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MEMORANDUM

TO: Commissioner Christine C. Ferguson and Members of the Public Health Council

THROUGH: Nancy Ridley, Assistant Commissioner
Bureau of Health Quality Management

FROM: Grant M. Carrow, Director
Drug Control Program

DATE: October 28, 2003

RE: Informational Memorandum Regarding Amendments to 105 CMR 721.000:
Standards for Prescription Format and Security in Massachusetts

Purpose

The regulations proposed here would facilitate authentication and validation of electronic prescriptions in the Commonwealth by establishing standards for secure electronic transmission of signed, written prescriptions for Schedule VI controlled substances (legend pharmaceuticals). The proposed regulations would also codify current state and federal standards for authentication and validation of unsecured, electronic transmission of prescriptions for controlled substances in Schedules III through V (narcotics and stimulants) and Schedule VI.

A brief overview of the proposed regulations is provided here. An in depth technical review of current statutory and regulatory requirements for prescriptions as well as our proposed regulatory strategy for authorizing secure electronic prescriptions is provided in Attachment A. The proposed regulation is shown in Attachment B.

Public Health Opportunity and Challenges

The electronic transmission of written prescriptions has the potential to improve patient care and reduce medication errors and prescription fraud. However, as is the case with any prescriptions, unsecured electronic prescriptions could have negative consequences, such as prescription forgery and other fraud, introduction of content errors and loss of confidentiality. Because certain errors, fraud and privacy breaches can be more difficult to detect in electronic

prescriptions than they are with original, signed, paper-based prescriptions, it is critical that electronic prescriptions be at least as secure as their paper-based counterparts.

Statutory Authority

The Department has the authority to set the standards for content, format, security, modes of transmission, validation and recordkeeping of prescriptions for all pharmaceuticals. However, Massachusetts is required to conform to U.S. Drug Enforcement Administration (DEA) requirements for prescriptions for federally controlled substances, that is, pharmaceuticals in Schedules II through V. Currently, the DEA permits only limited use of electronic prescriptions for these pharmaceuticals and imposes special validation requirements.

Regulatory Strategy

The regulations proposed here set forth standards for content, format and security for electronic prescriptions that are the electronic equivalent of those that apply to paper-based, signed, written prescriptions. The proposed regulations are technology neutral, that is, they avoid specifying a particular technology, in order to allow application of emerging and future technologies. The regulations are designed to enable this new technology while upholding, if not improving upon, existing protections for patient health and individual safety.

Enforcement Strategy

Under the proposed regulations, current enforcement mechanisms, including requirements for controlled substances registrations, pharmacy licensing and inspections, recordkeeping and complaint investigations, would apply to electronic prescriptions as they do to all other prescriptions today. In addition, the regulations would leverage professional and public interest in safe, reliable and verifiable transmission of prescriptions to help assure use of the safest and most efficient technologies. Because use of electronic prescriptions will be voluntary on the part of prescribers, pharmacists and patients, we expect that market forces will compel industry to adopt measures to earn and maintain the trust and confidence of the public. We plan to work closely with the health care and electronic transactions industries to make secure electronic prescriptions a reality in Massachusetts.

Expected Outcome

With the regulatory standards proposed here in place, we would expect existing technologies to enable a secure electronic prescription for a legend pharmaceutical to be generated and digitally signed in confidence by the prescriber, transmitted in a secure manner over a network and received only by the pharmacy of the patient's choosing in a format that can be read, validated and stored in a retrievable and readable form only by the pharmacy. For the subset of electronic prescriptions for which the prescriber requires override of mandatory generic interchange, we would expect that, for each separate prescription, the prescriber would make the required handwritten indication of "no substitution" by writing contemporaneously on an image digitizing device that attaches the writing to an electronic prescription.

Other prescriptions, including paper-based written prescriptions, oral prescriptions, unsecured electronic prescriptions (e.g., faxes) and prescriptions for federally controlled substances in Schedules II through V would continue to be handled as they are today. Recordkeeping requirements that apply to prescriptions today would apply to secure electronic prescriptions, except that records for secure electronic prescriptions could be stored

electronically rather than on paper. The proposed regulation would automatically adopt expected DEA standards for secure Schedule II through V electronic prescriptions once those are promulgated.

Public Hearing

This is to notify the Public Health Council that the Drug Control Program plans to hold a public hearing on these proposed changes to 105 CMR 721.000 by early December.

Enabling Electronic Prescriptions in Massachusetts

Technical Background and Regulatory Strategy

Purpose

The Department of Public Health (DPH) is proposing amendments to regulations at 105 CMR 721.000 that would facilitate authentication and validation of electronic prescriptions in Massachusetts by establishing standards for secure electronic transmission of signed, written prescriptions¹ for Schedule VI controlled substances (legend drugs). The proposed regulations would also codify current regulatory interpretations that establish standards for validation of unsecured, electronic transmission of prescriptions² for controlled substances in Schedules III through VI. The proposed regulations would have the potential to improve patient care as well as reduce medication errors and prescription fraud.

This document presents the current statutory and regulatory requirements for prescriptions in the Commonwealth, the strategy the Department is proposing for future regulation of electronic prescriptions and the Department's intent and expectations for implementation of the proposed regulations by government and the health care and electronic transactions industries.

Current Statutory and Regulatory Requirements

Schedules of Controlled Substances

Pharmaceuticals are scheduled in accordance with their potential for abuse. In Massachusetts, all prescription pharmaceuticals are controlled substances designated as Schedules II through VI (Schedule I consists of illegal drugs, such as heroin and marijuana, that are not available by prescription). Those controlled substances in Schedules II through V (e.g., narcotics and stimulants) are also federally controlled. All other controlled substances, that is those not in the federal Schedules, are designated Schedule VI (e.g. antibiotics, vaccines, anticoagulants, lithium). Pharmaceuticals in Schedule VI are those prescription drugs with the lowest potential for abuse.

Current Status of Electronic Prescriptions in Massachusetts

Currently in Massachusetts, in accordance with regulatory interpretations of the Department and the U.S. Drug Enforcement Administration (DEA), prescriptions for controlled substances in Schedules III – VI that may be transmitted orally (verbally) may also be transmitted electronically.^{3,4} Except in limited circumstances, state and federal law does not

¹ Massachusetts statute authorizes two formats of prescriptions: written and oral (verbal). "Electronic transmission of a signed, written prescription", herein referred to as a "secure e-prescription", is not a contradiction in terms. The terms "signature" and "signed" are technology neutral and encompass electronic signatures. "The term "written" denotes printed, typewritten or any other intentional reduction to tangible form. Courts have held that telexes, mailgrams, tape recordings, faxes and magnetic recordings on computer disks are "writings".

² Examples of unsecured, electronically transmitted prescriptions include those transmitted via facsimile, e-mail, e-mail attachments and the Internet.

³ Letter from Grant Carrow, Massachusetts Department of Public Health, Drug Control Program to Clifford Berman, Allscripts Healthcare Solutions, Mar. 2002.

permit oral or electronic transmission of Schedule II prescriptions. Because of legal requirements for prescription security and in the absence of specific regulatory authority or standards for secure electronic transmission of prescriptions, such prescriptions must currently be treated as oral, and not as written, prescriptions for the purposes of authentication and validation. That is, pharmacists are required to validate and authenticate both oral and electronic prescriptions without the benefit of an original written prescription signed by the prescriber.

Prerequisites for Electronic Transmission of Written Prescriptions

In order to enable electronic transmission of signed, written prescriptions in the Commonwealth while ensuring patient health and individual safety, existing security standards will need to be preserved and translated to the new technology. Because Massachusetts must conform to federal requirements with regard to prescriptions for Schedule II through V drugs, the Commonwealth will need to meet or exceed the federal standards for secure e-prescriptions for such pharmaceuticals. The DEA is currently developing regulations, under an initiative begun in 1999, to establish security requirements for electronic transmission of written prescriptions for federally controlled substances.⁵ Nevertheless, because the Department has the sole authority to set standards for prescriptions for controlled substances in Schedule VI, secure e-prescriptions for such legend drugs can be enabled regardless of the status of federal standards.

While there would be no prohibition against applying the security requirements proposed here to electronically transmitted prescriptions for federally controlled substances in Schedules III through V – and that would be a significant improvement over unsecured transmission – such prescriptions would still need to be validated as oral prescriptions until DEA regulations are promulgated and the requirements therein are met. Conversely, once DEA regulations are promulgated, the standards for electronic transmission of written prescriptions for federally controlled substances, which are expected to exceed those proposed here for secure Schedule VI e-prescriptions, could be used for such e-prescriptions as well.

Statutory Authority

In Massachusetts, several agencies have jurisdiction over various aspects of prescriptions and prescribing. The Department regulates prescriptions and prescribing pursuant to the Controlled Substances Act, M.G.L. c. 94C; a number of professional practice acts, M.G.L. c. 112; and the generic drug interchange law, M.G.L. c. 112, §12D. Within DPH, the Drug Control Program regulates the content, format, security and mode of transmission of prescriptions as well as recordkeeping requirements for practitioners and health care facilities. The Board of Registration in Pharmacy in DPH establishes the requirements for validation of prescriptions at the receiving pharmacy and any special corresponding responsibility requirements for pharmacists (dispensers) as well as recordkeeping requirements for community pharmacies. Certain Boards of Registration in DPH, the Board of Registration in Medicine and certain Boards of Registration in the Office of Consumer Affairs, Division of Professional Licensure establish the professional practice standards for clinical aspects of

⁴ Letter from Patricia Good, U.S. Drug Enforcement Administration, Office of Diversion Control to Cliff Berman, Allscripts, Inc., Dec. 2000.

⁵ U.S. Drug Enforcement Administration, *Electronic Prescriptions for Controlled Substances*, www.deadiversion.usdoj.gov

prescribing pursuant to the practice acts (M.G.L. c. 112).⁶ Federally, the DEA regulates the transmission and handling of prescriptions for controlled substances in Schedules II-V pursuant to the federal Controlled Substances Act of 1970 (21 U.S.C. 801 et. seq.). M.G.L. c. 94C, §43 requires conformity with federal controlled substances laws.

The Controlled Substances Act (M.G.L. c. 94C) sets forth technology neutral requirements for security and validation of prescriptions. Section 23 of the Act, as amended by Chapter 104 of the Acts of 1998, authorizes the electronic transmission of signed, written prescriptions.

Drug interchange law (M.G.L. c. 112, § 12D) specifies format requirements for prescriptions. While the law is technology neutral with respect to signature requirements it is currently not technology neutral with respect to the specific handwriting requirements for prescriptions for which the prescriber requires override of mandatory interchange. In Massachusetts, it is mandatory for a pharmacist to dispense a less expensive, interchangeable drug product when available. For those prescriptions for which the practitioner requires that a brand name drug product be dispensed, the practitioner must write "no substitution" in the practitioner's own handwriting. The law further states that "No other form or procedure, including initialing, checking or initialing a box, or pre-printing or stamping a prescription form shall be deemed by the pharmacist to be the equivalent of the practitioner's hand written statement "no substitution"."

Regulatory Strategy

Challenges

Medication errors and prescription fraud are issues that persistently challenge DPH and other regulatory and law enforcement agencies. The prospect of expanding the scope of prescription errors and fraud into the realm of e-prescriptions presents additional challenges. Cybersecurity is an issue that is not restricted to e-prescriptions but applies to other health care records as well as business transactions.⁷ The vulnerability of electronic systems to data errors and corruption as well as cybercrime (e.g., virus attacks, identity theft) is well known. Moreover, because certain errors, fraud and privacy breaches can be more difficult to detect in electronic prescriptions than they are in original, signed, paper-based prescriptions, it is critical that electronic prescriptions be at least as secure as their paper-based counterparts. The challenge for DPH is to design regulations that minimize opportunities for error and fraud and maximize opportunities to improve health status.

Overview

The regulatory approach proposed here is to translate the current level of regulatory oversight that is exercised over paper-based, signed, written prescriptions to the realm of electronically transmitted, signed, written prescriptions. That is, the prescribers, pharmacists and patients who participate in the communication of prescription information should have the same legal rights and obligations with regard to electronic prescriptions in the future that they

⁶ Health care providers authorized to prescribe in Massachusetts include: DPH: dentists, physician assistants and advanced practice nurses; BORIM: physicians; and DPL: veterinarians, podiatrists and optometrists.

⁷ Smedinghoff, Thomas J., *The Legal Requirements for Creating Secure and Enforceable Electronic Transactions*, Baker & McKenzie, www.bakerinfo.com/ecommerce, Sept. 2002.

have today with signed, paper-based prescriptions. In practical terms, this means that electronically transmitted written prescriptions must be at least as secure as paper-based written prescriptions. Ultimately, authentication and validation of e-prescriptions should be automatic and transparent to the pharmacist. Applied appropriately, the proposed regulations would achieve this goal and have the potential to increase prescription safety and decrease prescription fraud.

Scope

The standards proposed here are intended to ensure secure electronic transmission of written prescriptions for Schedule VI controlled substances to DPH-licensed pharmacies (i.e., community and outpatient pharmacies) transmitted over unsecured, public networks such as the Internet.⁸ Computerized provider order entry (CPOE) systems used on secure private networks in DPH-licensed hospitals (i.e., inpatient pharmacies) are outside the scope of the proposed regulations. Such CPOE systems should be able to achieve comparable security for medication orders by utilizing procedures that are not available on public networks and are, in general, already subject to similar security and privacy standards pursuant to HIPAA⁹ regulations. It should also be noted that hospitals are exempt from the requirements of the drug interchange laws.

Standards

The proposed regulations would establish standards for the content, format and security of e-prescriptions consonant with those attributes of paper-based, signed, written prescriptions. Content requirements for e-prescriptions would be the same as for any other written or oral prescriptions.

Format requirements for e-prescriptions would ensure that pharmacies could receive, read, store and retrieve such prescriptions. Further, the requirements would specify the format for electronic transmission of the prescriber's handwritten indication of "no substitution" for the subset of prescriptions that require such an indication. The Department proposes that prescribers would be able to handwrite "no substitution" onto an e-prescription by using a digitizing pen, tablet, PDA (personal digital assistant) or similar device.

Security requirements would include all elements essential to enabling pharmacists to authenticate prescribers and validate e-prescriptions as they are required to do for all prescriptions today. Security elements inherent in original, signed, written prescriptions, namely, a verifiable signature, prescriber and dispenser authentication, content integrity, non-repudiation and confidentiality,¹⁰ would be required for secure e-prescriptions. However, as is the case with paper-based written prescriptions, we do not propose to dictate the specific techniques or technologies with which such security should be achieved.

⁸ The issues of the legitimacy of prescribing and dispensing over the Internet are largely professional practice issues and are outside the scope of this regulation. Rather, the issue concerning the Internet that is addressed by the proposed regulation is that of its use solely as an unsecured network that may support the electronic transmission of a legitimate e-prescription from an authorized prescriber to an authorized pharmacy.

⁹ The federal Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191)

¹⁰ **Signature verification** means ascertaining that an identified signer intended to endorse a writing; **authentication** means establishing who is sending and receiving data; **non-repudiation** means that parties to an activity cannot reasonably deny having participated in the activity; **content integrity** means that the data has not been altered in transmission; and **confidentiality** means that only authorized persons have access to the data.

The electronic signature for an e-prescription must be the legal equivalent of a “wet”, handwritten signature on a paper-based, written prescription. This means that the electronic signature must be unique to and under the sole control of an identified signer, inextricably linked to the prescription and capable of verification. Most methods employed to “sign” an electronic record, such as entering digital images of handwritten signatures, personal identifiers, passwords or computer commands or clicking check boxes, are not generally recognized as meeting this standard. An example of a current technology that should be able to meet this standard is a secure, encrypted digital signature that is invalidated if the prescription data or the signature itself changes. This technology is the electronic signature standard established by the National Institute of Standards and Technology (NIST) in the U.S. Department of Commerce for all federal documents that require the electronic equivalent of a handwritten signature.

Technology Neutrality

The proposed standards are technology neutral in order to introduce flexibility and adaptability to emerging and future technologies. Given the rapid pace of change in technology and health care, it is important to promote innovation that might lead to more secure and safer health care technologies. Industry would need to determine which specific security procedures¹¹ would need to be built into the electronic systems for generating, signing, transmitting, receiving, verifying and storing electronic prescription records. A similar technology neutral approach and set of security standards are incorporated in HIPAA regulations that govern the security and privacy of protected health information.

Enforcement Strategy

Overview

Under the proposed regulations, current enforcement mechanisms, including requirements for controlled substances registrations, pharmacy licensing and inspections, recordkeeping requirements and complaint investigations, would apply to e-prescriptions as they do to all other prescriptions today. In addition, we feel that professional and public interest as well as market forces would combine to bolster the safety and reliability of the technology and government regulation of e-prescriptions.

Role of Industry

Since use and acceptance of e-prescriptions would be voluntary, the trust and confidence of prescribers, pharmacists and patients would ultimately determine the adoption rate of the technology. For an e-prescription transmission system to be trustworthy, the parties must be confident that the communication of prescription information will not be intercepted or modified; the parties are who they say they are; and transmission procedures are available, legal and sufficiently secure and reliable to obviate the need for separate verification. The adoption rate will also be dependent upon availability of technology solutions, their interoperability and cost. Therefore, we would expect that market forces would compel industry to adopt measures to ensure such trust, confidence and interoperability, including, but not limited to, accepted practice standards for secure transmissions, quality assurance and control procedures, recordkeeping, enforcement mechanisms and complaint resolution systems.

¹¹ Security procedures for electronic transmissions include, but are not limited to, algorithms, codes, digital signatures, cryptography and encryption.

An apropos example of a system of industry standards acting in concert with state regulation is the Verified Internet Pharmacy Practice Sites (VIPPS) program administered by the National Association of Boards of Pharmacy (NABP), which is a professional association. The VIPPS program and its accompanying VIPPS seal of approval identifies to the public those online pharmacy practice sites that are appropriately licensed, are legitimately operating via the Internet and have successfully completed a rigorous criteria review and inspection by NABP. VIPPS compliance criteria include having systems to ensure patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy and provision of meaningful consultation between patients and pharmacists.

DEA Approach

In contrast to the regulatory approach proposed here, the DEA and some states are taking technology specific and/or direct oversight approaches to regulating technologies and industry that would be involved in transmission of e-prescriptions. DEA is reviewing and pilot testing the applicability of public key infrastructure (PKI) technology to e-prescriptions for federally controlled substances.¹² PKI, which is the current “gold standard” for secure electronic transactions over unsecured public networks such as the Internet, is a dual key encryption system built around institution of a registration authority to establish user identity and a certificate authority to create encryption keys that can be utilized for authenticating and accessing encrypted data. DEA plans to serve as the registration authority and to have an approval process for certificate authorities. DEA is also planning to require adherence to NIST standards for cryptographic-based security and digital signatures. NIST, in turn, is considering PKI as the standard for all sensitive electronic communications in the federal government.

Such technology specific approaches, however, require additional government bureaucracy to evaluate and license technologies and industry vendors and can have unintended negative effects by erecting barriers to innovation, imposing additional costs and operational constraints and unfairly driving adoption of a particular technology. In addition, regulation of specific e-prescription technologies and the electronic transactions industry is a federal, and not a state, issue since the technologies and industry are national and global in scope. Moreover, such a level of oversight of prescription transmission does not exist now for paper-based prescriptions, which are transmitted by trusted third parties, that is, patients and their family members.

While such a level of regulatory bureaucracy and oversight might be necessary for prescriptions for federally controlled substances, we feel that it is unnecessary for Schedule VI prescriptions. Rather, we feel we can achieve similar ends¹³ by establishing technology neutral standards and enforcing them using a combination of current regulatory authority and industry cooperation. The potential benefits to enhancing consumer protections that could be facilitated by secure e-prescriptions should outweigh possible concerns with the proposed regulatory approach and DPH would retain the option to promulgate more stringent regulations should that become necessary.

¹² U.S. Drug Enforcement Administration, *Anticipated Standard for DEA Electronic Transmission of Prescriptions for Controlled Substances System*, www.dea diversion.usdoj.gov.

¹³ We believe that PKI is likely the only technology available today that could be employed to meet the standards for security of e-prescriptions set forth in the proposed regulations. We further believe that private vendors, such as those that provide PKI systems for authenticating credit card transactions over the Internet, already have most of the necessary infrastructure in place to support PKI-secured e-prescriptions.

Authentication and Validation

All parties to the prescription communication would need to agree to the electronic transmission of a written prescription. As with paper-based prescriptions, the patient would retain the right to a copy of their e-prescription information from the prescriber and use of the pharmacy of their choice. Ultimately, the pharmacist makes the final decision with regard to the authenticity and validity of a prescription, whether paper, oral or electronic. While use of e-prescriptions would be optional, once that option were exercised there would be no party autonomy¹⁴ and the parties would be required to adhere to the standards that would be established by the proposed regulation.

Unsecured Electronic and Other Prescriptions

As an alternative to operating under the proposed requirements for electronic transmission of written prescriptions for Schedule VI pharmaceuticals, if parties were unable to meet the standards, any unsecured, electronic prescription transmission would need to continue to be treated by the pharmacist as an oral prescription for the purposes of authentication and validation (as is the case currently for Schedule III through VI e-prescriptions and would continue to be the only way, for at least the immediate future, for the pharmacist to validate Schedule III through V e-prescriptions).

Expected Outcome

With the regulatory standards proposed here in place, we would expect that currently available technologies would be utilized to enable secure digital signing and transmission of e-prescriptions over unsecured public networks such as the Internet. We would further expect that each e-prescription would be directed to the pharmacy of the patient's choosing in a format that can be read, validated and stored in a retrievable and readable form only by the pharmacy.

For the subset of e-prescriptions for which the prescriber requires override of mandatory generic interchange, we would expect that, for each separate prescription, the prescriber would make the required handwritten indication of "no substitution" by writing contemporaneously on an image digitizing device that attaches the writing to the e-prescription.¹⁵

Other prescriptions, including paper-based written prescriptions, oral prescriptions, unsecured electronic prescriptions and prescriptions for federally controlled substances would continue to be handled as they are today. Recordkeeping requirements that apply to prescriptions today would apply to secure e-prescriptions, except that records for secure e-prescriptions could be stored electronically rather than on paper. The proposed regulation would automatically adopt the DEA standards for secure Schedule II through V e-prescriptions once those are promulgated.

With the appropriate application of the security standards proposed here, we would further expect that pharmacists would develop sufficient trust and confidence in secure

¹⁴ **Party autonomy**, such as that set forth in some electronic commerce statutes, means that the parties to a transaction may, by mutual agreement, vary statutory requirements for such a transaction.

¹⁵ While the digitized image of a handwritten indication of "no substitution" would satisfy the format requirements of the drug interchange law, a digitized image of a signature would not satisfy the security requirements of the Controlled Substances Act. We believe that only a secure, digitized signature, such as that required by NIST's Digital Signature Standard, would meet said signature security requirements.

electronic transmission systems to be able to accept automatic authentication of prescribers and validation of secure e-prescriptions without taking any additional validation steps, such as those necessary for unsecured e-prescriptions. The role of industry in this regard would be paramount since it is likely that development of safe and reliable technology and end user education would be key prerequisites to achieving the goal of meeting or exceeding the security of paper-based, signed, written prescriptions.

It should be noted that end user education would also be key to ensuring safe e-prescribing by prescribers. In this regard, the Institute for Safe Medical Practices has called for standards for safe electronic communication of prescriptions and medication orders.¹⁶

Ultimately, we would anticipate that the regulations would lead to significant reductions in medication errors and prescription fraud and thereby improve public health and safety.

¹⁶ Institute for Safe Medical Practices, *It's time for standards to improve safety with electronic communication of medication orders*, ISMP Medication Safety Alert, Feb. 2003.

ATTACHMENT B

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 721.000: STANDARDS FOR PRESCRIPTION FORMAT AND SECURITY IN MASSACHUSETTS

Section

- 721.001: Purpose
- 721.002: Authority
- 721.003: Citation
- 721.004: Scope and Application
- 721.010: Definitions
- 721.020: Prescription Formats
- 721.030: Security Standards for Prescriptions
- 721.040: Invalid Prescriptions
- 721.050: Prescribing More than One Product

721.001: Purpose

The purpose of 105 CMR 721.000 is to specify the requirements for prescription format and security in Massachusetts.

721.002: Authority

105 CMR 721.000 is adopted pursuant to M.G.L. c. 30A, § 2; c. 94C, § 6; c. 111, § 3; and c. 112, § 12D.

721.003: Citation

105 CMR 721.000 shall be known as 105 CMR 721.000: *Standards for Prescription Format and Security in Massachusetts*.

721.004: Scope and Application

105 CMR 721.000 establishes the standards for format and security in the Commonwealth that all prescriptions issued by practitioners or reduced to writing by pharmacists must meet in order to comply with M.G.L. c. 112, § 12D and M.G.L. c. 94C.

721.010: Definitions

The terms used herein shall have the meanings set forth below. Terms defined in M.G.L. c. 112, § 12D and c. 94C, § 1 and not defined herein shall have the meanings set forth therein when used in 105 CMR 721.000, unless the context clearly requires a different interpretation.

Authentication means that the identities of the parties sending and receiving electronic prescription data are duly verified.

Confidentiality means that only authorized persons have access to prescription data.

Content integrity means that the electronic prescription data have not been altered or compromised in transmission.

Drug product means the final dosage form of a drug that is marketed under a brand or generic name.

Electronic prescription means a prescription the data for which is transmitted electronically.

Electronic signature means an electronic sound, symbol or process attached to or logically associated with a prescription record and executed or adopted by a practitioner with the intent to sign said prescription record.

Non-repudiation means that parties to the generation, transmission, receipt or storage of an electronic prescription cannot reasonably deny having participated in said activities.

721.020: Prescription Formats

- (A) Every prescription written in the Commonwealth must be in a prescription format that conforms to the following requirements:
- (1) if the prescription is paper-based, including a prescription that is transmitted via facsimile or similar technology, the prescription must be on a form that contains a signature line for the practitioner's signature on the lower portion of the form. Hospital and clinic prescription forms shall contain a line directly below the signature line for the practitioner to print or type his/her name. Below the signature line, or in the case of hospital and clinic prescription forms, below the line provided for the practitioner to print or type his/her name, there shall be a space of at least 1/2 inch and no more than one inch in which the practitioner may write in his/her own handwriting the words "no substitution". Below this space shall be printed the words "Interchange is mandated unless the practitioner writes the words 'no substitution' in this space". No other form or procedure, including initialing, checking, initialing a box, pre-printing or stamping a prescription form shall be deemed by the pharmacist to be the equivalent of the practitioner's handwritten statement "no substitution";
 - (2) if the prescription is an electronic prescription, the practitioner shall utilize a system for generating and transmitting the prescription that:
 - (a) transmits the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form; and
 - (b) permits the practitioner to instruct the pharmacist to dispense a brand name drug product by indicating "no substitution". Said system shall ensure that:
 - (1) the indication of "no substitution" is not the default indication;
 - (2) the prescription indicates that "Interchange is mandated unless the practitioner writes the words 'no substitution' in this space";
 - (3) an indication of "no substitution" is handwritten and created contemporaneously with the writing of the prescription;
 - (4) a handwritten indication of "no substitution" is electronically attached to or logically associated with the prescription; and
 - (5) there is no mechanism or action, such as checking or initialing a checkbox or utilizing a computer command, that would cause a previously stored sample of the handwritten indication to be applied or attached to the prescription;

- (3) the name and address of the practitioner shall be clearly indicated on the prescription. A hospital or clinic prescription shall have the name and address of the hospital or clinic clearly indicated on the prescription;
- (4) the prescription shall contain the following information:
 - (a) the registration number of the practitioner;
 - (b) date of issuance of the prescription;
 - (c) name, dosage, and strength per dosage unit of the controlled substance prescribed, and the quantity of dosage units;
 - (d) name and address of the patient, except in a veterinary prescription;
 - (e) directions for use, including any cautionary statements required; and
 - (f) a statement indicating the number of times to be refilled.
- (B) Prescriptions for certified nurse midwives, nurse practitioners, psychiatric nurses and physician assistants shall also contain the name of the supervising physician.

721.030: Security Standards for Prescriptions

- (A) A prescription may be transmitted electronically provided that:
 - (1) if said prescription is for a controlled substance in Schedules II through V, it is validated and authenticated in accordance with M.G.L. c. 94C and applicable Department regulations, if any, and 21 CFR 1306 or other applicable federal regulations;
 - (2) if said prescription is for a controlled substance in Schedule VI it:
 - (a) is validated and authenticated in accordance with requirements in M.G.L. c.94C and applicable Department regulations for oral prescriptions; or
 - (b) meets accepted industry standards for security including, but not limited to, standards that provide for:
 - (1) practitioner and dispenser authentication;
 - (2) non-repudiation by practitioner and dispenser;
 - (3) content integrity;
 - (4) confidentiality; and
 - (5) an electronic signature that is:
 - (a) unique to an identified practitioner;
 - (b) under the sole control of such practitioner;
 - (c) capable of verification; and
 - (d) invalidated if either said electronic signature or the prescription record to which it is linked is altered or compromised;
 - (3) said prescription meets any applicable requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) and related regulations.
- (B) An electronic signature that meets the requirements of 105 CMR 721.031 shall have the full force and effect of a handwritten signature on a paper-based written prescription.
- (C) A paper-based written prescription must be written and signed by the practitioner in accordance with M.G.L. c. 94C, §23 and 105 CMR 721.000.

721.040: Invalid Prescriptions

- (A) A prescription in a format that does not conform to 105 CMR 721.000 is invalid and shall not be filled.
- (B) A prescription that does not meet the security requirements of 105 CMR 721.000 is invalid and shall not be filled.

721.050: Prescribing More Than One Drug Product

Practitioners who wish to prescribe more than one drug product, with the same or different dispensing instructions, shall place each prescription on a separate prescription form or entry. More than one drug product may be prescribed in the hospital setting on a single form or entry provided, however, that the prescription provides clear directions for use and interchange of each drug product.