AN ACT

To amend Section 2.030 and Section 2.040 of Chapter 2, and Section 4.070 of Chapter 4 of Act No. 194-2011, as amended, known as the “Puerto Rico Health Insurance Code”; and amend Section 5.02 of Act No. 247-2004, as amended, known as the “Puerto Rico Pharmacy Act,” in order to prohibit insurers from overriding clinical judgments, require insurers to immediately dispense patients a temporary supply of their prescription drugs until their claims are resolved, require that upon receiving a notice of denial of prescription drug coverage patients and enrollees be provided with a full explanation therefor; and for other related purposes.

STATEMENT OF MOTIVES

The Government of Puerto Rico has the responsibility to ensure that the People have a robust health system that addresses their needs efficiently and expeditiously. Our commitment is to safeguard patients’ welfare and rights by improving and facilitating access to healthcare services. Moreover, it is the public policy of this Administration to retain our health professionals to provide our People with the best services, and in turn, implement social justice policies for the more disadvantaged.

Act No. 194-2011, as amended, known as the “Puerto Rico Health Insurance Code,” covers a number of highly relevant areas to the health insurance industry, to wit: the regulation of group and individual health plans, health service organizations, service rendering systems, unfair practice prohibition, health insurance organization or issuer’s grievance procedures, network provider adequacy, and health plans for uninsurable individuals, among many others. This
Act specifically regulates prescription drug management by health insurance organizations or issuers, and establishes the rules to be followed to address patient claims and complaints upon denial of prescription drug coverage. Said Act interacts with Act No. 247-2004, as amended, known as the “Puerto Rico Pharmacy Act,” as to the process to dispense drugs by pharmacies.

In order to fulfill the current needs of patients or beneficiaries who are denied prescription drug coverage, as well as health professionals who issue the prescriptions and provide other professionally recognized health services in light of the modern communication and teaching mediums, it is necessary to amend the aforementioned legislation. At present, insurers do not provide prescription drug coverage until the patient meets the requirements of the approval process for medical exception requests. As a result, the patient does not receive neither the drug nor a full explanation or the appropriate information regarding the grounds for denial of prescription drug coverage, when the drug requires a medical exception approval. This situation delays patient treatment, which, in many cases, leads to the worsening of the disease or condition to the extent of requiring a visit to the emergency room or a hospitalization.

Furthermore, Act No. 194-2011, supra, establishes some clinical review criteria for the review process required to determine the medical necessity and appropriateness of the services provided by the health professionals, including prescription drugs. In most cases, insurers use as a subterfuge whether healthcare professionals meet the standards for diagnosis and treatment to delay payments for already rendered services. To such effect, this legislation clarifies that the use of clinical review criteria by a health insurance organization or insurer shall under no circumstances override the physician’s exercise of his clinical judgment to prescribe a drug or provide a health service recognized under the generally accepted standards of the medical practice.
We promulgate this Act to avoid causing harm to patients for not receiving the prescription drugs from the pharmacy due to hurdles in the claim process established by the insurer, and to strengthen the flow of income of health professionals. In doing so, we not only ensure patients’ timely access to healthcare services, but also benefit health professionals and stop the brain drain.

**BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF PUERTO RICO:**

Section 1.- Section 2.030 of Chapter 2 of Act No. 194-2011, as amended, known as the “Puerto Rico Health Insurance Code,” is hereby amended to read as follows:

“Section 2.030.- Definitions.

... 
A. ... 
E. “Clinical Review Criteria”: means the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by a health insurance organization or insurer to determine medical necessity and appropriateness of healthcare services. These practice guidelines are not obligatory for the health Professional in the performance of his functions when providing a healthcare service in accordance with the appropriate state and federal laws and regulations; provided, that the service rendered is recognized under the generally accepted standards of the medical practice and the generally accepted health standards, in light of the modern communication and teaching mediums. Hence, the guiding and exclusive principle to determine a patient’s treatment shall be the professional diagnosis. Therefore, clinical judgment shall not be overridden by the insurer. The foregoing notwithstanding, the provisions of this subsection shall be consistent with the federal laws and regulations on this topic. 
F. ...”
Section 2.- Section 2.040 of Chapter 2 of Act No. 194-2011, as amended, known as the “Puerto Rico Health Insurance Code,” is hereby amended to read as follows:

“The provisions of the Insurance Code of Puerto Rico shall apply to health insurance plans and entities regulated by this Code inasmuch as they are not inconsistent with the provisions thereof.

None of the provisions of this Code shall be construed to amend or repeal the laws, regulations, or procedures administered by the Patients’ Advocate Office and the Puerto Rico Health Insurance Administration (ASES) in accordance with their enabling acts.

Any insurer contracting with ASES to offer, advertise, or administer the Healthcare Plan of the Government (PSG, Spanish acronym) shall meet the requirements and comply with the provisions of this Code as well as meet the requirements and comply with the legal, regulatory, and contractual provisions established by ASES, except for matters related to the authorization or license required to engage in the insurance business in Puerto Rico, compliance with and oversight under this Code, and financial solvency to which the Puerto Rico Insurance Code and this Code shall apply.”

Section 3.- Section 4.070 of Chapter 4 of Act No. 194-2011, as amended, known as the “Puerto Rico Health Insurance Code,” is hereby amended to read as follows:

“Section 4.070.- Medical Exceptions Approval Process Requirements and Procedures.

A. ...

B. The health insurance organization or insurer that provides prescription drug benefits, the PBM, or any other entity to which the pharmacy benefit management has been delegated shall be required to offer immediate coverage by
providing a one-time fill while his medical exception request is being evaluated and until written notice of final determination is given, when the physician or health professional who issued the prescription states in writing that the drug prescribed is medically necessary for treating the disease or condition of the covered person or enrollee; even if the prescription drug is not in the drug formulary of the health insurance plan of the covered person or enrollee, or is subject to a prescription drug management process established in this Section. The health insurance organization or insurer that provides prescription drug benefits, the PBM, or any other entity to which the pharmacy benefit management has been delegated shall pay to the pharmacy the one-time fill of the prescription while the insurer adjudicates coverage for the prescribed drug. The pharmacy may submit an electronic bill to the insurer for the payment of the one-time fill of the prescription, and the insurer shall have the obligation to accept the electronic bill and shall not require a physical or printed bill as a condition for payment. Hence, the covered person or enrollee, under no circumstances, shall be left without his prescription drug while his medical exception request is being evaluated as provided in this Section or a grievance is being processed in accordance with the Chapter on Health Insurance Organizations or Issuers Grievance Procedure of this Code. This temporary supply rule shall not affect the existing regulations on drug transition. The foregoing notwithstanding, the provisions of this subsection shall be consistent with the federal laws and regulations on this topic.

Every health insurance organization or insurer that provides prescription drug benefits, pharmacy benefit manager or administrator, or any other entity to which the pharmacy benefit management or administration has been delegated shall include in the calculation or in the cost-sharing or out-of-pocket maximum requirement any payment, discount, or item that is part of a cost-sharing assistance program, a discount or a coupon plan, or any other contribution offered to the
enrollee by the manufacturer. These items shall be deemed to be for the exclusive benefit of the patient in the calculation of his contribution, out-of-pocket expenses, copayments, coinsurance, deductible, or his fulfillment of the cost-sharing requirement. These contributions, discounts, and manufacturer’s coupons shall be available and may be used in every healthcare provider, pursuant to the requirements of the program, regardless of the place where such discount or coupon was obtained. The use of accumulators or maximizers or any other similar program intended to implement restrictions on the liability established in this subsection is hereby prohibited.

C.

(1) A covered person...

D.

(1) Upon receipt...

E.

(1) The medical exceptions request process provided under this Section shall require the health insurance organization or issuer that provides prescription drug benefits, the PBM or any other entity to which the pharmacy benefit management has been delegated, to make a coverage determination on an exception request and notify the covered person or enrollee, or his authorized representative, as promptly as the covered person or enrollee’s particular medical condition requires, which shall never exceed forty-eight (48) hours from the date of receipt of the request, or the date of receipt of the certification, if required by the health insurance organization or issuer pursuant to subsection (B)(2), whichever is later. In the case of controlled drugs, such timeframe shall not exceed twenty-four (24) hours.

(2) ...

F.
(1) Whenever...

G.

(1) Any...

H. No...

I. No...

J. No....”

Section 4.- Section 5.02 of Act No. 274-2004, as amended, known as the “Puerto Rico Pharmacy Act,” is hereby amended to read as follows:

“Section 5.02.- Dispensation of Prescription Medications.

(a) ...

(o) Pharmacies shall be required to provide patients with the full and accurate information regarding the grounds for denying the dispensation of any prescription drug or medication.

(p) The Secretary shall prescribe by regulations any rules, requirements, and procedures as are necessary to implement the provisions of this Section within sixty days after the approval of this Act.”

Section 5.- The Health Insurance Services Administration (ASES) is hereby directed to adopt the amendments contained in this Act by regulations, in order apply them equally to the Healthcare Plan Government of Puerto Rico. Compliance with this Act shall be subject to the same penalties provided for noncompliance with the rules established in the Puerto Rico Health Insurance Code.

Section 6.- Severability.

If any clause, paragraph, subparagraph, sentence, word, letter, article, provision, section, subsection, title, chapter, subchapter, heading, or part of this Act were held to be null or unconstitutional, the ruling, holding, or judgment to such effect shall not affect, impair, or invalidate the remainder of this Act. The
effect of said holding shall be limited to the clause, paragraph, subparagraph, sentence, word, letter, article, provision, section, subsection, title, chapter, subchapter, heading, or part of this Act thus held to be null or unconstitutional. If the application to a person or a circumstance of any clause, paragraph, subparagraph, sentence, word, letter, article, provision, section, subsection, title, chapter, subchapter, heading, or part of this Act were held to be null or unconstitutional, the ruling, holding, or judgment to such effect shall not affect or invalidate the application of the remainder of this Act to such persons or circumstances where it may be validly applied. It is the express and unequivocal will of this Legislative Assembly that the courts enforce the provisions and application of this Act, even if it renders ineffective, nullifies, invalidates, impairs, or holds to be unconstitutional any part thereof, or even if it renders ineffective, invalidates, or holds to be unconstitutional the application thereof to any person or circumstance.

Section 7.- Supremacy.

The provisions of this Act shall prevail over any other general or specific provision of a law or regulation of the Government of Puerto Rico that is inconsistent with this Act.

Section 8.- Prospective Application.

The provisions of this Act shall apply prospectively and shall no impair any contractual obligation assumed prior to this Act.

Section 9.- Effectiveness.

This Act shall take effect sixty (60) days after its approval.