act;

i. Notify patient's preferred pharmacy of pending prior authorization;

d. Provide specific feedback to the prescriber on acceptable and approvable reasons for approval of a prior authorization request for a prescription drug prescribed for a patient; and

e. Provide real-time feedback on the prior authorization request to the prescriber and the patient's preferred pharmacy that facilitates an explanation of benefits for the patient with information on how to appeal the denial of the requested medication.

B. An advisory committee to the Bureau of Insurance shall be formed to provide input to the Bureau of Insurance on the design of the universal prior authorization format, including a comparable paper form when an electronic prescribing device is not used. Members of the advisory committee shall include:

a. Two practicing physicians utilizing eRx on a routine basis

b. One practicing nurse practitioner or physician's assistant

c. One pharmacist practicing in an environment where eRx are commonly received

d. Two patient advocates

e. One representative of the health insurance industry

Section 8. This Act shall become effective 120 days after enactment.