The Florida Senate

Interim Project Report 2006-135 *October 2005*

Committee on Health Care Senator Durell Peaden, Jr., Chair

REVIEW OF ISSUES RELATING TO ELECTRONIC PRESCRIBING

SUMMARY

Electronic prescribing of medications involves the use of computers or automated data systems by prescribing practitioners to generate prescriptions, rather than generating prescriptions by writing the information on paper. Electronic prescribing may provide several advantages over written prescriptions, such as the integration of the prescription information into an electronic medical record and a reduction of potential systematic errors that result from communications between prescribers and pharmacists using "paper and pen."

Electronic prescribing has become a significant part of recent government health care initiatives. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 has called for the development of electronic prescribing and the creation of a grant program that supports the implementation and adoption of electronic prescribing technology. The Florida Medicaid program has provided physicians participating in the program with integrated drug lists, interactive screening tools, and recipient medication histories through an electronic prescribing network.

This report describes state and federal requirements for prescriptions which may affect the use of electronic presribing, including generic drug substitution, specialized procedures for controlled substances, and procedures for the legibility of written prescriptions. The report outlines the procedures used by pharmacists to validate and authenticate a prescription; describes existing electronic prescribing networks and the unique measures used in such networks to ensure that the transmission of electronic prescriptions is secure; and discusses the confidentiality of pharmacy records and related patient information.

Consistent with the findings of this report, staff recommends that:

- The statutes governing generic drug substitution be amended to provide a mechanism for prescribers using electronic prescribing to prevent the generic substitution of a prescribed brand name drug product when the brand name drug is deemed medically necessary;
- The law governing written prescriptions for medicinal drugs in s. 456.42, F.S., be amended to limit its application to handwritten prescriptions; and
- The provisions in ss. 456.057 and 465.017, F.S., relating to the confidentiality of patient records be amended to recognize a third party custodian of medical and pharmaceutical records and to require the custodian to be subject to the same statutory confidentiality and disclosure requirements for the records as the licensed or regulated health care practitioner who created the records.

BACKGROUND

On June 6, 2005, the Secretary of the U.S. Department of Health and Human Services announced the formation of a national collaboration that will advance President Bush's call for most Americans to have electronic health records within ten years. 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. Electronic prescribing can be an integral part of the system for creating an electronic health record.

Electronic prescribing of medications involves the use of computers or automated data systems by prescribing practitioners to generate prescriptions, rather than generating prescriptions by writing the information on paper.[1] Electronic communication among health care

[1] See Rand Research Highlights, "Electronic Prescribing Systems, Making It Safer to Take Your Medicine?" at

providers is being recognized as a new standard of practice and many pharmacies are connected to electronic prescribing networks. The electronic transmission of written prescriptions has the potential to improve patient care, save time and money, and reduce medication errors and prescription fraud. However, unsecured electronic prescriptions could lead to prescription forgery, fraud, the introduction of errors, or the loss of confidentiality. Electronic prescribing is, in part, an integral part of a movement towards the use of electronic medical records.

Electronic Prescribing Networks and Recent Initiatives

Electronic prescribing networks are switching services or networks that receive prescriptions from prescribers and route the prescriptions to the designated pharmacist. The electronic system may reformat the prescriber's transaction so that it can be accepted by the pharmacy's system.[2] Such networks may provide prescribers and pharmacists with real-time access to a patient's medication history and drug information to improve patient safety. The networks make it easier for health care providers to comply with the drug formularies of the patient's health plan.[3] Advanced electronic prescribing networks can automatically provide this information with alerts, warnings, or reminders to prescribers and dispensers. Electronic prescribing networks eliminate the need for transcription of prescription data from paper or facsimile, since such networks communicate the prescription directly from prescriber to pharmacist.[4]

To assure that prescriptions have the appropriate confidentiality and data integrity, electronic prescribing networks may employ a combination of security features to secure the electronic transmission of prescriptions, which are outlined in Table 1 below.

Table 1 - Security Measures Used By Electronic Prescribing Networks To Secure Electronic Transmission of Prescriptions	
Credentialing	Credentialing upon enrollment of prescribers and pharmacies in a network (access authorization)
User ID and Password	A minimum of a user ID and password (authentication) for access to electronic prescribing software
Electronic Signature	Use of a network-assigned electronic signature process
Secured Transmission	Transmission of the prescription message through a private leased line or through the Internet using a virtual private network connection or protocol

Source: National Committee on Vital and Health Statistics

Electronic prescribing has become a significant part of recent government health care initiatives. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 has called for the development of electronic prescribing and the creation of a grant program that supports the implementation and adoption of electronic prescribing technology beginning in 2007.[5]

Since the Summer of 2002, the Florida Medicaid program has used an electronic prescribing system under which interactive handheld computers were given to 3,000 of the program's highest prescribing (by volume) physicians throughout Florida.[6] The system loads information on drugs, formularies, and recent prescription history of patients onto the handheld computers. The program has been developed in partnership with Gold Standard Multimedia, Inc., a company that develops and sells electronic prescribing software. The program has shown that the

<http://www.rand.org/publications/RB/RB9052/RAND_RB9052.pdf> and M. Susan Ridgely & Michael D. Greenberg, Pharmacy, Facsimile, and Cyberspace: An Examination of Legal Frameworks for Electronic Prescribing, 13 ALB. L.J. SCI. & TECH. 1 (2002).

[2] March 4, 2005 Letter to U.S. HHS Secretary Leavitt from National Committee on Vital and Health Statistics (NCVHS) regarding recommendations on electronic prescribing.

[3] Id.

[4] Id.

[5] See Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173), Section 108.

[6] See "First Interim Report - Governor's Health Information Infrastructure Advisory Board," Florida Agency for Health Care Administration, February 24, 2005.

implementation of electronic prescribing has the potential to save lives and money.[7]

In September, 2005, the federal government formed a consortium with private sector health care information technology companies, retail pharmacies, and pharmacy benefits managers to create a database of prescription information to give physicians electronic access to Hurricane Katrina evacuees' medication histories that were destroyed or lost as a result of the storm.[8] To protect the confidentiality of patient information, entities participating in the effort have entered into business associate agreements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to exchange data.[9]

State and Federal Regulatory Requirements for Prescriptions

Both the state and federal governments have established requirements for prescribing drugs. The State of Florida establishes requirements for prescribing through regulation of the health professions and under the "Florida Comprehensive Drug Abuse Prevention and Control Act." The U.S. Department of Justice, Drug Enforcement Administration (DEA) has jurisdiction over controlled substances.[10]

Regulations Relating to Prescribing Controlled Substances

Controlled substances are drugs that have a high potential for abuse. Prescribers must be authorized by the DEA to prescribe controlled substances. Controlled substances are classified in Schedules I through V. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and have a severely restricted medical use. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use.

The "Florida Comprehensive Drug Abuse Prevention and Control Act" (ch. 893, F.S.) defines "prescription"[11] for purposes of the act. A prescription for a controlled substance under Florida law means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, *or other means of communication* by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of s. 893.04, F.S.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only to dispense controlled substances upon a *written or oral prescription* under specified conditions. An oral prescription for controlled substances must be promptly reduced to writing by the pharmacist.

The written prescription for controlled substances must be dated and signed by the prescribing practitioner on the day when issued. There must appear on the face of the prescription or written record for the controlled substance: the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed; the full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number must be printed thereon; if the prescription is for an animal, the species of animal for which the controlled substance is prescribed; the name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof; the number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled; and the initials of the pharmacist filling the prescription and the date filled.

Under ch. 893, F.S., "prescription" also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than

[7] The Florida Medicaid program staff estimates that about $2 million is saved monthly by the use of the electronic prescribing system.

[8] Caroline Broder "Effort Under Way to Provide Medication Data on Katrina Evacuees" Healthcare IT News, September 16, 2005 at <http://www.healthcareitnews.com/NewsArticleView.aspx?ContentID=3662>. The national coordinator for health information technology noted that the consortium does not have any plans to continue the effort beyond the pilot phase or electronically sharing data other than medication lists because it is not a sustainable architecture.

[9] Id.

[10] See 21 CFR 1306.21, 21 CFR 1306.11, and 21 CFR 1306.05

[11] See s. 893.02(20), F.S.

Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist must obtain proof, to a reasonable degree of certainty, of the validity of the prescription.

Applicable federal regulations may preempt state law requirements for prescriptions for controlled substances. Federal law does not currently permit the electronic transmission of prescriptions for controlled substances. The DEA is currently researching the issue of whether to permit electronic transmission of prescriptions for controlled substances. Current federal regulations require prescriptions for controlled substances to be either written and manually signed by the practitioners, or for Schedules III – V prescriptions, they may be orally transmitted to the pharmacy and the pharmacy must then reduce the oral prescription to writing.[12]

Requirements for Prescribing under the Florida Pharmacy Act

State boards of pharmacy identify the qualifications for persons to write a prescription and the manner in which a prescription must be written in order for a pharmacist to validate and authenticate the prescription for dispensing drugs. As part of the regulation of pharmacy, states may impose requirements on prescriptions to ensure privacy, and to ensure that such prescriptions are valid and authenticated to protect consumers.

Electronic prescriptions are permitted under Florida law. Chapter 465, F.S., the "Florida Pharmacy Act," authorizes the regulation of the practice of pharmacy by the Florida Board of Pharmacy. Under ch. 465, F.S., a pharmacist may only dispense a prescription that meets the statutory requirements of a "prescription." A "prescription" includes any order for drugs or medicinal supplies written *or transmitted by any means of communication* by a duly licensed practitioner authorized by the laws of Florida to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist.[13] The term includes an orally transmitted order by the lawfully designated agent of such practitioner.

"Prescription" also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than Florida, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness.[14] Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data system, if the order can be produced in printed form upon lawful request. A pharmacist who dispenses a legend drug without a valid prescription is liable for disciplinary action.[15]

A Florida-licensed pharmacist may fill or refill a valid prescription which is on file in a pharmacy located in Florida or in another state and that has been transferred from one pharmacy to another by any means, including *electronic means*, under specified conditions. The Florida Pharmacy Act specifies requirements for the dispensing of medicinal drugs pursuant to a facsimile of a prescription.[16]

Requirements Relating to Confidentiality of Pharmacy Records

Section 465.017, F.S., provides that, except upon written authorization of the patient, a pharmacist is authorized to release patient prescription records only to the patient, the patient's legal representative, the patient's spouse if the patient is incapacitated, to the Department of Health, or upon the issuance of a subpoena. This section also recognizes certain other exceptions for the release of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of prescription drugs. Pharmacists are subject to discipline for using or releasing a patient's records, except as authorized by ch. 465, F.S., and ch. 456, F.S.

Section 456.057(5)(a), F.S., provides that, *except upon a patient's written authorization*, and a few exceptions listed by statute, both medical records and the medical condition of a patient may not be discussed with any person other than the patient, the patient's legal representative or other health care practitioners and providers involved in the care or treatment of the patient. Section 456.057, F.S., expressly excludes

[12] See 21 CFR 1306.05, 21 CFR 1306.11, and 21 CFR 1306.21.
[13] See s. 465.003(14), F.S.
[14] Id.
[15] See s. 465.016(1)(i), F.S.
[16] See s. 465.035, F.S.

pharmacists and pharmacies from the definition of "health care practitioner" for purposes of the section. Section 456.057, F.S., provides that pharmacists and pharmacies are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of that section to maintain those documents required by the part or chapter under which they are licensed or regulated.

Requirements of HIPAA[17] do not preempt the confidentiality requirements of s. 465.017, F.S., or s. 456.057, F.S., because both state laws are more stringent than HIPAA.[18] Section 456.057(5)(a), F.S., provides a broad and express privilege of confidentiality to medical records and the medical condition of a patient by providing that such records may not be furnished to, and the medical condition discussed with, any person other than the patient or the patient's legal representative or other health care practitioners and providers involved in the care or treatment of the patient, *except upon written authorization of the patient.*

Neither s. 456.057(5)(a), F.S., nor s. 465.017(2), F.S., is contrary to the Privacy Rule and a covered entity would not find it impossible to comply with both the state and federal requirements.[19] Sections 456.057(5)(a) and 465.017(2), F.S., do not stand as an obstacle to the accomplishment and execution of the full purposes and objectives of HIPAA.[20]

Requirements Relating to Written Prescriptions

Section 456.42, F.S., requires a written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug to be *legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription.* The prescription must also contain the name of the prescribing practitioner, the name and strength of the drug prescribed the quantity in both textual and numerical formats, and directions for use. The prescription must be dated with the month written out in textual letters and signed by the prescribing practitioner on the day when issued.

METHODOLOGY

Staff reviewed state and federal laws and regulations that establish requirements for the prescribing of medications. Staff reviewed the effectiveness and implementation of the current law and applicable industry standards for the authentication and validation of electronic prescriptions. Staff sought input from the Department of Health, professional regulatory boards, other relevant state and federal agencies, associations representing health care providers, and other interested stakeholders to determine if the current law should be revised.

FINDINGS

After reviewing state and federal laws relating to electronic prescribing and examining the evolving use of electronic prescribing and electronic health records, staff identified issues in the following areas:

- Validation and authentication of a prescription,
- Generic drug substitution,
- Requirements for written prescriptions, and
- Confidentiality of pharmacy records.

Each of these areas is discussed below.

Validation and Authentication of a Prescription

Pharmacists have the ultimate responsibility to assess the validity of a prescription. An order for legend drugs or controlled substances must identify certain elements in order to be considered valid by a pharmacist. In practice, the elements of an order for a legend drug should identify the patient, drug to be dispensed, quantity of the drug, directions for use of the drug, prescriber, and date of the order.

Pharmacists assess the validity of a prescription through various means. Pharmacists may rely upon their personal knowledge of the prescriber and the

[17] HIPAA also has security standards, which would be applicable to electronic prescription systems.

[18] See 45 C.F.R. 160.202. State laws that are contrary to the Privacy Rule and Security Rule are preempted by the federal requirements, unless a specific exception applies (see 45 CFR Part 160, Subpart B).

[19] See U.S. HHS website HIPAA Questions and Answers "Does the HIPAA Privacy Rule override State laws that require consent to use or disclose health information? No. The Privacy Rule does not prohibit a covered entity from obtaining an individual's consent to use or disclose his or her health information and, therefore, presents no barrier to the entity's ability to comply with State law requirements." at <http://healthprivacy.answers.hhs.gov/cgi-bin/hipaa.cfg/php/enduser/std_adp.php?p_faqid=360>.

[20] For a full discussion of HIPAA and state preemption, see Senate Interim Project 2005-142, "Review of Statutes Regulating Access to Patient Medical Records."

patient and may be aware of unique prescription format and prescribing patterns. The sheer volume of dispensed prescriptions and changes in prescribing patterns, as a part of changes in clinical practice, have made it almost impossible for pharmacists to have close relationships with prescribers and patients. Pharmacists must rely upon other methods to validate the authenticity and integrity of a prescription.

When a pharmacist is authenticating the validity of a prescription, some unique distinctions exist in practice between a written prescription, an oral prescription, and an electronic prescription. With a written prescription, a pharmacist authenticates a prescription by verifying the practitioner's unique signature and identity.[21] The authentication of an oral prescription is very labor intensive and requires the pharmacist to recognize the practitioner's or practitioner's agent's voice or to use caller identification.[22] With an electronic prescription, the prescribing practitioner may have a unique identification and password, which is transmitted via an electronic connection to the pharmacist.

Under an electronic prescribing network, the pharmacist may rely on technical support, such as prescribing software that does not involve direct contact between the prescribing practitioner and the dispensing pharmacist or physical signature of the prescribing practitioner.[23] The pharmacist must rely on the integrity and security of the system to authenticate the prescription. Many electronic prescribing systems have security measures that additionally allow the pharmacist to review the patient's medication claims history and return receipt processes that enhance the pharmacist's ability to validate the authenticity of prescriptions.[24] It appears that electronic prescribing systems have the capability to enable a pharmacist to authenticate a prescription.

Generic Drug Substitution

Florida law requires a less expensive generically equivalent drug to be substituted for a brand name drug unless the patient or the prescribing practitioner affirmatively prohibits the substitution by writing on the prescription that the brand name drug is medically necessary.[25] A "generically equivalent drug product" is defined to mean a drug product with the same active ingredient, finished dosage form, and strength. The generic substitution law only applies to drugs that are prescribed by brand name. If the prescription is written for a drug identified by its generic name, the pharmacist may use her or his professional judgment to select any drug product with the same active ingredients, including a brand-name drug product. The pharmacist must maintain a record of any drug substitution. Florida law governing the Medicaid program also authorizes generic substitution of brand-name drug products.[26]

The law governing generic substitution does not provide an explicit procedure for a prescriber to use to prevent generic substitution for a brand name drug when the prescription is transmitted electronically. Without a procedure outlined in the law for the prescriber to prevent generic substitution of the brand name drug product, if unclear, the dispensing pharmacist must contact the prescriber to determine whether generic substitution is allowed. Some of the proponents of electronic prescribing have indicated that this additional step is burdensome and negates the time and labor saving benefits of electronic prescribing.

Written Prescriptions for Medicinal Drugs

It is unclear under s. 456.42, F.S., whether the requirement for a prescription to be signed on the day when it is issued would preclude the use of an "electronic signature" via an electronic prescribing network. Under the Uniform Electronic Transaction Act, ch. 668, F.S., an "electronic signature" is defined

[21] Response from the Florida Board of Pharmacy to a staff questionnaire.
[22] Id.
[23] Electronic Prescribing Systems, Making It Safer to Take Your Medicine? Research Highlights available from the Rand Corporation at <http://www.rand.org/publications/RB/RB9052/RAND_RB9052.pdf>.
[24] March 4, 2005 Letter to U.S. HHS Secretary Leavitt from National Committee on Vital and Health Statistics (NCVHS) regarding recommendations on electronic prescribing.
[25] See s. 465.025, F.S.
[26] See s. 409.908(14), F.S., which requires Medicaid providers to dispense generic drugs if available at a lower cost and the Agency for Health Care Administration has not determined that the branded product is more cost-effective, unless the prescriber has requested and received approval to require the branded product. See also 42 CFR 447.331(c) relating to the Medicaid program, which provides that certain payment limitations do not apply if "a physician certifies in *his or her own handwriting* that a specific brand is medically necessary for a particular patient."

to mean an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign a record.[27]

Proponents of electronic prescribing have indicated that s. 456.42, F.S., appears to apply to conventional prescriptions, which are handwritten and generated by paper and ink, rather than those generated under a secure electronic prescribing system. Section 456.42, F.S., requires the date of the prescription to be written with the month in textual letters and for the prescriber to sign the prescription on the day issued. Such requirements, proponents of electronic prescribing systems suggest, may inhibit the future development of electronic prescribing systems. Many electronic prescribing systems are being designed to reduce the type of medication errors that s. 456.42, F.S., addresses within the context of handwritten prescriptions. A potential solution is to limit the applicability of s. 456.42, F.S., to handwritten prescriptions.

Confidentiality of Pharmacy Records

HIPAA provides exceptions to its requirements for the use and disclosure of protected health information. There is an exception to HIPAA's use and disclosure requirements for "treatment, payment, and health care operations" of a covered entity.[28] Scholars have argued that electronic prescribing systems that are used in direct clinical care are within HIPAA's exception for "treatment, payment, and health care operations."[29] Such electronic prescribing systems may involve the use of computers to facilitate prescription data entry, storage of prescription information, and the transmission of related data among prescribers and dispensing pharmacists.

If HIPAA does not preempt ss. 456.057(5)(a) and 465.017(2), F.S., HIPAA's exceptions do not apply.[30] The use and disclosure of protected health information for electronic prescribing activities must comply with applicable Florida law. Florida law does not expressly provide an exception to a third party custodian who simply holds protected health information and is not actually delivering health care to a patient, such as a clerical worker hired to transcribe a physician's medical records or an entity providing technical support to prescribing practitioners and dispensing pharmacists engaged in a bilateral communication as part of an electronic prescribing system.

Under HIPAA, the use and disclosure of health information would be governed by the exception for "treatment, payment, and health care operations" and would not require individual patients to provide written authorization for the release of protected health information. Unlike HIPAA, Florida law would expressly require the patient's written authorization to disclose the protected patient information. Florida law allows parties who are *not licensed health care providers* to acquire or hold patient records without imposing a duty on such records custodians to maintain the confidentiality of the records.[31] This potential glitch in Florida law applies to all such custodians of patient records, including those engaged in the technical support of electronic prescribing. Pharmacists and pharmacies are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of s. 456.057, F.S., to maintain those documents required by the part or chapter under which they are licensed or regulated. Pharmacists and pharmacies relying on technical support when engaged in electronic prescribing may need a written authorization from patients to allow persons maintaining those systems to have access to the patient information.

[27] See s. 668.50, F.S. Section 668.50(8)(b), F.S., provides that if a provision of law other than s. 668.50, F.S., requires a record to be posted or displayed in a certain manner; to be sent, communicated, or transmitted by a specified method; or contain information that is formatted in a certain manner, then the record must be posted or displayed in the manner specified in the other provision of law. Also see the Electronic Signatures in Global and National Commerce Act of 2000. Neither the federal nor the state law mandate the use or acceptance of electronic records or signatures.

[28] A covered entity may use or disclose protected health information for *treatment, payment, or health care operations* as permitted by and in compliance with 45 C.F.R. § 164.506. See also 45 CFR 164.501.

[29] See Michael D. Greenberg, M. Susan Ridgely, and Douglas S. Bell, "Electronic Prescribing and HIPAA Privacy Regulation" *Inquiry:* Vol. 41, No. 4, pp. 461–468.as reprinted by the Rand Corporation at <http://www.rand.org/pubs/reprints/2005/RAND_RP1175.pdf>.

[30] Under HIPAA, the Privacy Rule sets standards for who may have access to protected health information while the Security Rule (45 CFR Part 160) sets standards for ensuring that covered entities only allow those who should have access to *electronic* protected health information will actually have access.

[31] See s. 456.057, F.S.

In contrast to "paper and pen" prescribing activities that do not involve electronic systems, there is a greater chance for the protected information in electronic media to be inappropriately disclosed because of the ease and portability of the prescription data. Florida law may need to be revised to recognize a third party custodian of patient records and to impose the same statutory confidentiality and disclosure requirements that are currently imposed on licensed or regulated health care providers.

RECOMMENDATIONS

Consistent with the findings of this report, staff recommends that:

- The statutes governing generic drug substitution should be amended to provide a mechanism for prescribers using electronic prescribing to prevent the generic substitution of a prescribed brand name drug product when it is deemed medically necessary;
- The law governing written prescriptions for medicinal drugs in s. 456.42, F.S., should be amended to limit its application to handwritten prescriptions; and
- The provisions in ss. 456.057 and 465.017, F.S., relating to the confidentiality of patient records should be amended to recognize a third party custodian of medical and pharmaceutical records and to require the custodian to be subject to the same statutory confidentiality and disclosure requirements for the records as are imposed on the licensed or regulated health care practitioner who created the records.