

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill removes regulatory barriers to streamline the process of prescribing prescription drugs electronically.

Safeguard Individual Liberty – The bill protects the rights of consumers and their health care providers to determine appropriate pharmaceuticals and purchase from pharmacies of their choice; and to guarantee the confidentiality of medical records and prescriptions.

B. EFFECT OF PROPOSED CHANGES:

PRESENT SITUATION

Florida law permits electronic prescriptions under chapter 456, F.S., and authorizes the regulation of the practice of pharmacy by the Florida Board of Pharmacy. Section 465.003(14), F.S., further defines “prescription” to be any order for drugs or medicinal supplies written or transmitted by any means of communication by a licensed practitioner and intended to be dispensed by a pharmacist. Prescriptions may be transmitted from practitioners to pharmacies orally or through writing; and pharmacies may transfer prescriptions by any means, including electronic, under specified conditions.

Medical Records

Currently only certain health care practitioners and their employers (if agreed by contract) are considered records owners and subject to limitations on the handling of patient medical records under s. 456.072, F.S. Other individuals who later come into possession of patient medical records are not subject to these limitations.

Legible Prescribing Law

The Legible Prescribing Law, codified in s. 456.42, F.S, requires that all written prescription drugs must:

- Be legibly printed or typed;
- Contain the name of the prescribing practitioner;
- Contain the name and strength of the drug, the quantity of the drug in both textual and numerical formats;
- Contain directions for use;
- Be dated and signed with the month written in textual letters; and
- Be signed by the prescribing practitioner on the day when issued.

In order to fill a written prescription, Florida law requires that the prescription be signed by the prescribing practitioner. This poses a problem for electronically generated prescriptions.

Generic Substitution

Currently, under s. 456.025, F.S., a pharmacist may substitute a generic drug for a brand name drug when any written prescription does not include the words, “MEDICALLY NECESSARY” written by the prescribing practitioner. It is technically difficult for the prescribing practitioner to write on electronically generated prescriptions.

EFFECTS OF THE BILL

Electronic prescribing is integral to the achievement of state and national goals for integrated electronic medical records. The bill creates one and amends four provisions in state statute for the development of electronic prescribing practices, the regulation of electronic prescribing software, and the protection of patient rights.

Definition of Records Custodian

HB 7125 amends s. 456.057, F.S., to define “records custodian” and to require records custodians and records owners to maintain records and documents as provided under the confidentiality and disclosure requirements of this section. The bill provides that all those with access to medical or prescription records abide by confidentiality and disclosure requirements. According to the Department of Health (DOH), this helps address confidentiality concerns when patient medical records are abandoned by the practitioner. This provision is subject to enforcement by the Office of Attorney General through injunctive relief and fines of up to \$5,000 per violation.

Requirements for Electronic Prescriptions

The bill amends s. 456.42, F.S., to provide requirements for prescriptions that are electronically generated and transmitted. The bill requires that the electronic prescription contain the name of the prescribing practitioner, name and strength of the drug prescribed, quantity of the drug prescribed in numerical format (in contrast to handwritten prescriptions that require both textual and numerical format), directions for use of the drug, date, and signature by practitioner only on the day issued. The signature may be in an electronic format as defined by s. 668.003(4).

Consumer Choice of Pharmacy

The bill creates s. 456.43, F.S., to regulate electronic prescribing software for the protection of consumers and patient’s rights. As electronic prescribing becomes more prevalent it is necessary to protect consumer choice when choosing a pharmacy. This section provides restrictions and establishes that electronic prescribing software:

- Shall not interfere with patient’s freedom to choose a pharmacy;
- Shall not attempt to influence, through economic incentives or otherwise, the prescribing decision of a physician at the “point of care”—the time that the practitioner or agent is in the act of prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.
- Shall be permitted to show information regarding a payor’s formulary as long as nothing is designed to preclude or make more difficult the act of the patient or physician selecting any particular pharmacy or pharmaceutical.

Protections against Generic Substitution of Brand Name Drugs

The bill amends s. 456.025, F.S., to provide mechanisms to ensure that patients receive brand name drugs and not generic substitutes, when brand name drugs are medically necessary. The bill ensures that a pharmacist may fill electronically generated prescriptions with the brand name drug if the prescription reflects that it is medically necessary without requiring the prescribing practitioner to write the words, “MEDICALLY NECESSARY.”

The effective date of the bill is July 1, 2006.

BACKGROUND

Electronic prescribing (e-prescribing) utilizes computers and automated data systems rather than handwritten communications to generate prescriptions, and is the future standard practice in prescription writing. Although e-prescribing rates today vary between 5 percent and 18 percent for

physicians, usage is increasing¹ due to initiatives at the national and state levels, and because of independent efforts by health care providers and pharmacists. In June 2005, President Bush called for most Americans to have electronic health records² within ten years. The Florida Health Information Network was developed by the Agency for Health Care Administration (AHCA) to facilitate the development of a statewide privacy-protected health information infrastructure network as recommended by the Governor's Health Information Infrastructure Advisory Board. The program has received funding from the Florida Legislature to support personnel and grant programs aimed at developing regional health information exchanges and to encourage the use of electronic health records.³ Electronic prescribing is an integral component in the fulfillment of these national and state goals.

Concerns with patient safety, the efficiency of care, and integrated medical records are the key objectives driving efforts for electronic prescribing. More than 4 billion prescriptions are written each year⁴ and therefore even small improvements in the prescribing process will translate into significant healthcare cost and safety benefits. Studies suggest that the national savings from universal adoption of electronic prescribing systems could be as high as \$27 billion, due to a combination of injury prevention, better utilization of drugs⁵, and efficiency both at the point of care and subsequent to treatment.

Security Measures Used by Electronic Prescribing Networks

Currently, there are a number of methods through which electronic networks secure confidentiality and data integrity. These features include credentialing, where prescribers and pharmacies are enrolled in a network through access authorization; user ID and password for authentication and access to electronic prescribing software; the use of network-assigned electronic signatures; and the transmission of prescription messages through a private leased line or through the Internet using a virtual private network connection or protocol.⁶

Benefits of Electronic Prescribing

Reduction of potential errors of handwriting and transcription

The prescribing process is error-prone. Adverse drug events (ADE) are the 4th leading cause of death⁷ and cost as much as \$136 billion a year⁸. Among ADE's, 7,000 deaths a year are attributed to prescription error⁹. Causes of errors include illegible handwriting, wrong dosage, and the overlooking of dangerous drug-drug or drug-allergy interactions. Medication errors further account for 1 out of 131 ambulatory care deaths.¹⁰ As a solution for a portion of these errors, computer-assisted prescriptions have been shown to cut errors by 70% over handwritten prescriptions.¹¹ In addition to improving the readability of scripts and the accuracy of transcription from the prescription to the pharmacy, a reduction in errors accomplished by electronic prescribing is due to information made available to doctors about the correct dosage, use instructions, and other aspects of the prescription. At the point of

¹ Ferris, Nancy. 11/2/05. "CMS finalizes e-prescribing rules." *Government Health*. www.govhealthit.com/article91285-11-02-05-Web.

² According to the Florida Senate Interim Project 2006-135, "An electronic health record is a digital collection of information from a patient's medical history that may include diagnoses, prescribed medications, vital signs, immunizations, and personal characteristics."

³ Agency for Health Care Administration press release, January 6, 2006; http://www.fdhc.state.fl.us/dhii/press_release.shtml.

⁴ AllScripts analysis of e-prescribing at <http://www.allscripts.com/slncInclnfo.aspx>

⁵ Agency for Healthcare Research and Quality. MEPS Highlights #11: Distribution of health care expenses, 1999.

⁶ National Committee on Vital and Health Statistics. <http://www.cdc.gov/nchs/data/ncvhs/nchvs50th.pdf>

⁷ Committee on Quality of Health Care in America: Institute of Medicine. "To err is human: building a safer health system." Washington, D.C.: National Academy Press, 2000.

⁸ Lazarou, J., Pomeranz, B., Corey, PN. "Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies." *JAMA*. 1998; 279:1200-1205.

⁹ Johnson, JA., Bootman, JL. "Drug-related morbidity and mortality: a cost-of-illness model." *Arch Intern Med*. 1995; 155:1949-1956.

¹⁰ "Electronic Prescribing: Toward Maximum Value and Rapid Adoption." A report of the *Electronic Prescribing Initiative*. Washington, D.C., April 14, 2004.

¹¹ "HHS Accelerates Use of E-Prescribing and Electronic Health Records." *Press Release from the US Department of Health and Human Services*. 11/5/2005. <http://biz.yahoo.com/prnews/051005/dcw035.html?v=29&printer=1>.

care, electronic prescribing systems can provide an overall medication management process by performing checks against the patient's current medications, duplicate therapies, medical history, diagnoses, body weight, age, and more. The system then alerts the physician if problems are found.

Integration of prescription information into the electronic medical record

Electronic prescribing can further contribute to the integration of the prescription into a patient's consolidated medical record. Access to information about a patient's formulary can guide physicians to consider formulary-based drug coverage, including on-formulary alternatives and co-pay information. By checking with healthcare formularies at point-of-care, generic substitutions and generic first-line therapy choices are encouraged, thus reducing patient costs.

Efficiency

Electronic prescribing increases efficiency for physicians, patients, and pharmacists. At the point-of-care, electronic prescribing saves time for the physician's staff. For many practitioners, it is quicker to e-prescribe than to have a nurse spend time calling in a refill for the drug.¹² Physicians can expect fewer callbacks from pharmacies to clarify prescription details and refill renewal authorizations that are completed in a fraction of the time, so that more time can be dedicated to patient care and other activities.¹³ A 2003 survey of Boston area physicians found that 88 percent of those surveyed reported that they and their staff spend almost one-third of their time responding to phone calls from pharmacies regarding prescriptions, and that these call-backs interrupt office flow and reduce productivity related to chart-pulls, re-filing charts, faxing prescriptions, and so on.¹⁴ For patients, electronic prescribing means eliminated or significantly reduced waiting times at pharmacies.¹⁵ Benefits in efficiency for pharmacists are also significant. Because all necessary prescription information is transmitted and received, more time can be spent with customers. Electronic prescribing improves record keeping, reduces phone calls and faxes, and more readily alerts pharmacists to possible drug contraindications within a patient's file. Approximately 900 million prescription-related calls are made annually, for refills, questions and clarifications; and electronic prescribing reduces the expense of this for all parties.¹⁶

Protecting Against Abuses of Electronic Prescribing

Although electronic prescribing does have the demonstrated potential to save lives, time, and money, unsecured systems could lead to forgery, fraud, unfair trade practices, or the loss of patient confidentiality. In developing electronic programs it is critical that precautions be taken to expand consumer protection. Among these measures, the patient's right to choose medications and pharmacies should be protected; and therefore, software used in electronic prescribing should be prevented from directing the practitioner toward specific medications or pharmacies through pop-up ads or marketing of any other kind. Patient confidentiality must also be protected; and therefore, electronic data services ("records custodians") should be bound by the same specified requirements for confidentiality and disclosure as pharmacies and physicians already are. It is also important that electronic prescriptions include the same level of information as paper prescriptions; detailing patient and physician names, drug name and strength, quantity and directions for use of the drug, date, electronic signature, and an option to prevent automatic substitution of brand name drugs with generic drugs in cases where the brand name drug is medically necessary for the patient.

¹² Baldwin, Gary. 10/17/2005. "E-prescribing eliminates wait." *Health Leaders*. <http://www.healthleaders.com/news/print.php?contentid=73529>.

¹³ Institute of Medicine, Center for Information Technology Leadership, in Walgreens presentation on e-prescribing.

¹⁴ "Boston Area Physicians Embrace E-Prescribing Technology as a Tool To Improve Healthcare". Medco Health Solutions, Inc. – News and Pressroom article on 2/7/2003. http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=MHS&script=410&layout=-6&item_id=442064

¹⁵ Baldwin, Gary. 10/17/2005. "E-prescribing eliminates wait." *Health Leaders*. <http://www.healthleaders.com/news/print.php?contentid=73529>.

¹⁶ Healthcare Information and Management Systems Society at http://www.himss.org/ASP/topics_eprescribing.asp.

Expansion of Electronic Prescribing in Medicare and Florida Medicaid

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, electronic-prescribing is optional for physicians and pharmacies. However, starting on January 1, 2006, drugs covered under Medicare Part D are required to support electronic prescribing.¹⁷ The Act has also called for the creation of a grant program that supports the implementation and adoption of electronic prescribing technology beginning in 2007.

The Florida Medicaid program has used an electronic prescribing system since the summer of 2002. Three thousand of the state's highest prescribing (by volume) physicians were given interactive handheld computers that load information on drugs, formularies, and the previous 100 days of prescription history. This represents physicians writing 80 percent of all Medicaid prescriptions in FL, which involves approximately 25 million transactions per year.¹⁸ Florida Medicaid program staff estimate that about \$2 million is saved each month by the use of the electronic prescribing system, and that the program has demonstrated the potential for electronic prescribing to save lives as well.¹⁹

C. SECTION DIRECTORY:

Section 1. – Amends s. 456.057, F.S., to provide definitions for “records custodian” and to require records custodians and records owners to maintain records and documents as provided under the confidentiality and disclosure requirements of the section.

Section 2. – Amends s. 456.42, F.S., to provide requirements for prescriptions that are electronically generated and transmitted.

Section 3. – Creates s. 456.43, F.S., to regulate electronic prescribing software for the protection of consumers and patient's rights.

Section 4. – Amends s. 456.025, F.S., to prevent the substitution of generic drugs when brand name drugs are medically necessary, when a prescription is electronically transmitted and generated.

Section 5. – Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

¹⁷ For complete standards see “Government announces ePRESCRIPTION standards for drug plans” by Caroline Broder, Healthcare IT News, 11/2/2005. www.healthcareitnews.com/NewsArticleView.aspx?ContentID=3940.

¹⁸ Roop, Liz. 2005. “State by state programs” eMPOWEPrescription. www.gsm.com, or 813-258-4747.

¹⁹ The Florida Senate Interim Project Report 2006-135.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rulemaking authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES