

(S. B. 350)

**(No. 138)**

(Approved November 16, 2009)

## **AN ACT**

To amend subsection (ww) of Section 1.03 and Subsection (c) of Section 5.02 of Act No. 247 of September 3, 2004, known as the “Pharmacy Act,” to include within the term “prescription” any medical order generated and transmitted electronically; to eliminate present subsection (ccc), and add a new subsection (ccc) and a subsection (ddd) to Section 1.03 of the above mentioned Act, establishing the definition of the term “electronically generated and transmitted prescription” and “electronic signature”; amend subsections (e), (f), and (g) of Section 5.02 of said Act to modify the prescription drug dispensing process; amend subsection (j) of Section 5.02 and subsection (b) of Section 5.03 of said Act, to provide for the authentication of the identity of the pharmacist in cases of electronically generated and transmitted prescriptions, and amend subsection (m) of Section 5.02 of said Act to provide on the maintenance of electronic prescriptions; and for other purposes.

### **STATEMENT OF MOTIVES**

Presently, the communication and transmittal of information through electronic means are employed in all fields. Today, the advantages of the use of this type of technologies are unquestionable. Puerto Rico has a clear public policy in favor of the adoption of new information technologies and the development of electronic transactions. Thus, the Electronic Government Act was approved in 2004 with the purpose of incorporating such technology to Government programs and services. That same year, the Electronic Signature Act was approved to establish the infrastructure and regulations for the use of this authentication method. Likewise, the Electronic Transactions Act was approved in 2006,

to facilitate the use of electronic commerce and benefit therefrom. Although the risks inherent to the transmittal of information through electronic means are acknowledged, such risks have been greatly reduced in the last years and mostly overcome due to the advantages of this kind of transmissions in both public and private endeavors.

In the medicine field, the use of electronic means has been developing in the processing and transmittal of information for prescribing and dispensing medications. Commonly known as “e-prescribing,” this method allows for the creation and transmittal of a prescription through electronic means. Once the prescription is electronically generated and transmitted, it constitutes the original medical order; therefore, the order written by the physician is not required.

Due to the great number of prescriptions issued by physicians (over 4 billion prescriptions are generated in the United States every year) there is a significant margin of error related to the issue of prescriptions. On occasion, prescriptions written by the physicians may lead to errors when dispensing the prescribed medications, what may have serious consequences, including thousands of deaths each year. It is estimated that in the United States approximately 8.8 million adverse incidents related to prescribed medication occur annually. Furthermore, this kind of prescription causes that almost 30% of prescriptions require pharmacy callbacks to the prescribing physician for clarifications as to the content thereof. According to the Medicare and Medicaid Service Centers, this fact generates an annual average of 800 million prescription related calls, which entails high costs for all components of the medication prescription and dispensing process.

The use of the electronic prescription method has shown a 70% reduction in medical errors related to prescription medicines compared to the use of handwritten prescriptions, which are sometimes difficult to read. E-prescribing also improves patient safety through the use of computerized physician order entry, which in addition to electronically generating the prescription, allows the physician to verify the patient's electronic medical record for potential drug interactions or allergies that may be caused by the prescribed medication. The noted improvement as to the patient's safety attributable to the use of this kind of prescription led the Institute for Safe Medication Practices, a nonprofit organization devoted to medication error prevention, to encourage the universal adoption of e-prescribing as the main mechanism for the generation and transmittal of prescriptions. The fifty states of the United States have approved legislation that allows for the use of electronic prescriptions.

The efficiency and accuracy of the electronic prescription method also reduces costs and the time it takes a patient to receive a prescribed medication from the time the prescription is issued to the time the medication is finally dispensed by the pharmacy. The communication between the parties involved in the processing of prescriptions through this method also helps in the verification of coverage for medication under the health insurance of a certain patient. This would benefit not only the patient, but also health insurers and pharmacy benefit managers. Furthermore, the legibility of the electronically generated prescriptions reduces the number of callbacks to physicians by the pharmacies for clarifications of discrepancies.

As pertains to physicians, they also significantly benefit from this system, insofar as they need not to invest time and resources of their offices in callbacks to clarify the content of prescriptions. Moreover, the use of e-prescribing may entail economic benefits, since medical malpractice insurance companies are offering premium discounts to physicians who use the e-prescribing system. It is worth mentioning that, recently, a bill to establish incentives for physicians who issue electronic prescriptions for medications covered under Medicare Part D was introduced in the US Congress.

In addition to the many advantages listed above, the adoption of e-prescribing in Puerto Rico is necessary to comply with the electronic prescription program of the Medicare Prescription Drug, Improvement and Modernization Act. Said statute requires that Medicare Part D providers and insurers adopt and comply with final e-prescribing standards, once such standards are finally promulgated, although it does not compel the use of the e-prescribing system. As part of the development and drafting of such standards, pilot projects were conducted for the purpose of working with electronic prescriptions, thus observing improvements in the quality of the services rendered, and reductions in the dispensing time.

For all of the above, it is hereby established as the public policy of the Commonwealth of Puerto Rico to promote the adoption of the e-prescribing method in this jurisdiction. To enforce this public policy, it is necessary to amend the Pharmacy Act in effect, in order to adjust the definition of the term “prescription,” as well as those provisions of the law where reference is made to the traditional concept of handwritten prescription. It is further necessary to add to the Act, the definition of the terms “electronic signature” and “electronically generated and transmitted prescription” applicable to the use established in this Act, and amend the provisions regarding the procedure to be followed during the dispensation of prescriptions.

***BE IT ENACTED BY THE LEGISLATURE OF PUERTO RICO:***

Section 1.- Subsection (ww) of Section 1.03 of Act No. 247 of 2004, is hereby amended, subsection (ccc) is hereby eliminated, and new subsections (ccc) and (ddd) are hereby added to said Section to read as follows:

“Section 1.03.—Definitions.—

For the purposes of this Act, the following terms and phrases shall have the meaning stated below:

(a) ...

(ww) “Prescription” – original written order issued and signed, or electronically generated and transmitted by the prescribing professional in the normal course and legal exercise of his/her profession in Puerto Rico, in order for certain drugs or devices to be dispensed in compliance with the provisions of this Act. It shall be the obligation of the physician issuing the same to comply with the professional responsibility of a true physician-patient relationship. Provided, that both prescriptions issued by physicians authorized to practice in Puerto Rico and prescriptions issued by physicians authorized to practice in any state of the United States of America, whose original has been dispensed in the state of origin in accordance with the provisions of Act No. 4 of June 23, 1971, as amended, known as the “Controlled Substances Act”, may be refilled in Puerto Rico with the previous authorization of the prescribing professional.

(xx) ...

(ccc) “Electronically Generated and Transmitted Prescription” – means any electronically generated and transmitted prescription issued by a prescribing professional to a pharmacy freely selected by the patient, through a device that authenticates the electronic signature of the prescribing

professional and guarantees the security of transmittal according to the applicable rules, laws, and regulations. For the purposes of this Act, the electronically generated and transmitted prescription shall also be known as electronic prescription and shall constitute an original order, thus an order with a handwritten signature shall not be required.

(ddd) “Electronic Signature” – group of data in electronic format contained in a message, document or transaction attached to or logically associated with such message, document or transaction that may be used to identify the signatory, and indicate that the signatory approves and recognizes the information contained in the message, document or transaction.

Section 2.- Subsections (c), (e), (f), (g), (j), and (m) of Section 5.02 of Act No. 247 of 2004, are hereby amended to read as follows:

“Section 5.02.—Dispensation of Prescription Medications.—

(a) ...

(c) The original prescription shall be the written order issued and signed by hand or electronically generated and transmitted by the prescribing professional and shall include the following information, in addition to any other information required under other provisions of this Act and other applicable laws and regulations:

1. date of issue;
2. full name and address of the patient;
3. patient’s age;
4. full name, address, telephone number, license number, and signature of the prescribing professional; provided, that the electronic signature of the prescribing professional shall be deemed to be authenticated when the prescription is electronically generated and transmitted, as provided in this Act.

5. name of the medication prescribed with its form, dosage, potency, and amount;

6. use indications for the patient.

The pharmacist may complete any information not appearing on the prescription by recording the same on the back of the prescription, in the case of an order signed by hand, or recording the same in the device that receives and stores electronically transmitted prescriptions when the prescription has been electronically generated and transmitted, after having verified the same with the prescribing professional or the patient, as the case may be. The electronic device that receives and stores prescriptions shall have capacity to keep, print, and, upon request, provide any information as provided in this Act.

(d) ...

(e) To expedite the prescription dispersing process, the contents thereof may be transmitted verbally, or by fax, electronic image or e-mail, by the patient him/herself or his/her representative or by the prescribing professional to the pharmacy freely selected by the patient or his/her representative, thus guaranteeing the patient's right to freely select his/her pharmaceutical services provider. The pharmacist shall transcribe the prescription transmitted orally upon receipt. Both the prescription transmitted verbally and the prescription transmitted by fax, electronic image or e-mail, shall include all the data required under subsection (c) of this Section, and a record of the date and time such transmission was made. In these cases, the patient or his/her representative shall hand over the original prescription to the pharmacist when receiving the prescribed medication. This shall not apply when the prescription has been electronically generated and transmitted pursuant to this Act.

(f) The pharmacist may refill a prescription upon previous authorization of the prescribing professional, recorded in the original or subsequently received prescription, whether verbally or by fax, electronic image or e-mail, if the same is accessible in its original form, whether issued and signed by hand or electronically generated and transmitted or in the patient's pharmacy record. The pharmacist shall record the refill on the back of the original prescription or in the patient's pharmacy record.

(g) When handling emergency cases, to be defined as provided by the Secretary by regulation, the contents of a prescription may be transmitted verbally or by fax, electronic image or e-mail directly by the prescribing professional to the pharmacy selected by the patient. The pharmacist shall transcribe the prescription transmitted verbally upon receipt. Both the prescription transmitted orally and the prescription transmitted by fax, electronic image or e-mail shall include the data required under subsection (c) of this Section. The pharmacist shall record the date and time the transmission was made and shall dispense a limited amount of the medication which shall not exceed the amount needed for a period of one hundred twenty (120) hours. The prescribing professional who transmitted the contents of the prescription verbally or by fax, electronic image or e-mail shall deliver the prescription to the pharmacy that filled the prescription not later than one hundred twenty (120) hours from the time the same was issued, except when the prescription has been electronically generated and transmitted pursuant to this Act. Provided, that in the case of prescriptions for controlled substances, the term provided for such cases under Act No. 4 of June 23, 1971, as amended, shall apply.”

(h) ...

(j) When filling a prescription or verifying the filling of a prescription when a pharmacy technician, a pharmacist intern or a pharmacy technician intern has intervened in the prescription process filling, the pharmacist must sign the prescription on the front at the bottom right. Provided, that in cases where the prescription has been electronically generated and transmitted, the device that receives and processes the same shall authenticate the identity of the pharmacist assuming responsibility for such dispensation.

(k) ...

(m) The prescription shall be filed in a secure place at the pharmacy counter for a minimum term of two (2) years from the dispensation date. The prescription and any notes made thereon as required by this Act or other applicable laws, as well as the patient's pharmacy record, may be kept on electronic files. In the case of controlled substance prescriptions, the provisions of Section 2101 *et seq.* of Title 24, known as the "Puerto Rico Controlled Substances Act," shall apply.

Section 3.- Subsection (b)(4) of Section 5.03 of Act No. 247 of 2004, is hereby amended to read as follows:

"Section 5.03.— Interchange of Bioequivalent Medications.—

(a) ...

(b) Pharmacist's Authority to Interchange Bioequivalent Medication

The pharmacist may interchange bioequivalent medications in the manner stated below:

1. When a medication is prescribed under a brand name or trademark, it shall be construed that any medication which is bioequivalent to the latter has been prescribed, unless the prescribing professional writes down in his/her own handwriting the phrase "Do Not Interchange" or indicates in the electronically generated

and transmitted prescription that he/she does not authorize such interchange. The pharmacist shall advise the patient or his/her authorized representative of the possibility of interchanging the prescribed medication; provided, that in all cases the patient or his/her representative must be over the age of eighteen (18). If the patient or his/her representative agrees to the interchange, the pharmacist shall choose that bioequivalent medication which meets each and every one of the following conditions:

(A) ...

(C) The patient or his/her representative has given his/her consent to interchanging. The patient's consent shall be documented with his/her signature on the back of the prescription, except in the case of an electronically generated and transmitted prescription, which shall be documented in the patient's pharmacy record.

2. ...

3. ...

4. When interchanging the medication, the pharmacist shall record in the patient's pharmacy record or on the back of the prescription the date on which the medication is interchanged and he/she shall sign the prescription. Provided, that in the event that the prescription is electronically generated and transmitted, the device that receives and processes the same shall authenticate the identity of the pharmacist assuming responsibility for such medication dispensation. Furthermore, the pharmacist shall also record on the back of the prescription or on the patient's pharmacy record, the brand name or trademark of the medication thus dispensed.

Should the medication have no brand name or trademark, he/she shall record the generic name and the name of the manufacturer or distributor that appears on the medication's label.

5. ...”

Section 4.- Subsection (f) of Section 5.10 of Act No. 247 of September 3, 2004, is hereby amended to read as follows:

“Section 5.10.—Pharmacy.—

(a) ...

(f) As of the date of effectiveness of this Act, no physician, medical group, whether under a professional corporation or partnership, pharmacy benefits administrator or health insurance company may refer or direct patients to specific pharmacies, thus guaranteeing the patient's right to free selection. Likewise, no pharmacy may establish a contractual relation or a negotiation which promotes or allows this practice.

Any patient or his/her designated person, whose right to free selection of pharmacy has been violated by the persons or entities abovementioned in this subsection, may file a complaint before the Secretary of Health against such entity or person who incur such violation, subject to the jurisdiction of the Department and the application of the adjudicative regulations of the agency.”

Section 5.—Rulemaking Authority.—

The Secretary of Health shall amend the Pharmacy Regulations to temper the same to the provisions of this Act not later than sixty (60) days after the approval thereof. Any party adversely affected by noncompliance with such term may resort to the Court of First Instance by means of a writ of Mandamus.

Section 6.—Effectiveness.—

This Act shall take effect immediately after its approval, subject to the terms provided for regulations and transition in Section 5.

## CERTIFICATION

I hereby certify to the Secretary of State that the following **Act No. 138 (S. B. 350)** of the **2<sup>nd</sup> Session of the 16<sup>th</sup> Legislature** of Puerto Rico:

**AN ACT** to amend subsection (ww) of Section 1.03 and Subsection (c) of Section 5.02 of Act No. 247 of September 3, 2004, known as the "Pharmacy Act," to include within the term "prescription" any medical order generated and transmitted electronically; to eliminate present subsection (ccc), and add a new subsection (ccc) and a subsection (ddd) to Section 1.03 of the above mentioned Act, etc.

has been translated from Spanish to English and that the English version is correct.

In San Juan, Puerto Rico, on the 18<sup>th</sup> day of November, 2010.

Solange I. De Lahongrais, Esq.  
Director