

(S. B. 1856)
(Conference)

(No. 194-2011)

(Approved August 29, 2011)

AN ACT

To create the Puerto Rico Health Insurance Code; establish its general provisions and the manner in which this Code shall interact with the Insurance Code of Puerto Rico; regulate the management of prescription drugs by health insurance organizations or issuers, as defined; standardize the healthcare claims audit process in Puerto Rico; promote the availability of health plans to employers of small- and medium-sized businesses in Puerto Rico, regardless of the health conditions or claim experience of their employee group; prohibit the use of discretionary clauses in health plans and disability income protection coverage; provide rules to establish and maintain the procedures to be followed by health insurance organizations or issuers to ensure that the claims of covered persons or enrollees are resolved in a timely and adequate manner; establish uniform requirements for newborn and recently adopted children and children placed for adoption in both group and individual health plans; establish standards for long-term care insurance; and for other related purposes.

STATEMENT OF MOTIVES

Despite the countless amendments that have been made to the Insurance Code of Puerto Rico since its approval in 1957, health insurance has been left behind with regard to specific regulations, even though such sector has undergone drastic changes during the past years. This situation becomes more relevant given the changes introduced by the Federal Health Reform Act; that is, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, which will have a considerable effect on both our society and economy. Only a few chapters of the Insurance Code of Puerto Rico are dedicated to such an important area, to wit: Chapter 16, on Disability Insurance; Chapter 19,

on Health Services Organizations; Chapter 30, on Prompt Payment of Claims to Health Services Providers; and Chapter 31, on Collective Bargaining of Providers and Health Service Organizations. It is time to update the regulatory framework of an activity as important as the health of our People. In addition to adjusting the provisions of law in effect in Puerto Rico regarding health coverage to the latest Federal legislation approved, a new Health Insurance Code is hereby created to oversee this activity more effectively in the Island.

This Health Insurance Code covers many relevant areas of health insurance, such as consumer protection; the regulation of group and individual health plans; health service organizations; the availability and access to long-term care insurance; service systems; the prohibition of unfair practices; health service organization and issuer's grievance procedures; adequacy of network providers; health plans for uninsurable individuals; the regulation of third-party administrators; coverage for newborn and adopted children; among many others. All of the foregoing has been based on the model legislation developed by the National Association of Insurance Commissioners, (NAIC).

This regulatory initiative also addresses many areas in need, which have been identified through the years and with the experience obtained from managing different financing and medical service rendering models in Puerto Rico and the United States. Example of such areas in need include activities of vital importance for the effective regulation of this industry, such as prescription drug management benefits and restrictions; procedures for the examination and audit of claims; the availability of health plans for small- and medium-sized businesses and individual enrollees in Puerto Rico; the prohibition on unfair practices by health insurance organizations or issuers; the protection of medical information integrity and confidentiality; the issuer solvency protection and oversight; and protection guarantees for enrollees under managed care service systems.

Due to the complexity and importance of this issue, this Legislative Assembly of Puerto Rico deems it convenient to approve the new Puerto Rico Health Insurance Code in stages, so that the various chapters comprising it may be responsibly analyzed. This first stage includes the following chapters: General Provisions; Prescription Drug Management; Health Insurance Organization or Issuer Claim Audits; Availability of Health Insurance for Small- and Medium-sized Businesses (hereinafter PYMES, Spanish acronym); Prohibition on the Use of Discretionary Clauses; Health Insurance Organization or Issuer Grievance Procedures; Coverage for Newborn, Recently Adopted Children, and Children Placed for Adoption; and Long-term Care Insurance.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF PUERTO RICO:

Section 1.- A set of legal provisions is hereby adopted, which shall be known and may be cited as the “Puerto Rico Health Insurance Code,” which shall be complemented by the Insurance Code of Puerto Rico, Act No. 77 of June 19, 1957, as amended, in whatever the latter is not in conflict with the former. Nothing provided in the Insurance Code of Puerto Rico shall be deemed to be repealed, except as expressly provided in the Puerto Rico Health Insurance Code, or when the provisions of both codes are in conflict.

“Chapter 2. General Provisions

Section 2.010. -Title.-

This Act constitutes the Puerto Rico Health Insurance Code and may be cited as such.

Section 2.020. -Declaration of Public Policy.-

Guaranteeing the most effective regulation of the health insurance industry, including the regulation of those entities that offer group and individual health plans, is hereby adopted as public policy by the Government of Puerto Rico. As part of this public policy, it is vital to comply with the rules set forth under the

Federal Health Reform and implemented through the ‘Patient Protection and Affordable Care Act’ and the ‘Health Care and Education Reconciliation Act’. Likewise, in the Commonwealth, it is necessary to gather and standardize to the extent possible, all the legal norms that shall apply to such an important industry, which has experienced an unprecedented growth in the past years, into one new law to be known as the Puerto Rico Health Insurance Code.

The main purpose of the public policy herein adopted is to provide all Puerto Ricans with access to more and better healthcare services and to promote maximum growth and development in this industry.

Section 2.030. -Definitions.-

For purposes of this Code, except in those chapters in which a more specific definition is provided, the following terms shall have the meaning stated below:

A. ‘Covered Benefits’ or ‘Benefits’ means the healthcare services to which a covered person or enrollee is entitled under a health plan.

B. ‘Insurance Code of Puerto Rico’ refers to Act No. 77 of June 19, 1957, as amended.

C. ‘Commissioner’ means the Commissioner of Insurance of Puerto Rico.

D. ‘Emergency Medical Condition’ means a medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, that would lead a prudent layperson who possesses an average knowledge of health and medicine to reasonably expect that the absence of immediate medical attention could place an individual’s health in serious jeopardy; result in serious dysfunction of a bodily organ or part; or for a pregnant woman who is having contractions, the lack of sufficient time to transfer her to other facilities before delivery, or that her transfer would result in serious jeopardy to her health or the health of her unborn child.

E. 'Clinical Review Criteria' means the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by a health insurance organization or issuer to determine medical necessity and appropriateness of healthcare services.

F. 'Medical Care' means:

- (1) the diagnosis, mitigation, treatment, or prevention of disease;
- (2) transportation primarily for and essential to medical care referred to in subparagraph (1).

G. 'Dependent' means any person who is or may be eligible for a health plan due to his/her relationship with the subscriber and in accordance with the conditions set forth in the health plan. The following may be considered dependents of the subscriber:

- (1) The spouse;
- (2) a birth or adopted child or child placed for adoption under age twenty-six (26);
- (3) a birth or adopted child or child placed for adoption who, regardless of his/her age, is incapable of earning a living due to mental or physical disability existing before he/she has attained twenty-six (26) years of age, as provided in Public Law 111-148, known as the 'Patient Protection and Affordable Care Act,' Public Law 111-152, known as the 'Health Care and Education Reconciliation Act,' and the regulations thereunder;
Stepchildren;
- (4) Foster children who have lived since infancy under the same roof with the enrollee in a normal parent/child relationship and who are, and shall continue to be, totally dependent on the family of said enrollee to receive support, as provided in Section 16.330 of the Insurance Code of Puerto Rico;

(5) unemancipated minor whose custody has been awarded to the subscriber;

(6) a person of any age who has been declared incompetent by a court and whose custody has been awarded to the enrollee;

(7) a parent or parent-in-law of the main subscriber who permanently resides in the household of such main subscriber and is substantially dependent on him/her for support, and who may be classified in the optional or collateral dependents category, as such term is commonly accepted and defined in the health insurance market;

(8) a parent or parent-in-law of the main subscriber who does not reside in the household of such main subscriber, and who may be classified in the optional or collateral dependents category, as such term is commonly accepted and defined in the health insurance market.

H. 'Healthcare Facility' or 'Facility' means a licensed institution providing healthcare services or a healthcare setting, including hospitals and other inpatient centers; ambulatory surgical or treatment centers; skilled nursing centers; residential treatment centers; diagnostic, laboratory, radiology, and imaging centers; and rehabilitation and other therapeutic health settings.

I. 'NAIC' refers to the National Association of Insurance Commissioners.

J. 'Healthcare Service Organization' means any entity that contracts to provide or arrange for healthcare services to its subscribers, based on the prepayment thereof, except for the amount to be paid by the subscriber as copayment, coinsurance, or deductible, as provided in the Chapter on Healthcare Service Organizations of this Code.

K. 'Health Insurance Organization' or 'Issuer' means an entity, subject to the insurance laws and regulations of Puerto Rico or subject to the jurisdiction of the Commissioner, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse the costs of healthcare services, including any for-profit or nonprofit hospital and healthcare service corporation, healthcare service organization, or any other entity providing health benefit, service, or healthcare plans.

L. 'Covered Person' or 'Enrollee' means the holder of a policy or certificate, subscriber, or other individual participating in a health benefit plan.

M. 'Person' means any natural or juridical person, including corporations, partnerships, associations, joint association, limited partnership, trust, unincorporated organization, and similar entities or combination thereof.

N. 'Open-ended Plan' means a managed care plan that offers incentives, including economic incentives, for covered persons or enrollees to use participating providers under the terms of a health plan.

O. 'Closed Plan' means a managed care plan that requires covered persons or enrollees to use only participating providers under the terms of a health plan.

P. 'Managed Care Plan' means a health plan that provides economic or other kinds of incentives for covered persons or enrollees to use the participating providers of a healthcare service organization or issuer, or those that are administered, contracted, or employed by it.

Q. 'Indemnity Health Plan' means a health plan other than a managed care plan.

R. 'Health Plan' means a policy, contract, certificate, or agreement offered by a health insurance organization, healthcare service organization, or any other issuer provided in consideration of or in exchange for the payment of a

premium, or on a prepaid basis, through which a health insurance organization, healthcare service organization, or any other issuer commits to provide coverage or pay for the costs of specified healthcare, hospital, major medical, dental, mental health, or incidental services to the rendering thereof.

S. 'Healthcare Professional' means a physician or other healthcare practitioner, licensed, accredited, or certified by the appropriate entities, to perform specified healthcare services consistent with the corresponding laws or regulations of the Commonwealth.

T. 'Healthcare Provider' or 'Provider' means a healthcare professional or healthcare facility duly authorized to render or provide healthcare services.

U. 'Participating Provider' means a provider who, under a contract with a health insurance organization or issuer, or with its contractor or subcontractor, has agreed to provide healthcare services to covered persons or enrollees with an expectation of receiving payment, other than coinsurance, copayments, or deductibles, directly or indirectly from the health insurance organization or insurer.

V. 'Authorized Representative' means:

(1) a person to whom the covered person or enrollee has given express written consent to represent him/her for purposes of this Code;

(2) a person authorized by law to provide substituted consent for a covered person or enrollee;

(3) a family member of the covered person or enrollee or the healthcare professional who is treating such covered person or enrollee when he/she is unable to provide consent;

(4) a healthcare professional if the covered person or enrollee's health plan requires that a request for benefits be initiated by the healthcare professional.

(5) For any urgent care request, a healthcare professional with knowledge of the covered person or enrollee's medical condition.

W. 'Health Insurance Code Regulations' refer to the rules or regulations adopted by the Commissioner pursuant to any provision of this Code.

X. 'Healthcare Services' or 'medical services' mean services for the diagnosis, prevention, treatment, cure, or relief of a chronic health condition, illness, injury, or disease.

Y. 'Emergency Services' mean healthcare services furnished or required to treat an emergency medical condition.

Z. 'Subscriber' means an individual covered by a health plan issued by a healthcare service organization.

AA. 'Urgent Care' is a sudden illness that does not threaten the life or the integrity of a person, and may be treated in a physician's office or extended hours clinic, and not necessarily in an emergency room, but if it is not properly treated at the appropriate time, may become an emergency.

Section 2.040. -Insurance Code of Puerto Rico.-

The provisions of the Insurance Code of Puerto Rico shall apply to health plans and entities regulated under this Code, insofar as they are not inconsistent with the provisions of this Code.

Section 2.050. -Conformity to Federal Laws.-

Any provision of this Code that is in conflict with any Federal law or regulation applicable to Puerto Rico with regards to healthcare or health plans shall be deemed to be amended so as to conform to such Federal law or regulations. In addition:

A. No issuer or health insurance organization offering group or individual health plans shall establish:

(1) Lifetime limits on covered essential health benefits, in accordance with Public Law 111-148, known as the ‘Patient Protection and Affordable Care Act,’ Public Law 111-152, known as the ‘Health Care and Education Reconciliation Act,’ and the regulations adopted thereunder.

(2) Unreasonable annual limits on covered essential health benefits, pursuant to Public Law 111-148, known as the ‘Patient Protection and Affordable Care Act,’ Public Law 111-152, known as the ‘Health Care and Education Reconciliation Act,’ and the regulations adopted thereunder.

B. Subsection (A) shall not be construed to prevent an issuer or health insurance organization offering group or individual health plans that are not required to provide essential health benefits, as such term is defined in Federal and Commonwealth laws and regulations, from placing annual or lifetime limits on specific covered benefits to the extent that such limits are otherwise permitted under Federal or Commonwealth law.

C. An issuer or health insurance organization offering group or individual health plans shall at least provide coverage and shall not impose any cost-sharing requirements for:

(1) services included in the latest recommendations of the United States Preventive Services Task Force;

(2) immunizations that have a recommendation in effect from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and the Advisory Committee on Immunization Practices of the Department of Health of Puerto Rico;

(3) with respect to infants, children, and adolescents up to twenty-one (21) years of age, preventive care and screening services provided in the comprehensive guidelines supported by the Health Resources and Services Administration;

(4) with respect to women, preventive care and screening services as provided in the comprehensive guidelines supported by the Health Resources and Services Administration, including services related to breast cancer screening.

D. Every issuer or health insurance organization offering group or individual health plans shall at least have coverage available that includes the following services:

- (1) Ambulatory and medical surgical services
- (2) Emergency services
- (3) Hospitalization
- (4) Maternity and newborn care
- (5) Mental health and substance use disorder services
- (6) Laboratory, x-ray, and diagnostic testing services
- (7) Pediatric services, including the respiratory syncytial virus vaccine and the cervical cancer vaccine
- (8) Any other mandatory service or benefit required by Commonwealth or Federal laws or regulations

E. Nothing provided in this Section shall be construed to prohibit an issuer or health insurance organization from providing benefits in excess of those described herein.

F. No group or individual health plan that includes emergency service coverage shall require prior authorization for such services, whether the healthcare provider is a participating provider or not.

G. Every group or individual health plan that requires the designation of a primary care provider, when the enrollee is eighteen (18) years old or less, shall permit the designation of a physician who specializes in pediatrics as the child's primary care provider, provided that such provider participates in the network of participating providers of the health plan. 'Primary care provider' means the

participating provider designated by a health insurance organization or issuer to supervise, coordinate, or provide initial care or continuing care to the covered person or enrollee. In addition, the health insurance organization or issuer may require the primary care provider to initiate a referral for specialty care and maintain supervision of healthcare services rendered to the covered person or enrollee.

H. No individual or group health plan shall require prior authorization or referral to obtain obstetrical and gynecological care provided by participating providers.

I. No individual or group health plan shall not impose any preexisting condition exclusion in the case of persons under nineteen (19) years of age. After 2014, the right to nondiscrimination based on preexisting conditions shall apply to all persons regardless of their age.

J. The rights established in this Section shall have the scope and be governed by the requirements and procedures set forth in Public Law 111-148, known as the 'Patient Protection and Affordable Care Act,' Public Law 111-152, known as the 'Health Care and Education Reconciliation Act,' and the regulations adopted thereunder.

Section 2.060. -Powers and Duties of the Commissioner.-

According to this Code, the Commissioner shall have the powers, authorities, and duties vested in him/her by virtue thereof and, also, the powers, authorities, and duties established in the Insurance Code of Puerto Rico.

Section 2.070. -Severability.-

If any provision of this Code or the applicability thereof to any person or circumstance were held to be void or invalid by a court with jurisdiction and competence, such holding shall not affect the validity of all other provisions of the

Code or their applicability to persons or circumstances other than those that were held to be void or invalid.

Section 2.080. -Sanctions.-

Any violations of the provisions of this Code or the rules or regulations promulgated thereunder for which a sanction or penalty has not been expressly prescribed shall be subject to an administrative fine of not less than five hundred dollars (\$500) or more than ten thousand dollars (\$10,000) for each violation.

Chapter 4. Prescription Drug Management

Section 4.010. -Title.-

This Chapter shall be known and may be cited as the Chapter on Prescription Drug Management.

Section 4.020. -Purpose.-

The purpose of this Chapter is to provide standards for the development, maintenance, and management of prescription drug formularies and other procedures as part of the prescription drug benefits established by health insurance organizations or issuers that provide such services.

Section 4.030. -Definitions.-

For purposes of this Chapter:

A. ‘Prior Authorization’ means the process of obtaining prior approval from a health insurance organization or issuer, required under the terms of a health plan, for coverage of a prescription drug.

B. ‘Pharmacy and Therapeutics Committee’ means a committee or equivalent body that is comprised of individuals who are either employed by or under contract with the health insurance organization or issuer, which shall be composed of an odd number of members. The members of the Pharmacy and Therapeutics Committee shall be healthcare professionals, such as physicians and pharmacists, who have knowledge and expertise in:

(1) Clinically appropriate prescribing, dispensing, and monitoring of outpatient prescription drugs; and

(2) Drug use review, evaluation, and intervention.

If there were any representatives of the pharmacy benefits manager, the health insurance organization, or issuer among the members of the Pharmacy and Therapeutics Committee, the same shall only contribute with operations and logistic considerations, but shall not vote on issues related to adding or excluding prescription drugs from the formulary.

C. ‘Clinical Review Criteria’ mean the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by a healthcare organization or issuer to determine medical necessity and appropriateness of healthcare services.

D. ‘Medical or Scientific Evidence’ means evidence found in any of the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts;

(2) Peer-reviewed medical literature, including literature related to therapies reviewed and approved by a qualified institutional review board, biomedical compendia, and other medical literature that meets the criteria of the National Institutes of Health’s Library of Medicine for indexing in Index Medicus (Medline) and Elsevier Science Ltd. for indexing in Excerpta Medica (EMBASE);

(3) Medical journals recognized by the Secretary of Health and Human Services of the United States Government under the Federal Social Security Act;

- (4) The following standard reference compendia:
- (a) the American Hospital Formulary Service-Drug Information;
 - (b) Drug Facts and Comparisons;
 - (c) the American Dental Association Accepted Dental Therapeutics; and
 - (d) the United States Pharmacopeia-Drug Information;
- (5) Findings, studies, or research conducted by or under the auspices of Federal government agencies and Federal research institutes recognized in the United States of America, including:
- (a) the Agency for Healthcare Research and Quality;
 - (b) the National Institutes of Health;
 - (c) the National Cancer Institute;
 - (d) the National Academy of Sciences;
 - (e) the Centers for Medicare and Medicaid Services (CMS);
 - (f) the Food and Drug Administration (FDA); and
 - (g) any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of healthcare services; or
- (6) Any other medical or scientific evidence that is comparable to the sources listed in clauses (1) through (5) above.

E. ‘Categorical Exclusion’ means an express determination by a health plan not to provide coverage for a prescription drug, indentifying the same by its scientific or brand name.

F. ‘Formulary’ means a list of prescription drugs that has been developed by a health insurance organization or issuer or its designee, which is regularly evaluated to add or exclude prescription drugs, and which the health insurance

organization or issuer or its designee references in determining pharmacy coverage.

G. 'Prescription Drug' means a drug that has been approved or regulated and that the Food and Drug Administration (FDA) has allowed to be marketed, and which the laws of Puerto Rico and the United States requires to be dispensed only through a prescription order.

H. 'Prescription Drug Order' or 'Prescription' means an order from a licensed, certified or otherwise legally authorized prescriber to a pharmacist for a prescription drug to be dispensed.

I. 'Prescriber' means any healthcare professional legally authorized to issue prescription drug orders.

J. 'Pharmaceutical Benefit Management Procedure' or 'PBMP' includes any of the following:

- (1) A formulary;
- (2) Dose restrictions and quantity limits;
- (3) Prior authorization requirements; or
- (4) Step therapy requirements.

K. 'Grievance' means a written complaint requesting a remedy submitted by or on behalf of a covered person or enrollee, for the actions or determinations of a health insurance organization or issuer regarding:

(1) The availability, delivery, or quality of healthcare services, including a complaint regarding an adverse determination made pursuant to utilization review;

(2) Claims payment, handling, or reimbursement for healthcare services; or

(3) Matters pertaining to the contractual relationship between a covered person or enrollee and a health insurance organization or issuer.

L. 'Authorized Representative' means:

(1) a person to whom the covered person or enrollee has given express written consent to represent him/her in requesting a medical exception pursuant to this Chapter;

(2) a person authorized by law to provide substituted consent for a covered person or enrollee;

(3) a family member of the covered person or enrollee, or the healthcare professional who is treating such covered person or enrollee, when he/she is unable to provide consent;

(4) a healthcare professional who treats or dispenses prescription drugs to the covered person or enrollee, in order to request a medical exception on the latter's behalf, pursuant to the Chapter.

M. 'Dose Restriction' means imposing a restriction on the number of doses of a prescription drug that will be covered during a specific time period.

(1) 'Dose Restriction' does not include:

(a) A restriction set forth in the coverage that limits the number of doses of a prescription drug that will be covered during a specific time period; or

(b) a restriction on the number of doses of a prescription drug when it has been withdrawn from the market by the drug's manufacturer or it cannot be supplied.

N. 'Generic Substitution' means the substitution of a generic version of a brand name prescription drug that has the same active ingredients, strength, and intended use as the brand name prescription drug, whose therapeutic equivalence has been recognized by the Food and Drugs Administration (FDA), and is coded as such in the Approved Drug Products with Therapeutic Equivalence Evaluations, better known as the 'Orange Book.'

O. 'Step Therapy' means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition are to be prescribed.

Section 4.040. -Applicability and Scope.-

This Chapter shall apply to all health insurance organizations or issuers, or their designees, who provide or administer benefits for outpatient prescription drugs in accordance with the provisions of the health plan, through the use of a formulary or through the application of any other pharmaceutical benefit management procedure.

Nothing in this Chapter shall be construed to apply to prescription drugs that are categorically or contractually excluded from a covered person or enrollee's health plan. A provision in the benefit contract that purports to exclude all nonformulary prescription drugs shall not be considered a categorical exclusion for purposes of this Chapter.

Section 4.050. -Requirements for the Development, Maintenance, and Management of Prescription Drug Formularies and Other Pharmaceutical Benefit Management Procedures.-

A. Each health insurance organization or issuer that provides benefits for prescription drugs and manages such benefit through the use of a formulary or other procedure shall establish one or more Pharmacy and Therapeutics Committees, as considered appropriate by the health insurance organization or issuer, to develop, maintain, and manage such formulary and related procedures as provided in this Section. The Pharmacy and Therapeutics Committee shall not participate in the benefit determination process established by the health insurance organization or issuer for the dispensation of prescription drugs.

The health insurance organization or issuer shall ensure that any Pharmacy and Therapeutics Committee establishes policies and disclosure requirements that address potential conflict of interests that the members of the committees may have with developers or manufacturers of prescription drugs. No member of the Pharmacy and Therapeutics Committee may have any relationship or interest, financial or otherwise, with developers or manufacturers of prescription drugs.

B. The health insurance organization or issuer shall ensure that any Pharmacy and Therapeutics Committee establishes a process in writing to evaluate medical and scientific evidence concerning the safety and effectiveness of prescription drugs, including available comparative information on clinically similar prescription drugs, when deciding what prescription drugs to include on a formulary or bioequivalent and when developing other management processes. The health insurance organization or issuer shall also ensure that the Pharmacy and Therapeutics Committee uses a process for analysis and possible inclusion in the formulary of prescription drugs for off-label use, the effectiveness of which has been proven by medical and scientific evidence to treat other health conditions.

Every Pharmacy and Therapeutics Committee shall maintain documentation of the process required under this paragraph and make any records and documents related to the process available, upon request, to the health insurance organization or issuer.

C. The health insurance organization or issuer shall ensure that every Pharmacy and Therapeutics Committee adopts and follows a written process to enable it to consider the need for and implement appropriate updates and changes to the formulary in a timely manner based on:

(1) Newly available scientific and medical evidence or other information concerning prescription drugs currently listed on the formulary or subject to any other management process, and scientific and medical evidence on newly approved prescription drugs and other prescription drugs not currently listed on the formulary or subject to any other management process, to determine whether a change to the formulary or management process should be made;

(2) If applicable, information received from the health insurance organization or issuer with respect to medical exception requests to enable the Pharmacy and Therapeutics Committee to evaluate whether the prescription drugs currently listed on the formulary or subject to any other management process are meeting the healthcare service needs of covered persons or enrollees; and

(3) Information related to the safety and effectiveness of a prescription drug currently listed on the formulary or subject to any other management process, related to clinically similar or bioequivalent prescription drugs not currently listed on the formulary or subject to any other management process, information arising from the health insurance organization or issuer's quality assurance activities, or claims data that was received since the date of the Pharmacy and Therapeutics Committee's most recent review of the prescription drug.

(4) The health insurance organization or issuer shall require the Pharmacy and Therapeutics Committee to evaluate prescription drugs newly approved by the Food and Drug Administration (FDA) within a term that shall not exceed ninety (90) days counted as of the FDA's date of approval. Within a term that shall not exceed ninety (90) days, counted as of the release in the market of the new prescription drug, the Pharmacy and Therapeutics Committee shall issue its determination as to whether or not such prescription drug shall be listed in the formulary.

D. Subject to this Chapter, a health insurance organization or issuer may contract with another person to perform the functions of the Pharmacy and Therapeutic Committee as described in this Section. Such health insurance organization or issuer shall answer to the Commissioner for the Pharmacy and Therapeutics Committee's actions, noncompliance with, and violations of this Chapter.

Section 4.060. -Information to Prescribers, Pharmacies, Covered Persons or Enrollees, and Prospective Covered Persons or Enrollees.-

A. Health insurance organizations or issuers shall meet the following requirements:

(1) Every health insurance organization or issuer shall maintain and make available to covered persons or enrollees, prescribers, and pharmacies providing healthcare services to covered persons or enrollees, by electronic means or, upon the request of a covered person or enrollee or pharmacy, in writing, the following:

(a) Its formulary (list of prescription drugs) by therapeutic category;

(b) Information indicating which prescription drugs, if any, are subject to a management procedure that has been developed and maintained pursuant to this Chapter; and

(c) Information on how and what written documentation is required to be submitted in order for covered persons or enrollees, or their authorized representatives, to file a request under the health insurance organization or issuer's medical exceptions process established pursuant to Section 4.070 of this Chapter.

(2) A health insurance organization or issuer shall only make changes in the formulary or other prescription drug management process during the term of the policy, certificate, or contract if such change is being made for safety reasons, because the prescription drug cannot be supplied or has been withdrawn from the market by the drug's manufacturer, or if such change entails the inclusion of prescription drugs in the formulary. To such effects, the health insurance organization or issuer shall provide or entrust a third party to provide notice of that change to:

(a) All covered persons or enrollees and participating pharmacies not later than the effective date of the change.

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

A. If the health insurance organization or issuer that provides prescription drug benefits and manages this benefit through the use of a formulary or through the application of a dose restriction that causes a prescription for a particular drug not to be covered for the number of doses prescribed, or step therapy requirement that causes a particular drug not be covered until the requirements of that management process have been met, the health insurance organization or issuer shall establish and maintain a medical exceptions process that allows covered persons or enrollee, or their authorized representatives, to request approval for:

- (1) A prescription drug that is not covered based on the formulary;
- (2) Continued coverage of a particular prescription drug whose coverage the health insurance organization or issuer shall discontinue from the formulary for reasons other than safety or because the prescription drug cannot be supplied or has been withdrawn from the market by the drug's manufacturer; or

(3) An exception to a management process that causes a prescription drug to not be covered until the step therapy requirement is satisfied or not be covered at the prescribed number of doses.

B. (1) A covered person or enrollee, or his/her authorized representative, may only file a written request under this Section if the prescribing provider has determined that the requested prescription drug is medically necessary to treat the covered person or enrollee's disease or medical condition because:

(a) There is no prescription drug listed on the formulary that is a clinically acceptable alternative to treat the covered person or enrollee's disease or medical condition;

(b) The prescription drug alternative listed on the formulary or required in accordance with step therapy requirements:

(i) Has been ineffective in the treatment of the covered person or enrollee's disease or medical condition or, based on clinical, medical, and scientific evidence and the known relevant physical or mental characteristics of the covered person or enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(ii) Has caused or, based on clinical, medical, and scientific evidence, is likely to cause an adverse reaction or other harm to the covered person or enrollee; or

(iii) The covered person or enrollee was at the top level of a step therapy under another health plan, so that it would be unreasonable to start in a lower step therapy level.

(c) The doses available under a dose restriction for the prescription drug has been ineffective in the treatment of the covered person or enrollee's disease or medical condition or, based on clinical, medical, and

scientific evidence and the known relevant physical or mental characteristics of the covered person or enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(2) (a) The health insurance organization or issuer may require the covered person or enrollee, or his/her authorized representative, to provide a written certification from the prescribing provider of the determination made under paragraph (1).

(b) The health insurance organization or issuer may require the written certification to include only the following information:

(i) The name, group or contract number, subscriber number;

(ii) Patient history;

(iii) The primary diagnosis related to the requested prescription drug that is the subject of the medical exception request;

(iv) The reason:

(I) why the formulary drug is not acceptable for that particular patient;

(II) If the medical exception request involves a step therapy requirement, why the prescription drug required is not acceptable for that particular patient; or

(III) If the medical exception request involves a dose restriction, why the available number of doses for the prescription drug is not acceptable for that particular patient;

(v) The reason why the prescription drug that is the subject of the medical exception request is needed for the patient or, if the medical exception request involves a dose restriction, why an exception to the dose restriction is needed for that particular patient.

C. (1) Upon receipt of a medical exception request made pursuant to this Section, the health insurance organization or issuer shall ensure that the request is reviewed by appropriate healthcare professionals who, depending on the health condition for which the medical exception is requested, in reaching a decision on the request, shall take into account the specific facts and circumstances that apply to the covered person or enrollee for whom the request has been made using documented clinical review criteria that:

(a) Are based on solid clinical, medical, and scientific evidence; and

(b) If available, appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, practice guidelines developed by the health insurance organization or issuer's Pharmacy and Therapeutics Committee, or any other practice guidelines developed by the Federal government or by national or professional medical or pharmacist societies, boards, and associations.

(2) The healthcare professionals designated by the health insurance organization or issuer to review the medical exceptions request shall ensure that the decision reached on such request is consistent with the benefits and exclusions under the covered person or enrollee's health plan. The healthcare professionals designated to review medical exception requests shall have experience in the management of prescription drugs. Such determinations shall be duly stated in a report, which shall include the qualifications of the healthcare professionals who made such determination.

D. (1) The medical exceptions process under this Section shall require the health insurance organization or issuer to make a decision on a request made and provide notice of such decision to the covered person or enrollee, or his/her authorized representative, as quickly as the covered person or enrollee's particular

medical condition requires, but in no event later than seventy-two (72) hours after the later of the date of receipt of the request or, if required by the health insurance organization or issuer, the date of receipt of the certification under Subsection B(2).

(2) (a) If the health insurance organization or issuer fails to make a decision on the request and provide notice of the decision within the aforementioned time:

(i) The covered person or enrollee shall be entitled to coverage for up to thirty-day's supply of the prescription drug that is the subject of the request; and

(ii) The health insurance organization or issuer shall make a decision on the medical exception request prior to the covered person or enrollee's completion of the supply.

(b) If the health insurance organization or issuer fails to make a decision on the medical exception request and provides notice of such decision prior to the covered person or enrollee's completion of the supply, the health insurance organization or issuer shall maintain coverage on the same terms on an ongoing basis, as long as the prescription drug continues to be prescribed for that covered person or enrollee and is considered safe for the treatment of his/her disease or medical condition, unless the applicable benefit limits have been exhausted.

E. (1) Whenever a medical exception request made under this Section is approved, the health insurance organization or issuer shall provide coverage for the prescription drug that is the subject of the request and not require the covered person or enrollee to request approval under this Section for a refill or a new prescription to continue using the prescription drug after the refills for the initial

prescription have been exhausted. All of the foregoing shall be subject to the terms of the prescription drugs coverage under the health plan, provided:

(a) That the covered person or enrollee's prescribing provider continues to prescribe such prescription drug to treat the same disease or medical condition; and

(b) The prescription drug continues to be considered safe for treating the covered person or enrollee's disease or medical condition.

(2) The health insurance organization or issuer shall not establish a special formulary tier, co-payment, or other cost-sharing requirement that is applicable only to prescription drugs approved through medical exception requests.

F. (1) Any denial of a medical exception request made by a health insurance organization or issuer:

(a) Shall be notified to the covered person or enrollee or, if applicable, to his/her authorized representative, in writing or electronically, if the covered person or enrollee has agreed to receive information in this manner;

(b) Shall be notified electronically to the prescribing provider or, upon request, in writing; and

(c) May be appealed by filing a grievance pursuant to the Chapter on Health Insurance Organization or Issuer Grievance Procedures of this Code.

(2) The denial shall, in a manner that is comprehensible to the covered person or enrollee or, if applicable, his/her authorized representative, set forth:

(a) The specific reasons for the denial;

(b) A reference to the evidence or documentation, including the clinical review criteria practice guidelines, and clinical, medical, and scientific evidence considered in reaching the decision to deny the request;

(c) Instructions for requesting a written statement of the clinical, medical, or scientific rationale for the denial; and

(d) A description of the process and procedures that must be followed for filing a grievance to appeal the denial pursuant to the Chapter on Health Insurance Organization or Issuer Grievance Procedures of this Code, including any time limits applicable to those procedures.

G. A health insurance organization or issuer shall not be required to establish a medical exception request process or to comply with the provisions of subsections B, C, D, E(1), and F if such health insurance organization or issuer:

(1) Has an expedited utilization review process as provided in the Chapter on Utilization Review and Benefit Determination of this Code; and

(2) Allows covered persons or enrollees, or their authorized representatives, to use this process to seek approval for coverage of a prescription drug that is not covered because of formulary or other management process.

I. [sic] Nothing in this Section shall be construed to allow a covered person or enrollee to use the medical exception process set forth in this Section to request coverage for a prescription drug that is categorically excluded from coverage under his/her health plan.

Section 4.080. -Record Keeping and Reporting Requirements.-

A. Each health insurance organization or issuer shall maintain sufficient written or electronic records to demonstrate compliance with this Chapter, including records documenting the process for making decisions on formularies and other prescription drug management processes and records documenting the application of the medical exception request process. The records shall be maintained for a period of three (3) years or until the completion of the health insurance organization or issuer's next market conduct examination, whichever is later, and shall be made available to the Commissioner upon request.

B. Each health insurance organization or issuer shall maintain data on and make available to the Commissioner upon request the following information with respect to medical exception requests:

(1) The total number of medical exception requests;

(2) From the total number of medical exception requests provided under paragraph (1):

(a) The number of requests made for coverage of a nonformulary prescription drug;

(b) The number of requests made for continuing coverage of a prescription drug that the health insurance organization or issuer was discontinuing from coverage on the formulary for reasons other than safety or because the drug cannot be supplied or has been withdrawn from the market by the drug's manufacturer; and

(c) The number of requests made for an exception to a management process that subjects a prescription drug to dose restrictions or step therapy requirements;

(3) The number of medical exceptions requests approved and denied; and

(4) Any other information that the Commissioner may request.

Section 4.090. -Oversight and Contracting Responsibilities.-

A. A health insurance organization or issuer shall be responsible for the oversight of all activities carried out under this Chapter and for ensuring that all the requirements thereof and applicable regulations are met.

B. If a health insurance organization or issuer contracts with another person to carry out activities required under this Chapter or applicable regulations, the Commissioner shall hold the health insurance organization or issuer responsible for the oversight of the activities of the contracted person and for

ensuring that the requirements of this Chapter and applicable regulations with respect to such activity are met.

Section 4.100. -Disclosure Requirements.-

A. Each health insurance organization or issuer that uses a formulary or any other prescription drug management process shall, in the policy, certificate, membership booklet, outline of coverage, evidence of coverage, or any other document provided to a covered person or enrollee;

(1) Disclose the existence of the formulary and any other management processes and the fact that there may be other plan restrictions or requirements that may affect the specific prescription drugs that will be covered;

(2) Describe the medical exception process that may be used to request coverage of nonformulary prescription drugs or to obtain an exception to dose restriction or step therapy requirements; and

(3) Describe the process for filing a grievance, as set forth in the Chapter on Health Insurance Organization or Issuer Grievance Procedure of this Code, to appeal a denial of a medical exception request.

B. The policy, certificate, membership booklet, outline of coverage, evidence of coverage, or any other document provided to covered persons or enrollees shall explain, in layperson's terms, the information on the health insurance organization or issuer's formulary and each prescription drug management process. Such explanation shall also state that the health insurance organization or issuer shall provide covered persons or enrollees with a copy of the formulary and information about which prescription drugs are subject to a management process.

Section 4.110. -Incentive or Bonus Programs.-

A. No pharmacy, pharmacy benefit manager (PBM), drug manufacturer or distributor, or health insurance organization or issuer shall encourage the practice or participate in incentives programs, or bonus programs or similar transactions directed to healthcare professionals in order to influence them, directly or indirectly, to write prescriptions, prescribe, dispense, or exchange certain bioequivalent drugs for a brand-name drug or vice versa.

B. Healthcare professionals are hereby banned from receiving or participating in incentives or bonus programs, or other similar transactions, sponsored by a pharmacy, pharmacy benefit manager (PBM), drug manufacturer or distributor, or health insurance organization or issuer in order to influence healthcare professionals, directly or indirectly, to write prescriptions, prescribe, dispense, or exchange certain bioequivalent drugs for a brand-name drug or vice versa.

C. Notwithstanding subsections A and B of this Section, there shall be allowed the establishment of incentives or bonus programs, or other similar transactions based on the positive results achieved in the management or control of the clinical or health condition of covered persons or enrollees, in accordance with healthcare quality standards established by national organizations devoted to improve results in healthcare, such as the Healthcare Effectiveness Data and Information Set. These programs shall be implemented for the purpose of improving and obtaining optimum results in healthcare management and must meet the parameters that allow sufficient time to identify patterns in the results of the management or control of the clinical or health condition of covered persons or enrollees.

The persons or entities that establish incentives or bonus programs, or other similar transactions, shall submit them to the Commissioner within ninety (90) days before the effective date of such programs, so that the Commissioner may evaluate and approve the same in accordance with the provisions set forth herein. The Commissioner shall prescribe by regulations the criteria to be used to evaluate such programs. Such criteria shall take into account the healthcare quality standards established by the national organizations devoted to improve results in healthcare, such as the Healthcare Effectiveness Data and Information Set.

D. The Commissioner may establish those rules and regulations deemed necessary to implement the provisions of this Section.

E. Any person who violates the provisions of this Section, in addition to any other penalty established in this Code or the laws of the Government of Puerto Rico, shall be subject to a fine in an amount equal to three times the amount received or granted on account of incentives or bonuses.

Section 4.120. -Maintenance Drugs.-

A. When the history of the covered person or enrollee so requires, insofar as it does not jeopardize the patient's health, and at the discretion of the healthcare provider, such healthcare provider may prescribe refills for maintenance drugs up to a term that shall not exceed one hundred eighty (180) days, subject to the limitations of the health plan's coverage.

Chapter 6. Health Insurance Organizations or Issuers Claim Audits

Section 6.010. -Title.-

This Chapter shall be known and may be cited as the Chapter on Health Insurance Organizations or Issuers Claim Audit.

Section 6.020. -Purpose.-

The purpose of this Chapter is to provide for the standardization of claim audits of bills for healthcare services presented to health insurance organizations or

issuers, third party administrators, or any other health plans. Such audits shall be carried out to determine whether data in a healthcare record of a provider is supported by services listed on the claim for payment of an enrollee or a provider. It is also intended to alleviate the potential conflict of the audit with medical uses of the health record and to reduce the cost entailed by unnecessary audits.

Section 6.030. -Definitions.-

For purposes of this Chapter:

A. 'Qualified Claim Auditor' means a person employed or hired by a health insurance organization or issuer that is recognized as competent to perform or coordinate claim audits and that abides by policies and procedures geared to protect the confidentiality and properly manage all patient information in his/her possession.

B. 'Claim Audit' means a process to determine whether data in a claimant's medical record documents healthcare services listed on a claim for payment submitted to a health insurance organization or issuer. Claim audit does not mean a review of the medical necessity of the services provided, or the reasonableness of charges for the services.

C. 'Overcharges' or 'Unsupported Charges' means the volume of services indicated on a claim exceeds the total volume identified in the provider's medical documentation.

D. 'Unbilled Charges' means charges or services provided for and not billed.

E. 'Underbilled Charges' means the volume of services indicated on a claim is less than the volume identified in the provider's documentation.

F. 'Ambulatory Surgical Center' means an establishment with an organized medical staff of physicians, with permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures. Such

centers provide continuous physician services and registered nursing services whenever a patient is in the center. An ambulatory surgical center does not provide services for patients to stay overnight, but provide the following services whenever a patient is in the center:

- (1) drug services as needed for medical operations performed;
- (2) provisions for physical and emotional well-being of patients;
- (3) emergency services;
- (4) administrative structure; and
- (5) administrative, statistical, and medical records.

G. ‘Medical Record’ means a compilation of charts, records, reports, documents, and other memoranda maintained by a provider wherever located, to record or indicate the present, past, or prospective physical or mental condition, sickness, or disease of a patient and treatment rendered.

H. ‘Provider’ means healthcare professional or healthcare facility duly authorized to render or provide healthcare services.

I. ‘Final Claim’ means the final itemized bill from a provider detailing all the charges for which the provider is seeking payment.

J. “Claimant” means a covered person or enrollee under a health plan who has received healthcare services, the costs of which are submitted to a health insurance organization or issuer for payment, either by the claimant or by another on the claimant’s behalf.

Section 6.040. -Applicability and Scope.-

This Chapter shall apply to all health insurance organizations or issuers. The provider accepting payment of benefits of a covered person or enrollee shall be responsible for the conduct and results of the claim audit whether conducted by an employee or by contract with another firm. The provider and health insurance organization or issuer shall:

A. Supervise the process to ensure that the audit is conducted in accordance with the requirements of this Chapter;

B. Be aware of the actions being undertaken by the auditor in connection with the claim audit; and

C. Take prompt remedial action if inappropriate behavior by the auditor is discovered.

Section 6.050. -Qualifications of Auditors and Provider Audit Coordinators.-

A. Claim auditors and provider audit coordinators shall have appropriate knowledge, experience, and expertise in the field of healthcare including, but not limited to, the following areas:

(1) Format and content of the health record as well as other forms of medical and clinical documentation;

(2) Generally accepted auditing principles and practices as they apply to claim audits;

(3) Billing claims forms in effect in the health insurance industry and billing procedures;

(4) All Commonwealth and Federal regulations concerning the use, disclosure and confidentiality of patient records;

(5) Specific critical care units, specialty area, and ancillary units involved in a particular audit; and

(6) Medical terminology and coding, including ICD-9, CPT, HCPCS.

B. If a provider or health insurance organization or issuer finds that audit personnel do not meet these qualifications shall immediately contact the auditor's firm or sponsoring party.

C. Audit personnel shall conduct themselves in a professional manner and adhere to ethical standards and confidentiality requirements, and shall remain objective. They shall be required to completely document their findings and problems.

D. All unsupported, unbilled or underbilled charges identified in the course of an audit shall be documented in the audit report by the auditor.

E. Individual audit personnel shall not be placed in a situation through their remuneration, benefits, fees or other instructions that would call their findings into question. Compensation of audit personnel shall be structured so that it does not create incentives to produce questionable audit findings. Providers or health insurance organizations or issuers that encounter an individual who appears to have a conflict of interest shall contact the appropriate officers of the organization conducting the audit.

Section 6.060. -Notice of Audit.-

A. Health insurance organizations or issuers and providers shall make every effort to resolve claim inquiries directly. The name, contact telephone number, and fax number of each representative of the health insurance organization or issuer or the provider shall be exchanged no later than at the time of billing for a provider and the point of first inquiry by a health insurance organization or issuer.

B. If a satisfactory resolution of the questions surrounding the bill is not achieved by the representatives of the health insurance organization or issuer and the provider, then a full audit process may be initiated by the health insurance organization or issuer.

C. Claim audits may require documentation from or review of a patient's medical record and other similar medical or clinical documentation. Medical records exist primarily to ensure continuity of care for a patient. Therefore, the use of a patient's record for an audit must be secondary to its use in patient care.

D. All health insurance organization or issuer claim audits shall begin with a notification to provider of an intent to audit. Notification to the provider by the qualified claim auditor shall occur within six (6) months following receipt of the final claim for payment by the health insurance organization or issuer. Once notified, the provider shall respond to the qualified claim auditor within thirty (30) days with a schedule for the conduct of the audit. The qualified auditor shall complete the audit within thirty-six (36) months of receipt of the final claim by the health insurance organization or issuer. Each party shall make reasonable provisions to accommodate circumstances in which the schedule specified cannot be met by the other party. The health insurance organization or issuer shall not request nor accept audits after thirty-six (36) months from the date of receipt of the final claim. Provided, that it shall not be construed that the thirty-six (36) month term provided to complete the audit shall render ineffective shorter terms that have been agreed on for the same purposes under a contract.

E. All claim audits shall be conducted on the premises of the provider, except in instances where a provider chooses to allow individual, reasonable requests for off-site audits.

F. All requests for claim audits, whether telephonically, electronically or written, shall include the following information:

(1) The basis of the health insurance organization or issuer's intent to conduct an audit on a particular bill or group of bills. When the intent is to audit only specific charges or portions of the bills, this information should be included in the notification;

- (2) Name of the patient;
- (3) Admit and discharge dates, if apply;
- (4) Name of the auditor and the name of the audit firm, if the health insurance organization or issuer has contracted with a third party to conduct the audit;
- (5) Medical record number and the provider's patient account number, if known; and
- (6) Whom to contact to discuss the request and scheduled audit.

G. Providers that cannot accommodate an audit request that conforms to these provisions shall explain, within a term that shall not exceed thirty (30) days, why the request cannot be met. Along with the explanation, providers shall propose a new date to reschedule the audit, which shall not exceed sixty (60) days as of the date of the original audit. Auditors shall group audits to increase efficiency whenever possible.

H. It shall be the responsibility of the provider seeking payment of a claim or reimbursement to notify the auditor prior to the scheduled date of audit, if the auditor shall have problems accessing records. The provider shall be responsible for supplying the auditor with any information that could affect the efficiency of the audit once the auditor is on-site.

Section 6.070. -Provider Audit Coordinators.-

A. Providers shall designate an individual to coordinate all claim audit activities. An audit coordinator shall have the same qualifications as required for an auditor pursuant to Section 6.050 of this Chapter. The duties of an audit coordinator include, among others, the following:

- (1) Scheduling an audit;
- (2) Advising other provider personnel and departments of a pending audit;

- (3) Ensuring that the condition of admission statement is part of the medical record;
- (4) Verifying that the auditor is an authorized representative of the health insurance organization or issuer;
- (5) Gathering the necessary documents for the audit;
- (6) Coordinating auditor requests for information, space in which to conduct an audit, and access to records and provider personnel;
- (7) Orienting auditors with respect to the provider's audit procedures, record documentation conventions, and billing practices;
- (8) Acting as a liaison between the auditor and other personnel of the provider;
- (9) Conducting an exit interview with the auditor to answer questions and review audit findings;
- (10) Reviewing the auditor's final written report and following up on any charges still in dispute;
- (11) Arranging for payment as applicable; and
- (12) Arranging for any required adjustment to bills or refunds.

Section 6.080. -Conditions and Scheduling of Audits.-

A. In order to have a fair, efficient, and effective audit process, providers and health insurance organization or issuer' auditors shall adhere to the following requirements:

- (1) Whatever the original intended purpose of the claim audit, all parties shall agree to recognize, record or present any identified unsupported, unbilled or underbilled charges discovered by the audit parties;
- (2) The scheduling of an audit shall not preclude late billing;

(3) The parties involved in the audit shall mutually agree to set a time frame for the resolution of any discrepancies, questions or errors that surface in the audit;

(4) An exit conference and a written report shall be part of each audit. If the provider waives the exit conference, the auditor shall note that action in the written report. The specific content of the final report shall be restricted to those parties involved in the audit;

(5) The provider shall be afforded sixty (60) days to contest all findings, after which the audit shall be considered final;

(6) Once both parties agree to the audit findings, audit results are final;

(7) All personnel involved shall maintain a professional, courteous manner and resolve all misunderstandings amicably; and

(8) If the auditor notes ongoing problems either with the billing or documentation process and it cannot be corrected as part of the exit process, the management of the provider and health insurance organization or issuer shall be contacted to apprise them of the situation. The provider and health insurance organization or issuer shall take appropriate steps to resolve the identified problem. Parties to an audit shall eliminate ongoing problems or questions whenever possible as part of the audit process.

Section 6.090. -Confidentiality and Authorizations.-

A. All parties to a claim audit shall comply with all Federal and Commonwealth laws and any contractual agreements regarding the confidentiality of patient information.

B. The release of medical records requires authorization from the patient. An authorization shall be provided for in the condition of admission or equivalent statement procured by the provider upon admission of the patient. If no such

statement is obtained, an authorization for a claim audit is required. The authorization need not be specific to the health insurance organization or issuer or auditor conducting the audit.

C. The authorization shall be obtained by the claim audit firm or provider and shall include at least the following information:

(1) The name of the health insurance organization or issuer and, if applicable, the name of the audit firm that is to receive the information;

(2) The name of the institution that is to release the information;

(3) The full name, birth date, and address of the patient whose records are to be released;

(4) The extent or nature of the information to be released, with inclusive dates of treatment;

(5) The provider's patient account number, if included on the bill; and

(6) The signature of the patient or his/her legal representative and the date the consent is signed.

D. A patient's assignment of benefits shall include a presumption of authorization to review records.

E. The audit coordinator shall confirm for the audit representative that a condition of admission statement is available for the particular audit that needs scheduling.

F. The provider shall inform the patient or requestor, on a timely basis, if there are any Federal or Commonwealth laws prohibiting or restricting review of the medical record and if there are institutional confidentiality policies and procedures that affect the review of such documents. These institutional confidentiality policies shall not be specifically oriented in order to delay an external audit.

Section 6.100. -Documentation.-

A. Verification of charges shall include the investigation of whether or not:

- (1) Charges are reported on the bill accurately;
- (2) Services are documented in medical or other records as having been rendered to the patient; and
- (3) Services were delivered in accordance with the physician's plan of treatment. In appropriate situations, professional staff may provide supplies or follow procedures that are in accordance with established institutional policies, procedures, or professional licensure standards. Many procedures include items that are not specifically documented in a record but are referenced in medical or clinical policies. All those policies shall be reviewed, approved, and documented as required by the Joint Commission on Accreditation of Healthcare Organizations or other accreditation agencies. Policies shall be available for review by the auditors.

B. The medical record documents clinical data on diagnoses, treatments and outcomes, and is not designed to be a billing document. A patient medical record generally documents pertinent information related to care and does not back up each individual charge on the patient bill. Other signed documentation for services provided to the patient may exist within the provider's ancillary departments in the form of department treatment logs, daily records, individual service or order tickets, and other documents.

C. Auditors may have to review a number of other documents to determine valid charges and must recognize that these sources of information are accepted as reasonable evidence that the services ordered by the physician were actually provided to the patient. Providers must ensure that proper policies and procedures exist to specify what documentation and authorization must be in the

medical record and in the ancillary records and logs. Furthermore, these procedures shall document that services have been properly ordered for and delivered to patients. When sources other than the medical record are providing documentation, the provider shall notify the auditor and make those sources available to the auditor.

Section 6.110. -Fees and Payments.-

A. A health insurance organization or issuer shall make prompt payment of a bill in accordance with the provisions of Chapter 3 or the Insurance Code of Puerto Rico and shall not delay payment for an audit process. Payment on a submitted bill from a third-party shall be based on amounts billed and covered by the patient's health plan.

B. Audit fees shall be paid upon commencement of the claim audit.

C. A payment identified in the audit results that is owed to either party by the other, shall be settled by the audit parties within a reasonable period of time not to exceed thirty (30) days after completion of the audit unless the parties agree otherwise.

Chapter 8. Small- and Medium-sized Businesses Employer

Health Insurance Availability

Section 8.010. -Title.-

This Chapter shall be known and may be cited as the Chapter on Small- and Medium-sized Businesses (PYMES, Spanish acronym) Employer Health Insurance Availability.

Section 8.020. -Purpose.-

The purpose of this Chapter is to enhance the availability of health insurance coverage to PYMES employers, regardless of the health status or claims experience of their employee group, to prevent abusive rating practices, to prevent segmentation of the health insurance market based upon health risk; to spread

health insurance risk more broadly; to require disclosure of rating practices to purchasers; to establish rules regarding renewability of health plans; to limit the use of preexisting condition exclusions; to provide for development of ‘basic’ and ‘standard’ health plans to be offered to all PYMES employers, to provide for establishment of a Reinsurance Program; and to improve the overall fairness and efficiency of the small group health insurance market.

Section 8.030. -Definitions.-

For purposes of this Chapter:

A. ‘Affiliate’ or ‘Affiliate Company’ means any entity or person that directly or indirectly, through one or more intermediaries, controls or is controlled by, or is under the same control that a specific entity or person.

B. ‘Geographic Service Area’ means a geographic area, as approved by the Commissioner, within which the issuer is authorized to provide coverage under the provisions of this Chapter. The issuer shall faithfully comply with the provisions of Act No. 194 of August 25, 2000, as amended, particularly Section 6(b), related to all geographic service areas in which it is authorized to provide coverage.

C. ‘Issuer’ or ‘PYMES Employer Issuer’ means any entity authorized by the Commissioner to offer health plans to eligible employees of one or more PYMES employers pursuant to this Chapter. For purposes of this Chapter, ‘issuer’ includes an insurance company, a prepaid hospital or medical care plan, a fraternal benefit society, a health services organization, and any other entity offering and providing a health plan or health benefits subject to insurance regulation in Puerto Rico.

D. ‘Risk-Assuming Issuer’ means a PYMES Employer Issuer whose application to offer and provide health plans to one or more PYMES employers in Puerto Rico is approved by the Commissioner pursuant to this Chapter.

E. ‘Insurer-reinsurer’ means a PYMES employer issuer which participates in the Reinsurance Program established by virtue of this Chapter.

F. ‘Actuarial Certification’ shall mean a signed statement from a member of the American Academy of Actuaries or other individual acceptable to the Commissioner that a PYMES employer issuer is in compliance with the provisions of this Chapter. Such certification shall be based upon the person’s examination, including a review of the appropriate records and of the actuarial assumptions and methods used by the issuer in establishing premium rates for applicable insurance coverage.

G. ‘Committee’ means the Health Plan Committee created under this Chapter.

H. ‘Creditable Coverage’ means, with respect to an individual, the health benefits or coverage provided under any of the following:

- (1) A health plan, whether group or individual;
- (2) Part A or Part B of Title XVIII of the Social Security Act (Medicare);
- (3) Title XIX of the Social Security Act (Medicare), other than coverage consisting solely of benefits under Section 1928 (the program for distribution of pediatric vaccines);
- (4) Chapter 55 of Title 10, United States Code; (medical and dental care for members and certain former members of the uniformed services, and for their dependents. For purposes of Title 10, U.S.C. Chapter 55, “uniformed services” means the armed forces and the Commissioned Corps of the National Oceanic and Atmospheric Administration and of the Public Health Service);
- (5) A state health benefits risk pool;
- (6) A health plan offered under Chapter 89 of Title 5, United States Code (Federal Employees Health Benefits Program (FEHBP));

(7) A public health plan, which for purposes of this Chapter, means a plan established or maintained by a state, the United States government or a foreign country or any political subdivision of a state, the United States government or a foreign country that provides health insurance coverage to individuals enrolled in the plan;

(8) A health plan under Section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)); or

(9) Title XXI of the Social Security Act (State Children's Health Insurance Program).

A period of creditable coverage shall not be counted, with respect to the enrollment of an individual who seeks coverage under a group plan, if, after such period and before the enrollment date, the individual experiences a significant break in coverage. Significant break in coverage shall be understood as a period of sixty-three (63) consecutive days during which the individual does not have any creditable coverage. A waiting period or an affiliation period shall be taken into account in determining the sixty-three (63)-day period.

I. 'Dependent' means any person who is or may be eligible for a health plan due to his/her relationship with the eligible employee and in accordance with the conditions set forth in the health plan. The following may be considered dependents of the employee:

(1) The spouse;

(2) a birth or adopted child or child placed for adoption under age twenty-six (26);

(3) a birth or adopted child or child placed for adoption who, regardless of his/her age, is incapable of earning a living due to mental or physical disability existing before he/she has attained twenty-six (26) years of age, as provided in Public Law 111-148, known as the 'Patient Protection and Affordable

Care Act,' Public Law 111-152, known as the 'Health Care and Education Reconciliation Act,' and the regulations thereunder;

(4) Stepchildren;

(5) Foster children who have lived since infancy under the same roof with the employee in a normal parent/child relationship and who are, and shall continue to be, totally dependent on the family of said employee to receive support, as set forth in Section 16.330 of the Insurance Code of Puerto Rico.

(6) unemancipated minor whose custody has been awarded to the employee.

(7) a person of any age who has been declared incompetent by a court and whose custody has been awarded to the employee;

(8) a relative of the employee or his/her spouse who permanently resides in the household of the employee and is substantially dependent on him/her for support, and whom may be classified in the optional or collateral dependents category, as such term is commonly accepted and defined in the health insurance market;

(9) a parent or parent-in-law of the main subscriber who does not reside in the household of the main subscriber, and may be classified in the optional or collateral dependents category, as such term is commonly accepted and defined in the health insurance market.

J. 'Eligible Employee' means an employee who works for a PYMES employer on a full-time basis— a normal work week of 30 or more hours— or on a part-time basis —a normal week of at least seventeen point five (17.5) hours— in a bona fide employer-employee relationship which has not been established for the purpose of acquiring a health plan. In this computation, those employees who are not currently working as a result of any leave or right recognized by law, such as the benefits provided by the State Insurance Fund Corporation or the Family and

Medical Leave Act of 1993, shall be included. The term ‘eligible employee’ shall not include temporary employees or independent contractors.

K. ‘Preexisting Condition Exclusion’ means a limitation or exclusion of benefits relating to a condition based on the fact that the condition, injury, or disease was present before the enrollment date of the health plan. Genetic information shall not be treated as a condition for which a preexisting condition exclusion may be imposed in the absence of a diagnosis of the condition related to the information.

L. ‘Health Status-related Factor’ means any of the following factors:

- (1) Health status;
- (2) Medical condition, including both physical and mental illnesses;
- (3) Claims experience;
- (4) Receipt of healthcare services;
- (5) Medical history;
- (6) Genetic information;
- (7) Evidence of insurability, including conditions arising out of acts of domestic violence and participation in activities such as motorcycling, all-terrain vehicle riding, horseback riding, skiing and other similar high-risk activities; or
- (8) Disability.

M. ‘Enrollment Date’ means the first day of coverage, or if there is a waiting period, the first day of the waiting period, whichever comes first.

N. ‘Genetic Information’ means information about genes, gene products and inherited characteristics that may derive from the individual or a family member. This includes information regarding carrier status and information derived from laboratory tests that identify mutations in specific genes or

chromosomes, physical medical examinations, family histories and direct analysis of genes or chromosomes.

O. 'Board' means the Board of Directors of the PYMES Employers Reinsurance Program created under this Chapter.

P. 'Small- and Medium-sized Businesses (PYMES) Employer' means a for profit or non profit person, corporation, partnership, association that on at least fifty percent (50%) of its working days during the preceding calendar year, employed at least two (2), but not more than fifty (50) eligible employees. In determining the number of eligible employees, companies that are affiliated companies or that are eligible to file a combined tax return for purposes of taxation in Puerto Rico, shall be considered one single employer. Subsequent to the issuance of a health plan to a small employer and for the purpose of determining continued eligibility, the size of a PYMES employer shall be determined annually.

Q. 'Waiting Period' means the period of time that must pass before coverage for a covered person or enrollee who is otherwise eligible to enroll under the terms of a health plan can become effective. In no case the waiting period shall exceed ninety (90) days.

R. 'Enrollment Period' means a period of time established for an eligible employee to enroll in a PYMES employer-sponsored health plan.

S. 'Covered Person' or 'Enrollee' means the holder of a policy or certificate, or other individual participating in a PYMES employer-sponsored health plan.

T. 'Preferred Network Plan' means a health plan under which benefits shall be provided, in whole or in part, through providers under contract with the issuer.

U. 'Health Plan' means an insurance policy, contract, or certificate provided in consideration of or in exchange for the payment of a premium, or on a pre-paid basis, through which an issuer commits to provide coverage or pay for the costs of or specified healthcare services, hospital, major medical, dental coverage, mental health services or services incidental to the rendering thereof.

(1) 'Health Plan' shall not include:

(a) Coverage only for accident, or disability income insurance, or any combination thereof;

(b) Coverage issued as a supplement to liability insurance;

(c) Liability insurance, including general liability insurance and automobile liability insurance;

(d) Workers' compensation insurance;

(e) Automobile medical payment insurance;

(f) Credit-only insurance;

(g) Coverage for on-site medical clinics; or

(h) Other similar insurance coverage under which benefits for health services are secondary or incidental to other insurance benefits.

(2) 'Health Plan' shall not include the following benefits if they are provided under a separate policy, certificate or contract of insurance or are otherwise not an integral part of the plan:

(a) Limited scope dental or vision benefits;

(b) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof; or

(c) Other similar, limited benefits.

For purposes of this subsection, benefits shall not be considered an integral part of the plan, if they fail to meet the following requirements:

(i) Enrollees may choose not to receive coverage for such benefits, that is, the benefits provided are optional; and

(ii) Enrollees are required to pay a premium or additional contribution for such optional benefit coverage.

(3) 'Health Plan' shall not include the following benefits if the benefits are provided under a separate policy, certificate or contract of insurance:

(a) Coverage only for a specified disease or illness;

(b) Hospital indemnity or other fixed indemnity insurance;

(c) Medicare supplemental health insurance;

(d) Coverage supplemental to the coverage provided (known as TRICARE supplemental programs); or

(e) Similar supplemental coverage provided to coverage under a group health plan.

V. 'Basic Health Plan' means a health plan of lower cost developed by the Health Plan Committee in accordance with this Chapter.

W. 'Standard Health Plan' means a health plan designed by the Health Plan Committee in accordance with this Chapter, the cost of which is higher than that of the Basic Health Plan.

X. "Group Health Plan" means a policy, contract, or certificate offered by a health insurance organization or issuer to a PYMES employer or group of PYMES employers whereby healthcare services are provided to eligible employees and their dependents.

Y. 'Premium' means all moneys paid to an issuer as a condition of receiving the benefits of a health plan for the eligible employees of PYMES employers.

Z. 'Producer' means a person who, in accordance with the Insurance Code of Puerto Rico, holds a license duly issued by the Commissioner to transact insurance in Puerto Rico.

AA. 'Program' means the PYMES Employers Reinsurance Program created under this Chapter.

BB. 'Late Enrollee' means an eligible employee or dependent that enrolls in a PYMES employer-sponsored health plan after the initial enrollment period, provided that such term shall never be less than thirty (30) days.

No eligible employee or dependent shall be considered a late enrollee:

(1) If the eligible employee or dependent meets each one of the following criteria:

(a) was covered under a creditable coverage at the time of initial enrollment;

(b) lost creditable coverage as a result of cessation of employer contribution, termination of employment or loss of eligibility, reduction in the number of work hours, involuntary termination of a creditable coverage, death of a spouse, legal separation or divorce; and

(c) requests enrollment within thirty (30) days after termination of creditable coverage or the change in conditions that gave rise to the termination of coverage.

(2) If, where provided for in the health plan, or as otherwise provided by law, the eligible employee or dependent enrolls during a specified enrollment period;

(3) If the eligible employee is employed by an employer that offers multiple health plans, and he/she elects a different health plan during the enrollment period.

(4) If a court has ordered coverage be provided for a spouse or minor or dependent child under an employee's health plan and a request for enrollment is made within thirty (30) days after the change in status;

(5) If the individual changes status from not being an eligible employee to becoming an eligible employee and requests enrollment within thirty (30) days after the change in status.

(6) If the eligible employee or dependent had coverage under a Consolidated Omnibus Budget Reconciliation Act (COBRA) continuation provision and the coverage under that provision has been exhausted; or

(7) The eligible employee meets the requirements for special enrollment pursuant to this Chapter.

CC. 'Community Adjusted Rate' means a method used to develop rates, which spreads financial risk across the entire small group population of the issuer in accordance with the requirements in Section 5 of this Chapter.

Section 8.040. -Applicability and Scope.-

A. This Chapter shall apply to an issuer that offers health plans to the employees of PYMES employers in Puerto Rico, provided that the PYMES employer pays all or part of the premium or benefits, or the eligible employee is reimbursed for any portion of the premium, whether through wage adjustments or otherwise, as agreed upon by the parties.

B. For the purposes of this Chapter, issuers that are affiliated companies or that are eligible to file a consolidated tax return shall be treated as one issuer and any restrictions or limitations imposed by this Chapter shall apply as if all health plans issued for delivery to PYMES employers in Puerto Rico by such affiliated issuers were issued by one issuer.

C. Those issuers that wish to contract with the Puerto Rico Health Insurance Administration (ASES, Spanish acronym) to offer, market, or administer the Mi Salud Plan for PYMES, shall meet the requirements and legal and regulatory provisions established by ASES, the Insurance Code of Puerto Rico, and this Chapter. Provided, that in the case of the Mi Salud Plan for PYMES, the rules established by ASES regarding the following shall apply to issuers:

- (1) geographic service area;
- (2) the criteria to determine the eligibility of the PYMES employer, as well as the employees thereof and their dependents;
- (3) the development and definition of the health plan or plans and the coverage and benefits thereof; and
- (4) issues related to premium rates models, methods, and practices, and premiums to be paid.

It is hereby provided further that those issuers that are not offering, marketing or administering a health plan for any PYMES employer in Puerto Rico and wish to contract with ASES for the Mi Salud Plan for PYMES, shall request and obtain the approval or dispensation of the Commissioner to participate in such Mi Salud Plan for PYMES.

Section 8.050. -Restrictions Relating to Premium Rates.-

A. Premium rates for health plans shall be subject to the following provisions:

- (1) PYMES employer issuer shall develop its rates based on an adjusted community rate and may only vary the adjusted community rate for geographic area, family composition, and age.
- (2) The adjustment for age in the preceding paragraph may not use age brackets smaller than five (5)-year increments and these shall begin with age thirty (30) and end with age sixty-five (65).

(3) Issuers shall be permitted to develop separate rates for individuals age sixty-five (65) or older notwithstanding that Medicare is the primary payer. Both rates shall be subject to the requirements of this Section.

(4) As of the approval of this Act, rate adjustments based on age shall be those determined by the Commissioner of Insurance.

B. The premium charged for a health plan may not be adjusted more frequently than annually, except that the rates may be changed to reflect:

- (1) Changes to the enrollment of the PYMES employer;
- (2) Changes to the family composition of the eligible employee; or
- (3) Changes to the health plan requested by the PYMES employer.

C. Premium rates shall not be altered by issuers based on paid or payable fee as part of the Reinsurance Program established in this Chapter.

D. Rating factors shall produce premiums for identical groups which differ only by the amounts attributable to plan design and do not reflect differences due to the nature of the groups assumed to select particular health plans.

E. The Commissioner may establish, through regulations, the rating practices to be used by PYMES employer issuers that are consistent with the purposes of this Chapter.

F. Each issuer shall maintain at its principal place of business, for review by the Commissioner, a complete and detailed description of its rating practices and renewal underwriting practices. In addition, such issuer shall maintain information and documentation that demonstrate that its rating methods and practices are based upon commonly accepted actuarial assumptions and are in accordance with sound actuarial principles. Also, issuers shall meet the following requirements:

(1) Each PYMES employer issuer shall file with the Commissioner annually, not later than March 15, an actuarial certification certifying that it is in compliance with this Chapter and that the rating methods of the PYMES employer issuer are actuarially sound. The certification shall be in a form and manner, and shall contain such information, as specified by the commissioner. A copy of the certification shall be retained by the PYMES employer issuer at its principal place of business.

(2) A PYMES employer issuer shall make the information and documentation described in subsection F available to the Commissioner upon request. Except in cases of violations of this Chapter, the information shall be considered proprietary and trade secret information and shall not be subject to disclosure by the Commissioner to persons outside of the Office except as agreed to by the issuer or as ordered by a court of competent jurisdiction.

G. The requirements of this Section shall apply to all health plans issued or renewed on or after the effective date of this Chapter.

Section 8.060. -Renewability of Health Plan.-

A. An issuer providing health plans to PYMES employers shall renew the same to all eligible employees and their dependents, except in any of the following cases:

- (1) Failure to pay premiums, considering the grace period;
- (2) When the covered person or enrollee has performed an act that constitutes fraud. In such case the issuer may choose not to renew the health plan of such covered person or enrollee for one (1) year as of the of the coverage's termination date;

(3) When the covered person or enrollee has or made an intentional misrepresentation of material fact under the terms of coverage. In such case the issuer may choose not to renew the health plan of such covered person or enrollee for one (1) year as of the of the coverage's termination date;

(4) Noncompliance with the issuer's minimum participation requirements, pursuant to the provisions of this Chapter;

(5) Noncompliance with the issuer's employer contribution requirements;

(6) When the issuer elects to discontinue offering all of its health plans to PYMES employers in Puerto Rico. In these cases, the issuer shall provide a written notice to the Commissioner, the PYMES employer, and the covered persons or enrollees, of its decision not to renew coverage at least one hundred and eighty (180) days prior to the nonrenewal of the health plans. The issuer that elects to discontinue offering health plans, as provided herein, shall be impaired from underwriting new business in the PYMES employer market in Puerto Rico for a term of five (5) years, beginning on the date in which the issuer ceased to offer such health plans.

(7) When the commissioner finds that the continuation of the coverage would not be in the best interests of the policyholders or would impair the issuer's ability to meet its contractual obligations;

(8) In the case of health plans that are made available in the small group market through a preferred network plan, there is no longer an employee of the PYMES employer living, working, or residing within the issuer's established geographic service area.

B. In the case of a PYMES employer issuer doing business in one established geographic service area of Puerto Rico, the rules set forth in this Section shall apply only to the issuer's operations in that service area.

C. In addition to comply with the provisions of this Section, the issuer shall comply, at all times, with the applicable Federal regulations, as codified under 45 C.F.R. Section 146.152 (Guaranteed renewability of coverage for employers in the group market).

Section 8.070. -Availability of Health Plan.-

A. Every issuer offering insurance to PYMES employers shall, as a condition of transacting business in Puerto Rico with PYMES employers and as otherwise provided in this Chapter, actively offer all health plans it actively markets to PYMES employers, including at least one (1) basic health plan and one (1) standard health plan. Issuers shall also meet the following availability requirements:

(1) A PYMES employer issuer shall issue a health plan to any eligible employer that applies for such plan and agrees to make the required premium payments and to satisfy the other reasonable provisions of the health plan not inconsistent with this Chapter.

(2) Unless otherwise provided by the Commissioner, the PYMES employer issuer shall not enter into one or more ceding agreements with respect to health plans delivered or issued for delivery for PYMES employers in Puerto Rico, if such arrangements would result in less than fifty (50) percent of the insurance obligation or risk for such health plan being retained by the ceding issuer.

B. PYMES employer issuers shall file with the Commissioner the health plan forms and rates they intend to market. The PYMES employer issuer may begin using such forms and rates sixty (60) days after they are filed unless the Commissioner disapproves its use. Provided that:

(1) The Commissioner, at any time, may extend such term for not more than sixty (60) additional days.

(2) The Commissioner at any time may, after providing notice and an opportunity for a hearing, disapprove the use of a basic or standard health plan on the grounds that the plan does not meet the requirements of this Chapter or the regulations thereunder.

C. Health plans covering PYMES employers shall comply with the following provisions:

(1) A health plan shall not deny, exclude or limit benefits due to a preexisting condition in the case of an individual under the age of 19.

(2) In the case of an individual older than 19 years, the issuer may deny, exclude or limit the benefits due to a preexisting condition for a maximum period of six (6) months as of the effective date of the health plan.

(3) The health plan shall not define a 'preexisting condition' more broadly than 'a condition, regardless of the cause of the condition, for which medical advice, diagnosis, care or treatment was recommended or received during the six (6) months immediately before the individual's enrollment date.'

(4) As of 2014, health plans shall not deny, exclude or limit benefits for a person due to a preexisting condition regardless of the person's age.

(5) Furthermore, PYMES employer issuers shall comply with the following provisions regarding preexisting conditions:

(a) A PYMES employer issuer shall reduce the period of any preexisting condition denial, limitation, or exclusion provided that the person has had creditable coverage and that such creditable coverage ended on a date not more than ninety (90) days prior to the enrollment date of new health plan. The reduction provided in this paragraph shall be for the entirety of the creditable coverage period.

(b) An issuer that does not use preexisting condition limitations in any of its health plans may impose an affiliation period that shall not exceed sixty (60) days for new enrollees and ninety (90) days for late enrollees. Such affiliation periods shall apply uniformly without regard to any health status-related factor.

(6) PYMES employer issuers shall not impose exclusion for preexisting condition relating to pregnancy.

(7) Issuers shall permit late enrollees to enroll for coverage under the terms of the health plan during a special enrollment period if:

(a) The late enrollee was covered under a health plan at the time PYMES employer sponsored health plan was previously offered, including a health plan under the Consolidated Omnibus Budget Reconciliation Plan Act (COBRA).

(b) The other health plan of the late enrollee has been terminated as a result of loss of eligibility for coverage, including a legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment or employer contributions towards that other coverage have been terminated; and

(c) the late enrollee requests enrollment in a PYMES employer sponsored health plan not later than thirty (30) days after the date termination of coverage under another plan.

If an employee requests enrollment pursuant to paragraph (7), the PYMES employer-sponsored health plan shall be effective not later than the first calendar month after the date on which the request for enrollment was received.

(8) Issuers that provide PYMES employer-sponsored health plans shall establish a dependent special enrollment period during which the dependent and the eligible employee, if not otherwise enrolled, may be enrolled under the

health plan and, in the case of the birth or adoption of a child, award of custody or guardianship, or marriage. The special enrollment period for persons who comply with the provisions of this paragraph (8) shall be a period of thirty (30) days and shall begin on the later date of:

(a) The date on which the health plan is made available for such dependent; or

(b) The date of the marriage, birth or adoption, or award of custody or guardianship.

If an eligible employee seeks to enroll a dependent during the first thirty (30) days of the dependent special enrollment period, the effective date of the health plan of the dependent shall be:

(i) In the case of marriage, the first day of the month beginning after the date on which the request for enrollment was received;

(ii) In the case of a dependent's birth, as of the date of birth; and

(iii) In the case of a dependent's adoption award of custody or guardianship, the date of the adoption or award.

(9) PYMES employer issuers shall not require a minimum participation level greater than:

(a) One hundred percent (100%) of eligible employees working for employers of three (3) or less employees; and

(b) Seventy-five percent (75%) of eligible employees working for employers with more than four (4) employees.

In applying minimum participation requirements with respect to a PYMES employer, an issuer shall not consider employees or dependents who have creditable coverage in determining whether the applicable percentage of

participation is met. Individuals covered under a health plan pursuant to continuation provisions of COBRA shall not be considered.

Issuers shall not increase any requirement for minimum employee participation or modify any requirement for minimum employer contribution applicable to a PYMES employer at any time after such employer has been accepted for the health plan.

(10) (a) An issuer that offers a health plan shall offer the same plan to all eligible employees of such PYMES employer and their dependents. Issuers shall not offer coverage to only certain individuals or dependents in a group.

(b) PYMES employer issuers shall not place any restriction in regard to any health status-related factor on an eligible employee or dependent with respect to enrollment or plan participation.

(c) Except as permitted under this Chapter, issuers shall not modify a health plan with respect to a PYMES employer or any eligible employee or dependent, through riders, endorsements or otherwise, to restrict or exclude coverage or benefits of the health plan related to specific diseases, medical conditions, or services.

D. PYMES employer issuers shall not be required to offer health plans or accept applications in the case of the following:

(a) To a PYMES employer, if such employer is not located in the issuer's established geographic service area;

(b) To an employee, if the employee does not live, work or reside within the issuer's established geographic service area.

Issuers shall apply the provisions of this Section uniformly to all PYMES employers, regardless of their claim experience or any health status-related factor of their eligible employees and their dependants.

E. PYMES employer issuers shall not be required to offer health plans to PYMES employers if, for any period of time, the Commissioner determines the issuer does not have the financial reserves necessary to underwrite health plans. In these cases, the issuer may not offer health plans in the PYMES employer market for the later of:

(a) A period of one hundred and eighty (180) days after the date the Commissioner made the decision; or

(b) Until the issuer has demonstrated to the Commissioner that it has sufficient financial reserves to underwrite additional health plans to PYMES employer and the Commissioner has authorized it again to offer health plans to PYMES employer.

F. A PYMES employer issuer shall not be required to provide coverage to PYMES employers if the issuer elects not to offer new health plans to PYMES employers in Puerto Rico. Provided, further, that:

(1) the issuer that elects not to offer new health plans to PYMES employers may be allowed to maintain its existing policies in Puerto Rico, as determined by the Commissioner.

(2) the issuer that elects not to offer new health plans to PYMES employers shall provide notice of its election to the Commissioner, who shall ban the issuer from writing new health plans in the PYMES employer market in Puerto Rico for a period of five (5) years beginning on the date the issuer ceased offering new health plans in Puerto Rico.

Section 8.080. -Certification of Creditable Coverage.-

A. PYMES employer issuers shall provide written certification of creditable coverage to individuals in accordance with subsection B.

B. The certification of creditable coverage shall be provided:

(1) At the time an individual ceases to be covered under the health plan or otherwise becomes covered under a COBRA continuation provision;

(2) In the case of an individual who becomes covered under a COBRA continuation provision at the time the individual ceases to be covered under that provision;

C. The certificate of creditable coverage required to be provided pursuant to Section shall contain:

(1) The period of creditable coverage of the individual under the other health plan; and

(2) The waiting period, if any, and, if applicable, affiliation period imposed with respect to the individual for any coverage under another health plan.

Section 8.090. -Notice of Intent to Operate as a Risk-Assuming Insurer or a Reinsurer.-

A. Not later than thirty (30) days after the plan of operation of the Reinsurance Program established under Section 8.110 is approved by the Commissioner, each issuer shall notify the Commissioner of its intention to operate as a risk-assuming insurer or a reinsurer. An issuer seeking to operate as a risk-assuming insurer shall make an application pursuant to Section 8.100.

B. The initial decision of the issuer to operate as a risk-assuming insurer shall be binding for two (2) years. Subsequent decisions shall be binding for five (5) years. The Commissioner may authorize an issuer to modify its decision at any time for just cause.

C. The Commissioner shall establish an application process for PYMES employer issuers seeking to change their status under this Section. In the case of a PYMES employer issuer that has been acquired by another such issuer, the

Commissioner may waive or modify the time periods established in subsection (B) of this Section.

D. An insurer-reinsurer that applies and is approved to operate as a risk-assuming insurer shall not be permitted to continue to reinsure any health plan with Reinsurance Program established in Section 8.110. In such cases, the issuer shall pay a prorated assessment based upon policies issued as a reinsurer for any portion of the year that it participated as reinsurer.

Section 8.100. -Application to Become a Risk-Assuming Insurer.-

A. PYMES employer issuers interested in offering and marketing or continue offering and marketing the health plans authorized under this Chapter, or any other designed for PYMES employers in Puerto Rico, may apply to become a risk-assuming insurer by filing an application with the Commissioner in a form and manner prescribed by the latter.

(1) As a transition measure and while the application required under this Section is evaluated, it is hereby provided that any issuer that at the time of the approval of this Chapter is offering, marketing or administering any health plan for one or more PYMES employers, may continue to do so.

(2) The preceding paragraph notwithstanding, such issuer shall provide, within a term of thirty (30) days, a notice to the Commissioner stating:

(a) the date on which it began offering, marketing or administering health plans for PYMES employers.

(b) the number of health plan models available for PYMES employers, classified as marketed, exclusive or administered, and if the latter has any stop loss coverage;

(c) the number of PYMES employers and enrollees that are enrolled by type of health plan, following the aforementioned classification;

(d) rate or rates for these health plans and the basis to determine the same, as well as those used and underwritten;

(e) a table itemizing the covered benefits, exclusions, and limitations, applicable deductible, copayments and coinsurance, eligible employees and dependents, and premiums applicable for individuals, family groups, the employee and one dependent (partner), for optional dependents or collaterals, as such terms and practices are commonly accepted and defined in the health insurance market; and

(f) any other information that may be necessary to achieve the purposes of this Chapter.

B. The Commissioner shall consider the following factors in evaluating applications to become a risk-assuming insurer:

(1) The issuer's financial condition;

(2) The issuer's history of rating and underwriting PYMES employer groups;

(3) The issuer's commitment to market fairly to all PYMES employers in Puerto Rico or its established geographic service area, as applicable; and

(4) The issuer's experience with managing the risk of PYMES employer groups.

C. The Commissioner may rescind the approval granted to a risk-assuming insurer if he/she finds that:

(1) The issuer's financial condition will no longer support the assumption of risk from issuing coverage to PYMES employers;

(2) The issuer has failed to market fairly to all PYMES employers in Puerto Rico or its established geographic service area, as applicable; or

(3) The issuer has failed to provide coverage to eligible PYMES employers as required in Section 8.070.

D. An issuer electing to be a risk-assuming insurer as well as those that offer and issue group health insurance with stop-loss limit shall not be subject to the provisions of the PYMES Employers Reinsurance Program.

E. It is hereby further provided, that every issuer that, at the time of the approval of this Chapter has underwritten any health plan for a PYMES employer, may continue to renovate the same, as provided in the applicable Federal regulations, codified under 45 C.F.R. Section 146.152 (Guaranteed renewability of coverage for employers in the group market) and 147.140 (Preservation of right to maintain existing coverage), promulgated pursuant to Public Law 111-148, known as the Patient Protection and Affordable Care Act, and Public Law 111-152, known as the Health Care and Education Reconciliation Act.

Section 8.110. -Puerto Rico PYMES Employer Health Reinsurance Program.-

A. Every insurer or reinsurer shall be subject to the provisions of this Section.

B. There is hereby created a nonprofit entity to be known as the Puerto Rico PYMES Employer Health Reinsurance Program, in which all issuers that have notified the Commissioner of their intent to operate as an insurer-reinsurer shall participate, as provided in Section 8.090.

C. The program shall operate subject to the supervision and control of a Board. The Board shall consist of four (4) members appointed by the Governor, with the advice of the Commissioner, plus the Commissioner or his/her designated representative, who shall serve as an ex officio member thereof. The Board shall be presided by one of the members appointed by the Governor.

(1) In selecting the members of the Board, the Governor shall include one (1) representative of the PYMES employers and two (2) representatives of the PYMES employer issuers, and one (1) individual qualified as determined by such official. These members shall be selected pursuant to procedures and guidelines developed by the Commissioner.

(2) In the event that the Program becomes eligible for additional financing pursuant to subsection K, the Board shall be expanded to include two (2) additional members who shall be appointed by the Governor with the advice of the Commissioner. In selecting the additional members of the Board, the Governor shall choose individuals who represent the financing sources identified in subsection K. The expansion of the Board under this subsection shall continue for the period that the Program continues to be eligible for such additional financing.

(3) The initial Board members shall be appointed as follows: two (2) of the members to serve a term of two (2) years; two (2) of the members to serve a term of four (4) years; and one (1) of the members to serve a term of six (6) years. Subsequent Board members shall serve for a term of three (3) years. A Board member's term shall continue until his/her successor is appointed.

(4) If a vacancy arises in the Board, due to the completion of the term or resignation, or death of a Board member, the Governor, with the advice of the Commissioner, shall appoint a new member who shall hold office for the term provided in this Code. The Governor may remove a Board member for just cause.

D. Not later than sixty (60) days as of the effective date of this Chapter, each PYMES employer issuer shall file with the Commissioner a document containing the its net health insurance premium derived from health plans delivered or issued for delivery to PYMES employers in Puerto Rico in the previous calendar year.

E. Not later than one hundred and eighty (180) days after the appointment of the initial Board, the Board shall submit to the Commissioner a plan of operation and thereafter any amendments thereto necessary or suitable to assure the fair, reasonable and equitable administration of the Program. The Commissioner shall approve the plan of operation, if he/she determines it to be suitable to assure the administration of the Program, and to provide for the sharing of program gains or losses on an equitable and proportionate basis in accordance with the provisions of this Section. The plan of operation shall become effective upon written approval by the Commissioner.

F. The plan of operation shall establish the following:

(1) the procedures for handling and accounting of program assets and moneys and for an annual fiscal reporting to the Commissioner;

(2) the procedures for selecting an administering issuer and setting forth the powers and duties of the administering issuer;

(3) the procedures for reinsuring risks in accordance with the provisions of this Section;

(4) the procedures for collecting assessments from reinsurers to fund claims and administrative expenses incurred or estimated;

(5) a methodology for applying the dollar thresholds contained in this Section in the case of issuers that pay or reimburse healthcare providers through capitation or salary;

(6) a methodology for determining the premiums to be collected by the Reinsurance Program established herein;

(7) the rules to determine levels and the form of payment for producers with respect to the sale of basic and standard health plans; and

(8) any additional matters necessary for the implementation and administration of the Program.

G. The Program shall have the general powers and authority granted by the laws of Puerto Rico to issuers and health service organizations, except the power to issue health plans directly to either groups or individuals. In addition, the Program shall have the specific authority to:

(1) Enter into contracts as are necessary or proper to carry out the provisions and purposes of this Chapter;

(2) Sue or be sued, including taking any legal actions necessary to recover any assessments and penalties of the Program or any reinsurers or on their behalf;

(3) Take any legal action necessary to avoid the payment of improper claims against the Program;

(4) Define the health plans for which reinsurance shall be provided, and to issue reinsurance policies, in exchange for the corresponding payment, in accordance with the requirements of this Chapter;

(5) Establish rules, conditions, and procedures for reinsuring risks under the Program;

(6) Establish actuarial functions as appropriate for the operation of the Program;

(7) Assess fees or assessments to reinsurers in accordance with the provisions of this Section and to impose advance interim assessments as may be reasonable and necessary for organizational and interim operating expenses. Any interim assessments shall be credited as offsets against any regular fee or assessments due following the close of the fiscal year;

(8) Appoint legal, actuarial, and other committees as necessary to provide technical assistance in the operation of the Program, policy and other contract design, and any other function within the authority of the Program; and

(9) Borrow money to implement the purposes of the Program. Any notes or other evidence of indebtedness of the Program not in default shall be legal investments and may be carried as admitted assets.

H. With respect to a basic health plan or a standard health plan, the Program shall reinsure the level of coverage provided and, with respect to other plans, the Program shall reinsure up to the level of coverage provided in a basic or standard health plan.

(1) A PYMES employer issuer may reinsure an entire employer group within sixty (60) days of the commencement of the group's coverage under a group health plan.

(2) A newly eligible employee or dependent of the reinsured PYMES employer may be reinsured within sixty (60) days of the commencement of his/her coverage.

(3) The Program shall not reimburse an insurer-reinsurer with respect to the claims of a reinsured employee or dependent until the issuer has incurred an initial level of claims for such employee or dependent of \$5,000 in a policy year for covered benefits. In addition, the insurer-reinsurer shall be responsible for ten percent (10%) of the next \$50,000 of benefit payments during a policy year and the Program shall reinsure the remainder. An insurer-reinsurer's liability under this paragraph shall not exceed \$10,000 in any one policy year with respect to any reinsured individual.

(a) The Board annually shall adjust the initial level of claims and the limit to be retained by the issuer to reflect increases in costs and utilization within the standard market for health plans within Puerto Rico. The adjustment shall not be less than the annual change in the medical component of the Consumer Price Index for All Urban Consumers (ICP-U) of the Department of Labor, Bureau

of Labor Statistics, unless the Board proposes and the Commissioner approves a lower adjustment factor.

(4) A PYMES employer issuer may terminate reinsurance with the Program for one or more of the reinsured employees or dependents on any anniversary of the health plan.

(5) Premium rates charged for reinsurance to a health service organization that qualifies under 42 U.S.C. Sec. 300c(c)(2)(A), and as such is subject to requirements that limit the amount of risk that may be ceded to the Program, shall be reduced to reflect that portion of the risk that may not be ceded to the Program, if any.

(6) The insurer-reinsurer shall apply all managed care and claims handling techniques, including utilization review, individual case management, preferred provider provisions, and other managed care provisions or methods of operation consistently with respect to reinsured and nonreinsured policies.

I. The Board, as part of the plan of operation, shall establish a methodology for determining premium rates to be charged by the Reinsurance Program. The methodology shall include a system for classification of PYMES employers that reflects the types of case characteristics commonly used by PYMES employer issuers in Puerto Rico. The methodology shall provide for the development of base reinsurance premium rates which shall be multiplied by the factors set forth in paragraph (2) to determine the premium rates for the Program. The base reinsurance premium rates shall be established by the Board, subject to the approval of the Commissioner.

(1) Premiums for the program shall be as follows:

(a) An entire PYMES employer may be reinsured for a rate that is one and one-half (1.5) times the base reinsurance premium rate for the group.

(b) The reinsurance rate for eligible employees or dependents shall be five (5) times the base reinsurance premium rate for the individual.

(2) The Board periodically shall review the methodology established, including the system of classification and rating factors, to assure that it reasonably reflects the claims experience of the Program. In addition, the Board shall be empowered to propose changes to the methodology which shall be subject to the approval of the Commissioner.

(3) The Board may consider adjustments to the premium rates charged by the Program to reflect the use of effective cost containment and managed care arrangement.

J. If a health plan for a PYMES employer is entirely or partially reinsured with the Program, the premium charged to the PYMES employer shall meet the requirements relating to premium rates set forth in this Chapter.

K. (1) Prior to March 31 of each year, the Board shall determine and report to the Commissioner the Program net loss for the previous calendar year, including administrative expenses and incurred losses for the year, taking into account investment income and other appropriate gains and losses.

(2) Any net loss for the year shall be recouped by assessments of insurer-reinsurers.

(3) The Board shall establish, as part of the plan of operation, a formula by which to make assessments against insurer-reinsurers.

(a) The assessment formula shall be based on:

(i) Each insurer-reinsurer's share of the total premiums earned in the preceding calendar year from health plans issued to PYMES employers in Puerto Rico.

(b) No insurer-reinsurer shall be imposed an assessment share that is less than fifty percent (50%) nor more than one hundred and fifty percent (150%) of an amount which is based on the proportion of:

(i) the insurer-reinsurer's total premiums earned in the preceding calendar year from health plans issued to PYMES employers in Puerto Rico with respect to the total premiums earned by all insurer-reinsurers in the preceding calendar year from health plans issued to PYMES employers in Puerto Rico.

(c) Subject to the approval of the Commissioner, the Board shall make an adjustment to the assessment formula for insurer-reinsurers that are approved health service organizations, which are qualified under 42 U.S.C. Sec. 300, et seq., to the extent, if any, that restrictions are placed on them that are not imposed on other issuers.

(4) Prior to March 31 of each year, the Board shall determine and file with the Commissioner an estimate of the assessments needed to fund the losses incurred by the Program in the previous calendar year.

(a) If the Board determines that the assessments needed to fund the losses incurred by the Program in the previous calendar year will exceed five percent (5%) of total premium earned during such year from health plans delivered to PYMES employers in Puerto Rico, the Board shall evaluate the operation of the Program and report its findings to the Commissioner. Such determinations shall include any recommendations for changes to the plan of operation and shall be filed before March 31 of the next calendar year in which the losses were incurred. The evaluation shall include an estimate of future assessments and consideration of the administrative costs of the Program, the appropriateness of the premiums charged, the level of issuer retention under the Program and the costs of coverage for PYMES employers. If the board fails to file

a report with the Commissioner on the established date, the Commissioner may evaluate the operations of the Program and implement such amendments to the plan of operation he/she deems necessary to reduce future losses and assessments.

(b) If assessments in each of two (2) consecutive calendar years exceed the amount specified in paragraph (b), the program shall be eligible to receive additional financing. The additional funding shall be obtained from the same sources provided in the Chapter on Health Plan for Uninsurable Individuals of this Code. The amount of additional financing to be provided to the Program shall be equal to the amount by which total assessments in the preceding two (2) calendar years exceed five percent (5%) of total premiums earned during that period from PYMES employers from health plans issued in Puerto Rico. If the Program has received additional financing as provided in this paragraph, the amount of such financing shall be subtracted from the amount of total assessments for the purpose of the calculation in the previous sentence. Additional financing received by the Program pursuant to this paragraph shall be distributed to insurer-reinsurers in proportion to the assessments paid by such carriers over the previous two (2) calendar years.

(5) If assessments exceed net losses of the Program, the excess shall be held at interest. The Board shall use such excess to offset future losses or to reduce Program premiums. As used in this paragraph, 'future losses' includes reserves for incurred but not reported claims (IBNR).

(6) Each insurer-reinsurer's proportion of the assessment shall be determined annually by the Board based on annual statements and other reports deemed necessary by the Board.

(7) The plan of operation shall provide for the imposition of an interest penalty for late payment of assessments.

(8) An insurer-reinsurer may seek from the Commissioner a deferment from all or part of an assessment imposed by the Board. The Commissioner may defer all or part of the assessment of an insurer-reinsurer, if he/she determines that the payment of the assessment would place the insurer-reinsurer in a financially impaired condition. If the Commissioner grants the deferment, the amount deferred shall be assessed against the other participating insurer-reinsurers in a manner consistent with the basis for assessment set forth in this Section. The insurer-reinsurer receiving the deferment shall remain liable to the Program for the amount deferred and shall be prohibited from reinsuring any individuals or groups with the Program until such time as it pays the assessments.

L. The Board, as part of the plan of operation, shall develop standards setting forth the manner and levels of compensation to be paid to producers for the sale of basic and standard health plans. In establishing such standards, the Board shall take into consideration the need to assure the broad availability of health plans, the objectives of the Program, the time and effort expended in placing the coverage, the need to provide on-going service to the PYMES employers, the levels of compensation currently used in the industry, and the overall costs of the health plan to PYMES employers.

M. The program shall be exempt from any and all taxes.

Section 8.120. -Health Plan Committee.-

A. The Commissioner shall appoint a Health Plan Committee. The Committee shall be composed of five (5) members. The Secretary of Health, who shall preside, the Patient's Advocate, and the Commissioner shall be the three ex-officio members of the Committee. The other two (2) members shall be one (1) competent professional of the insurance industry and one (1) representative of the public interest, who shall be selected in accordance with the procedures and guidelines established by the Commissioner.

B. The Committee shall recommend the form and level of coverage to be made available by PYMES employer issuers pursuant to this Chapter. In discharging this function the Committee may consult as necessary those persons or entities engaged in the rendering of healthcare services, the offering and marketing of health plans to this sector of the market, and other activities related to health plans, particularly to PYMES employers.

C. The Committee shall recommend and design benefit levels, cost sharing levels, exclusions and limitations for the basic health plan and the standard health plan taking into account that all the provisions set forth by Federal and Commonwealth laws and regulations. The plans recommended and designed by the Committee may include cost containment features such as:

(1) Utilization review of healthcare services, including review of medical necessity of hospital and physician services;

(2) Improve quality and access to services, preventive programs and case management, among others;

(3) Selective contracting with hospitals, physicians and other healthcare providers;

(4) Reasonable benefit differentials applicable to providers that participate or do not participate in arrangements using preferred network provisions; and

(5) Other managed care provisions.

D. Upon the approval of this Chapter, but not later than one hundred and eighty (180) days after its appointment, the Committee shall submit to the Commissioner for approval a basic health plan and a standard health plan, and other health plans deemed convenient to attain the purposes described in this Section. After the initial recommendation, and at least once every year, the

Committee shall introduce and recommend any necessary amendments to such health plans.

Section 8.130. -Periodic Market Evaluation.-

At least every three (3) years, the Board of Directors of the PYMES Employers Health Reinsurance Program, in consultation with members of the Health Plan Committee, shall conduct a study on the effectiveness of this Chapter and report the Commissioner of the findings thereof. The report shall analyze the effectiveness of the provisions of this Chapter in promoting rate stability, product availability, and coverage affordability of health plans for PYMES employers. The report may contain recommendations for actions to improve the overall effectiveness, efficiency and fairness of the PYMES group health insurance marketplace. The report shall address whether issuers and producers are fairly and actively marketing or issuing health plans to PYMES employers in fulfillment of the purposes of the Chapter. The report may contain recommendations for market conduct or other regulatory standards or action.

Section 8.140. -Waiver of Certain Commonwealth Laws.-

No Commonwealth law or regulation approved after the effective date of this Chapter requiring the coverage of a healthcare service or benefit, or requiring the reimbursement, utilization or inclusion of a specific category of healthcare provider or person, shall apply to the health plans delivered by PYMES employer issuers in Puerto Rico, unless as otherwise provided by the law or regulation in question. However, any issuer may elect to comply with the provisions of the law or approved regulation, if doing so inures to the benefit of PYMES employers, as well as their employees and the dependents thereof.

Section 8.150. -Administrative Procedures.-

The Commissioner shall issue regulations as necessary for the implementation of the provisions of this Chapter following the procedure established therefor in Chapter 2 of the Insurance Code of Puerto Rico.

Section 8.160. -Standards to Assure Fair Marketing.-

A. Each issuer shall actively market all health plans sold by the issuer to all PYMES employers in Puerto Rico.

B. No PYMES employer issuer or producer shall, directly or indirectly, engage in the following activities:

(a) Encouraging or directing PYMES employers to refrain from filing an application for coverage with the PYMES employer issuer because of any health status-related factor, industry, occupation or geographic location of the PYMES employer. This provision shall not apply with respect to information provided by a PYMES employer issuer or producer regarding the established geographic service area or a preferred network provision.

C. No issuer shall, directly or indirectly, enter into any contract, agreement or arrangement with a producer that provides for or results in the compensation paid to a producer for the sale of a health plan to be varied because of any initial or renewal health status-related factor of eligible employees or dependents, or industry, occupation or geographic location of the PYMES employer. This provision shall not apply with respect to a compensation arrangement that provides compensation to a producer on the basis of percentage of premium, provided that the percentage shall not vary because of any health status-related factor of eligible employees or dependents, or industry, occupation or geographic location of the PYMES employer.

D. No issuer may terminate, fail to renew or limit its contract or agreement of representation with a producer for any reason related to any initial or renewal health status-related factor of eligible employees or dependents, or industry, occupation or geographic location of the PYMES employer placed by the producer.

E. An issuer or producer may not induce or otherwise encourage a PYMES employer to separate or otherwise exclude an eligible employee or dependent from the benefits of a health plan.

F. Denial by an issuer of an application for health plan from a PYMES employer, for any of the reasons permitted in accordance with the provisions of this Chapter, shall be in writing and shall state the reason or reasons for the denial.

G. Any violation of this Section shall be an unfair trade practice under Chapter 27 of the Insurance Code of Puerto Rico and shall be subject to the sanctions provided therein. If an issuer enters into a contract, agreement or other arrangement with a third-party administrator to provide administrative, marketing or other services related to the offering of health plans to PYMES employer in Puerto Rico, the third-party administrator shall be subject to this Section as if it were an issuer.

Section 8.170. -Required Disclosure.-

A. In connection with the offering for sale of any health plan to a PYMES employer, the issuer shall make a reasonable disclosure, as part of its solicitation and sales materials, of all of the following:

(1) The provisions of the health plan that, in accordance with this Chapter, grant the issuer the right to change rates and the factors therefor, other than claim experience.

(2) The provisions related to the possibility of renewal of policies and contracts.

(3) The provisions related to preexisting conditions.

(4) A listing and descriptive information, including benefits and premiums, on all health plans available for PYMES employers.

Chapter 12. Prohibition on the Use of Discretionary Clauses

Section 12.010. -Title.-

This Chapter shall be known and may be cited as the Chapter on the Prohibition on the Use of Discretionary Clauses.

Section 12.020. -Purpose.-

The purpose of this Chapter is to assure that health insurance benefits and disability income protection coverage are contractually guaranteed so as to prevent the conflict of interest that occurs when health insurance organizations or issuers have discretionary authority to decide what benefits are due. Nothing in this Chapter shall be construed as imposing any requirement or duty on any person other than a health insurance organization or issuer that offers disability income protection coverage.

Section 12.030. -Definitions.-

A. ‘Disability Income Protection Coverage’ is a policy, contract, certificate or agreement that provides for periodic payments, weekly or monthly, for a specified period during the continuance of disability resulting from either sickness or injury or a combination of them.

B. ‘Healthcare Services’ means services for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury or disease.

Section 12.040. -Discretionary Clauses Prohibited.-

A. No policy, contract, certificate or agreement offered or issued in Puerto Rico by a health insurance organization or issuer to provide, deliver, arrange for, pay for or reimburse any of the costs of healthcare services may contain a provision purporting to reserve discretion to health insurance

organizations or issuers to interpret the terms of the contract, or to provide standards of interpretation or review that are inconsistent with the laws of Puerto Rico. An adverse determination by a health insurance organization or issuer, as well as disputes or controversies that may arise between a health insurance organization or issuer and a covered person or enrollee, shall be subject to the internal and external review procedures established in this Code.

B. No policy, contract, certificate or agreement offered or issued in Puerto Rico providing for disability income protection coverage may contain a provision purporting to reserve discretion to the insurer to interpret the terms of the contract, or to provide standards of interpretation or review that are inconsistent with the laws of Puerto Rico.

Chapter 22. Health Insurance Organization or Issuer Grievance Procedure

Section 22.010. -Title.-

This Chapter shall be known and may be cited as the Chapter on Health Insurance Organization or Issuer Grievance Procedure.

Section 22.020. -Purpose.-

The purpose of this Chapter is to provide standards for the establishment and maintenance of procedures by health insurance organizations and issuers to ensure that covered persons or enrollees have the opportunity for the appropriate resolution of grievances, as defined in this Chapter.

Section 22.030. -Definitions.-

For purposes of this Chapter:

A. ‘Covered Benefits’ or ‘Benefits’ means those healthcare services to which a covered person or enrollee is entitled under the terms of a health plan.

B. 'Certification' means a document that contains a determination by a health insurance organization or issuer, or a utilization review organization, that a request for a benefit under a health plan has been reviewed and, based on the information provided, satisfies the health insurance organization or issuer's requirements for medical necessity, appropriateness, healthcare setting, level of care and effectiveness.

C. 'Clinical Review Criteria' means the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by the health insurance organization or issuer to determine the medical necessity and appropriateness of healthcare services.

D. 'Adverse Determination' means:

(1) A determination by a health insurance organization or issuer, or a utilization review organization that, based upon the information provided, a request for a benefit under a health plan, upon application of any utilization review technique, does not meet the health insurance organization or issuer's requirements for medical necessity, appropriateness, healthcare setting, level of care or effectiveness, or is determined to be experimental or investigational, and the requested benefit is therefore denied, reduced, or terminated, or payment is not provided or made, in whole or in part, for such benefit.

(2) The denial, reduction, termination, or failure to make payment, in whole or in part, for a benefit based on a determination by a health insurance organization or issuer, or a utilization review organization, of a covered person or enrollee's eligibility to participate in the health plan; or

(3) Any prospective review or retrospective review determination that denies, reduces, or terminates, or fails to make payment, in whole or in part, for a benefit.

E. 'Stabilized' means, with respect to an emergency medical condition, that no deterioration of the condition of the patient is likely, within reasonable medical probability, before the transfer of such individual from a facility.

F. 'Clinical Peer' means a physician or other healthcare professional who holds a non-restricted license in a state of the United States or in Puerto Rico, and in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review.

G. 'Case Management' means a coordinated set of activities established by a health insurance organization or issuer and conducted for individual patient management of serious, complicated, protracted, or other health conditions.

H. 'Managed Care Plan' means

(1) a health plan that requires a covered person or enrollee to use, or creates incentives, including financial incentives, for a covered person or enrollee to use healthcare providers managed, owned, under contract with, or employed by the health insurance organization or issuer.

(2) A 'Managed Care Plan' includes:

(a) A preferred network plan, as defined in Section 2.020 of this Code; and

(b) An open-ended plan, as defined in Section 2.020 of this Code.

I. 'Utilization Review Organization' means an entity contracted by a health insurance organization or issuer to conduct utilization review when such health insurance organization or issuer does not perform utilization review for its own health plan. It shall not be construed as a requirement for health insurance organizations or issuers to subcontract an independent entity to carry out utilization review processes.

J. 'Health Plan' means an insurance policy, contract, certificate, or agreement issued by a health insurance organization, healthcare service organization, or any other issuer, in exchange for the payment of premiums or on a prepaid basis, through which such health insurance organization, healthcare organization, or other issuer provides or pay for certain medical, hospital, major medical, dental, mental health, or incidental services.

K. 'Discharge Planning' means the formal process for determining, prior to discharge from a facility, the coordination and management of the care that a patient receives following discharge from a facility.

L. 'Grievance' means a written complaint or an oral complaint if the complaint involves an urgent care request, submitted by or on behalf of a covered person or enrollee regarding:

(1) Availability, delivery, or quality of healthcare services, including complaints regarding an adverse determination made pursuant to utilization review;

(2) Claims payment, handling, or reimbursement for healthcare services; or

(3) Matters pertaining to the contractual relationship between a covered person or enrollee and a health insurance organization or issuer.

M. 'Network' means the group of participating providers providing services to a managed care plan.

N. 'Concurrent Review' means utilization review conducted during a patient's stay or course of treatment in a facility, the office of a healthcare professional, or other inpatient or outpatient healthcare setting.

O. 'Ambulatory Review' means utilization review of healthcare services performed or provided in an outpatient setting.

P. 'Utilization Review' means a set of formal techniques designed to monitor healthcare services, procedures, or facilities or to evaluate the medical necessity, appropriateness, efficacy, or efficiency thereof. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning, or retrospective review.

Q. 'Prospective Review' means utilization review conducted prior to the provision of a healthcare service or a course of treatment, in accordance with a health insurance organization or issuer's requirement that such healthcare service or course of treatment, in whole or in part, be approved prior to its provision.

R. 'Retrospective Review' means any review of a request for a benefit that is not a prospective review request. 'Retrospective Review' does not include the review of a claim that is limited to veracity of documentation or accuracy of coding.

S. 'Second Opinion' means an opportunity or requirement to obtain a clinical evaluation by a provider other than the one originally making a recommendation for a proposed healthcare service to assess the medical necessity and appropriateness of such initial proposed healthcare service.

T. 'Urgent Care Request' means:

(1) a request for a healthcare service or course of treatment with respect to which the time period for making a non-urgent care request determination:

(a) Could seriously jeopardize the life or health of the covered person or enrollee or his/her ability to regain maximum function; or

(b) In the opinion of an attending healthcare professional with knowledge of the covered person or enrollee's medical condition, would subject said covered person or enrollee to severe pain that cannot be adequately

managed without the healthcare service or treatment that is the subject of the request.

(2) In determining whether a request is to be treated as an urgent care request, an individual acting on behalf of the health insurance organization or issuer shall apply the judgment of a prudent layperson that possesses an average knowledge of health and medicine. Any request that an attending healthcare professional with knowledge of the covered person or enrollee's medical condition determines is an urgent care request within the meaning of paragraph (1) shall be treated as an urgent care request.

Section 22.040. -Applicability and Scope.-

Except as otherwise specified, this Chapter shall apply to all health insurance organizations or issuers.

None of the provisions of this Chapter shall limit or in any way impair the legal powers of the Office of the Patient's Advocate, the Medical Discipline and Licensure Board, or the Puerto Rico Health Insurance Administration to initiate, investigate, process, or adjudicate new or pending grievances. None of the provisions of this Chapter shall be construed to amend or repeal the laws, regulations, or procedures of the Office of the Patient's Advocate, the Medical Discipline and Licensure Board, or the Puerto Rico Health Insurance Administration.

Section 22.050. -Requirements to Report Grievances to the Commissioner.-

A. Health insurance organizations or issuers shall maintain written records to document all grievances received during a calendar year (the register).

B. A request for a first level review of a grievance involving an adverse determination shall be processed in compliance with Section 22.070. A request for a standard review of a grievance not involving an adverse determination shall be processed in compliance with Section 22.080.

C. A request for an additional voluntary review of a grievance shall be processed in compliance with Section 22.090.

D. For each grievance, the register shall contain at least the following information:

- (1) A general description of the reason(s) for the grievance;
- (2) The date received;
- (3) The date of each review or, if applicable, review meeting;
- (4) Decision/resolution at each level of the grievance, if applicable;
- (5) Date of decision/resolution at each level, if applicable; and
- (6) Name of the covered person or enrollee for whom the grievance was filed.

E. The register shall be maintained in a manner that is clear and accessible to the Commissioner.

F. (1) Health insurance organizations or issuers shall retain the register compiled for a calendar year for the longer of five (5) years or until the Commissioner has issued a final report of an examination that contains a review of the register for that calendar year.

(2) (a) Health insurance organizations or issuers shall submit to the Commissioner, at least annually, a report in the format specified by him/her.

(b) The report shall include the following for each type of health plan offered by the health insurance organization or issuer:

- (i) The certificate of compliance required by Section 22.060(C);
- (ii) The number of covered persons or enrollees;
- (iii) The total number of grievances;
- (iv) The number of grievances for which a covered person or enrollee requested an additional voluntary grievance review pursuant to Section 22.090;
- (v) The number of grievances resolved at each level, if applicable, and their decision/resolution;
- (vi) The number of grievances appealed to the Commissioner of which the health insurance organization or issuer has been informed;
- (vii) The number of grievances referred to alternative dispute resolution procedures, such as mediation or arbitration, or resulting in litigation; and
- (viii) A synopsis of actions taken to correct the problems identified.

Section 22.060. -Grievance Review Procedures.-

A. Except as specified in Section 22.100, health insurance organizations or issuers shall receive and resolve grievances from covered persons or enrollees as provided in Sections 22.070, 22.080, and 22.090.

B. Health insurance organizations or issuers shall file a copy with the Commissioner of the procedures required under Subsection A, including all forms used to process the requests made. Any subsequent modifications to such procedures shall also be filed. The Commissioner may disapprove a filing received if it fails to comply with this Chapter or the applicable regulations.

C. In addition to the provisions of Subsection B, health insurance organizations or issuers shall file annually with the Commissioner, as part of the annual report required by Section 22.050, a certificate of compliance stating that such health insurance organizations or issuers have established and maintain, for each of their health plans, grievance procedures that fully comply with the provisions of this Chapter.

D. A description of the grievance procedures required under this Section shall be included in the policy, certificate, membership booklet, outline of coverage, or other evidence of coverage provided to covered persons or enrollees.

E. The grievance procedures included in the aforementioned documents shall include a statement of a covered person or enrollee's right to contact the Office of the Commissioner of Insurance or the Office of the Patient's Advocate for assistance at any time. The statement shall include the telephone number and address of the Office of the Commissioner of Insurance and the Office of the Patient's Advocate.

Section 22.070. -First Level Reviews of Grievances Involving an Adverse Determination.-

A. Within one hundred eighty (180) days after the receipt of a notice of an adverse determination, a covered person or enrollee, or his/her authorized representative, may file a grievance with the health insurance organization or issuer requesting a first level review of the adverse determination.

B. The health insurance organization or issuer shall provide the covered person or enrollee with the name, address, and telephone number of a person or organization designated to coordinate the first level review on behalf of the health insurance organization or issuer.

C. (1) (a) If the grievance arises from an adverse determination involving utilization review, the health insurance organization or issuer shall designate one or more clinical peers of the same or similar specialty as would typically manage the case being reviewed to review the adverse determination. The designated clinical peer(s) shall not have been involved in the initial adverse determination.

(b) The health insurance organization or issuer shall ensure that, if more than one clinical peer is involved in the review, they have appropriate expertise.

(2) In conducting a review under this Section, the reviewer(s) shall take into consideration all comments, documents, records, and other information regarding the request for services submitted by the covered person or enrollee, or his/her authorized representative, without regard to whether the information was submitted or considered in making the initial adverse determination.

D. (1) (a) The covered person or enrollee or, if applicable, his/her representative shall be entitled to:

(i) Submit written comments, documents, records, and other material related to the grievance under review; and

(ii) Receive from the health insurance organization or issuer, upon request and free of charge, access to and copies of all documents, records, and other information relevant to the grievance.

(b) For purposes of subparagraph (a)(ii), a document, record, or other information shall be considered relevant to a grievance if the document, record, or other information:

(i) Was relied upon in making the benefit determination;

(ii) Was submitted, considered, or generated in the course of making the adverse determination, without regard to whether the document, record, or other information was relied upon in making the benefit determination;

(iii) Demonstrates that, in making the benefit determination, the health insurance organization or issuer consistently applied the same administrative procedures and safeguards with respect to the covered person or enrollee as other similarly situated covered persons or enrollees; or

(iv) Constitutes a statement of policy or guidance with respect to the health plan concerning the denied healthcare service or treatment for the covered person or enrollee's diagnosis, without regard to whether the statement or guidance was relied upon in making the initial adverse determination.

(2) The health insurance organization or issuer shall make the provisions of paragraph (1) known to the covered person or enrollees or, if applicable, his/her authorized representative, within three (3) working days after the date of receipt of the grievance.

E. For purposes of calculating the time periods within which a determination is required to be made and notice provided under Subsection F, the time period shall begin on the date the grievance is filed with the health insurance organization or issuer, without regard to whether all of the information necessary to make the determination accompanies such filing. If the health insurance organization or issuer understands that the grievance does not include all the necessary information to make a determination, it shall clearly indicate the covered person or enrollee or, if applicable, his/her authorized representative, the reasons for which it cannot process such grievance and the additional documents or information that the covered person or enrollee must provide.

F. (1) Health insurance organizations or issuers shall notify and issue a decision in writing, or electronically if the covered person or enrollee or, if applicable, his/her authorized representative, has agreed to be thus notified, within the timeframes provided in paragraph (2) or (3).

(2) With respect to a grievance requesting a first level review of an adverse determination involving a prospective review request, the health insurance organization or issuer shall notify and issue a decision within a reasonable period of time that is appropriate given the covered person or enrollee's medical condition, but not later than fifteen (15) calendar days after the receipt of the grievance.

(3) With respect to a grievance requesting a first level review of an adverse determination involving a retrospective review request, the health insurance organization or issuer shall notify and issue a decision within a reasonable period of time, but not later than thirty (30) calendar days after the receipt of the grievance.

G. The decision issued pursuant to Subsection F shall set forth in a manner that is comprehensible to the covered person or enrollee or, if applicable, his/her authorized representative:

(1) The titles and qualifying credentials of the person or persons participating in the first level review process (the reviewers);

(2) A statement of the reviewers' understanding of the covered person or enrollee's grievance;

(3) The reviewers' decision in clear terms and the contract basis or medical rationale for the covered person or enrollee or, if applicable, his/her authorized representative, to respond to the health insurance organization or issuer's position;

(4) The evidence or documentation used as the basis for the decision;

(5) In the event that the health insurance organization or issuer's first level review decision results in an adverse determination, the following shall also be included:

(a) The specific reasons for the adverse determination;

(b) The reference to the specific health plan provisions on which the determination is based;

(c) A statement that the covered person or enrollee is entitled to receive, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant, as the term 'relevant' is defined in Subsection D(1)(b);

(d) If the health insurance organization or issuer relied upon an internal rule, guideline, protocol, or other similar criterion to make the final adverse determination, a copy of such rule, guideline, protocol, or other similar criterion in which the final adverse determination was based shall be provided, upon request and free of charge, to the covered person or enrollee or, if applicable, his/her authorized representative;

(e) If the final adverse determination is based on a medical necessity, experimental or investigational treatment, or similar exclusion or limit, either an explanation of the scientific or clinical judgment for making the determination or a statement that an explanation shall be provided, upon request and free of charge, to the covered person or enrollee or, if applicable, his/her authorized representative; and

(f) If applicable, instructions for requesting:

(i) A copy of the rule, guideline, protocol, or other similar criterion relied upon in making the final adverse determination, as provided in subparagraph (5)(d); and (ii) A written statement of the scientific or clinical rationale for the determination, as provided in subparagraph (5)(e).

(6) If applicable, a statement indicating:

(a) A description of the process to obtain an additional voluntary review if the covered person or enrollee wishes to request a voluntary review pursuant to Section 22.090;

(b) The written procedures governing the voluntary review, including any required timeframe for the review;

(c) A description of the procedures for obtaining an independent external review, pursuant to this Code's Chapter on Health Insurance Organization or Issuer External Review, if the covered person or enrollee decides not to file for an additional voluntary review; and

(d) The covered person or enrollee's right to bring a civil action in a court of competent jurisdiction;

(7) If applicable, and stressing its voluntary nature, the following statement: 'You and your health plan may have other voluntary alternative dispute resolution options, such as mediation or arbitration. One way to find out what may be available is to contact the Commissioner of Insurance'; and

(8) A statement of a covered person or enrollee's right to contact the Office of the Commissioner of Insurance or the Office of the Patient's Health Advocate for assistance at any time, including the telephone number and address of the Office of the Commissioner of Insurance and the Office of the Patient's Advocate.

Section 22.080. -Standard Reviews of Grievances Not Involving an Adverse Determination.-

A. Health insurance organizations or issuers shall establish written procedures for standard reviews of grievances that do not involve an adverse determination.

B. (1) The procedures shall permit a covered person or enrollee, or his/her authorized representative, to file a grievance that does not involve an adverse determination with the health insurance organization or issuer under this Section.

(2) (a) A covered person or enrollee, or his/her authorized representative, shall be entitled to submit written material for the persons designated by the health insurance organization or issuer to consider when conducting the standard review.

(b) The health insurance organization or issuer shall notify the covered person or enrollee or, if applicable, his/her authorized representative, of such covered person or enrollee's rights pursuant to subparagraph (2)(a) within three (3) business days after receiving the grievance.

C. (1) Upon receipt of the grievance, a health insurance organization or issuer shall designate one or more persons to conduct the standard review.

(2) To conduct the standard review of the grievance, the health insurance organization or issuer shall not designate the same person that handled the matter that is the subject of such grievance.

(3) The health insurance organization or issuer shall provide the covered person or enrollee or, if applicable, his/her authorized representative, with the name, address, and telephone number of the persons designated to conduct the standard review.

D. The health insurance organization or issuer shall provide written notification of the decision to the covered person or enrollee or, if applicable, his/her authorized representative, within thirty (30) calendar days after the receipt of the grievance.

E. The written decision issued pursuant to Subsection D shall contain:

(1) The titles and qualifying credentials of the persons participating in the standard review process (the reviewers);

(2) A statement of the reviewers' understanding of the grievance;

(3) The reviewers' decision in clear terms and the contract basis or medical rationale for the covered person or enrollee to respond to the health insurance organization or issuer's position;

(4) A reference to the evidence or documentation used as the basis for the decision;

(5) If applicable, a written statement including:

(a) A description of the process to obtain an additional voluntary review if the covered person or enrollee wishes to request a voluntary review pursuant to Section 22.090; and

(b) The written procedures governing the voluntary review, including any required timeframe for the review; and

(6) A statement of a covered person or enrollee's right to contact the Office of the Commissioner of Insurance or the Office of the Patient's Advocate for assistance at any time, including the telephone number and address of the Office of the Commissioner of Insurance and the Office of the Patient's Advocate.

Section 22.090. -Voluntary Level of Reviews of Grievances.-

A. (1) A health insurance organization or issuer that offers managed care plans shall establish a voluntary review process for its managed care plans to give those covered persons or enrollees who are dissatisfied with the first level review decision made pursuant to Section 22.070, or who are dissatisfied with the standard review decision made pursuant to Section 22.080, the option to request an additional voluntary review, at which they shall be entitled to appear before the designated representatives of the health insurance organization or issuer.

(2) This Section shall not apply to health indemnity plans.

B. (1) A health insurance organization or issuer required by this Section to establish a voluntary review process shall provide covered persons or enrollees, or their authorized representatives, with a notice pursuant to Section 22.070(G)(6) or Section 22.080(E)(5), as appropriate. Such notice shall indicate the option to file a request for an additional voluntary review.

(2) Upon receipt of a request for an additional voluntary review, the health insurance organization or issuer shall send notice to the covered person or enrollee or, if applicable, his/her authorized representative, of the covered person or enrollee's right to:

(a) Request, within the timeframe specified in paragraph (3)(a), the opportunity to appear in person before a review panel of the health insurance organization or issuer's designated representatives;

(b) Receive from the health insurance organization or issuer, upon request, copies of all documents, records, and other information that is not confidential or privileged, related to the covered person or enrollee's request for an additional voluntary review;

(c) Present the covered person or enrollee's case to the review panel;

(d) Submit written comments, documents, records, and other material related to the request for an additional voluntary review for the review panel to consider both before and during the review meeting, if applicable;

(e) If applicable, ask questions to any representative of the health insurance organization or issuer on the review panel; and

(f) Be assisted or represented by an individual of the covered person or enrollee's choice, including an attorney.

(3) A covered person or enrollee, or his/her authorized representative, who wishes to appear in person before the review panel shall make a written request to the health insurance organization or issuer not later than fifteen (15) business days after the receipt of the notice sent in accordance with paragraph (2).

(b) The covered person or enrollee's right to a fair review shall not be made conditional on such covered person or enrollee's appearance at the review.

C. (1) (a) With respect to a request for voluntary review of a decision made pursuant to Section 22.070, a health insurance organization or issuer shall appoint a review panel to review the request.

(b) In conducting the review, the review panel shall take into consideration all comments, documents, records, and other information regarding the request for an additional voluntary review submitted by the covered person enrollee, or his/her authorized representative, without regard to whether the information was submitted or considered in making the first level review decision.

(c) The panel shall have the legal authority to bind the health insurance organization or issuer to the panel's decision. If, after twenty (20) calendar days, the health insurance organization or issuer fails to comply with the decision of the review panel, the latter shall notify such fact to the Commissioner.

(2) (a) Except as provided in subparagraph (2)(b), a majority of the panel shall be comprised of individuals who were not involved in the first level review decision made pursuant to Section 22.070.

(b) An individual who was involved in the first level review decision may be a member of the panel or appear before the same to present information or answer questions.

(c) The health insurance organization or issuer shall ensure that the individuals conducting the additional voluntary review are healthcare professionals with the appropriate expertise.

(d) The individuals conducting the additional voluntary review shall not:

(i) Be a provider in the covered person or enrollee's health plan; or

(ii) Have a financial interest in the outcome of the review.

D. (1) (a) With respect to a request for an additional voluntary review of a decision made pursuant to Section 22.080, a health insurance organization or issuer shall appoint a review panel to review the request.

(b) The panel shall have the legal authority to bind the health insurance organization or issuer to the panel's decision. If, after twenty (20) calendar days, the health insurance organization or issuer fails to comply with the decision of the review panel, the latter shall notify such fact to the Commissioner.

(2) (a) Except as provided in subparagraph (2)(b), a majority of the panel shall be comprised of employees or representatives of the health insurance organization or issuer who were not involved in the standard review conducted pursuant to Section 22.080.

(b) An employee or representative of the health insurance organization or issuer who participated in the standard review may be a member of the panel or appear before the same to present information or answer questions.

E. (1) (a) Whenever a covered person or enrollee, or his/her authorized representative, requests, within the timeframe specified in subsection C or D, to appear in person before the review panel, the procedures for conducting the additional voluntary review shall be governed by the provisions described hereinbelow.

(b) (i) The review panel shall schedule and hold a review meeting not later than thirty (30) calendar days after the receipt of the request for an additional voluntary review.

(ii) The covered person or enrollee or, if applicable, his/her authorized representative, shall be notified in writing, at least fifteen (15) business days in advance, of the date of the review meeting.

(iii) The health insurance organization or issuer shall not unreasonably deny a request for postponement of the review made by the covered person enrollee, or his/her authorized representative.

(c) The review meeting shall be held during regular business hours at a location reasonably accessible to the covered person or enrollee or, if applicable, his/her authorized representative.

(d) In cases where a face-to-face meeting is not practical for geographic reasons, a health insurance organization or issuer shall offer the covered person or enrollee or, if applicable, his/her authorized representative, the opportunity to communicate with the review panel, at the health insurance organization or issuer's expense, by conference call, video conferencing, or other appropriate technology.

(e) If the health insurance organization or issuer intends to have legal representation, such health insurance organization or issuer shall notify the covered person or enrollee or, if applicable, his/her authorized representative, at least fifteen (15) calendar days in advance of the date of the review meeting. It shall also notify the covered person or enrollee that he/she may obtain legal representation of his/her own.

(f) The review panel shall issue a written decision, as provided in subsection F, to the covered person or enrollee or, if applicable, his/her authorized representative, not more than ten (10) business days of completing the review meeting.

(2) Whenever the covered person or enrollee or, if applicable, his/her authorized representative, does not request the opportunity to appear in person before the review panel, such panel shall issue a decision and notify it in writing or electronically (if it has been agreed to thus notify this decision) as provided in Subsection F, within forty-five (45) calendar days after the earlier of:

(a) The date on which the covered person or enrollee, or his/her authorized representative, notifies the health insurance organization or issuer of the decision not to appear in person before the review panel; or

(b) The date on which the covered person's or enrollee's, or his/her authorized representative's opportunity to request to appear in person before the review panel expires, pursuant to subsection B(3)(a).

F. The written decision issued pursuant to Subsection E shall include:

(1) The titles and qualifying credentials of the members of the review panel;

(2) A statement of the review panel's understanding of the request for an additional voluntary review and all pertinent facts;

- (3) The rationale for the review panel's decision;
- (4) A reference to evidence or documentation considered by the review panel in making that decision;
- (5) In cases concerning a request for an additional voluntary review involving an adverse determination:
 - (a) The instructions for requesting a written statement of the clinical rationale, including the clinical review criteria used to make the determination; and
 - (b) If applicable, a statement describing the procedures for obtaining an independent external review of the adverse determination pursuant to the Chapter on Health Insurance Organization or Issuer External Review of this Code; and
- (6) A statement of a covered person or enrollee's right to contact the Office of the Commissioner of Insurance or the Office of the Patient's Advocate for assistance at any time, including the telephone number and address of the Office of the Commissioner of Insurance and the Office of the Patient's Advocate.

Section 22.100. -Expedited Reviews of Grievances Involving an Adverse Determination.-

A. Health insurance organizations or issuers shall establish written procedures for the expedited review of urgent care requests involving an adverse determination.

B. The procedures shall allow a covered person or enrollee, or his/her authorized representative, to request an expedited review under this Section to the health insurance organization or issuer either orally or in writing.

C. A health insurance organization or issuer shall appoint an appropriate clinical peers in the same or similar specialty as would typically manage the case being reviewed to conduct the expedited review. Such clinical peers shall not have been involved in making the initial adverse determination.

D. In an expedited review, all the necessary information, including the health insurance organization or issuer's decision, shall be transmitted between the health insurance organization or issuer and the covered person or enrollee or, if applicable, his/her authorized representative, by telephone, fax, or the most expeditious method available.

E. An expedited review decision shall be made and the covered person or enrollee or, if applicable, his/her authorized representative, shall be notified of the decision in accordance with Subsection G as expeditiously as the covered person or enrollee's medical condition requires, but in no event in more than forty-eight (48) hours after the receipt of the request for the expedited review.

F. For purposes of calculating the time periods within which a decision is required to be made and notified under Subsection E, the time period shall begin on the date the request for an expedited review is filed with the health insurance organization or issuer without regard to whether all of the information necessary to make the determination accompanies such filing.

G. (1) A notification of a decision shall indicate the following, in a manner that is comprehensible to the covered person or enrollee or, if applicable, his/her authorized representative:

(a) The titles and qualifying credentials of the persons participating in the expedited review process (the reviewers);

(b) A statement of the reviewers' understanding of the covered person's request for an expedited review;

(c) The reviewers' decision in clear terms, and the contract basis or medical rationale for the covered person or enrollee to respond to the health insurance organization or issuer's position;

(d) A reference to the evidence or documentation used as the basis for the decision; and

(e) If the decision results in a final adverse determination, the notice shall provide:

(i) The specific reasons for the final adverse determination;

(ii) Reference to the specific plan provisions on which the determination is based;

(iii) If the health insurance organization or issuer relied upon an internal rule, guideline, protocol, or other similar criterion to make the adverse determination, a copy of such specific rule, guideline, protocol or other similar criterion relied upon to make the adverse determination shall be provided, upon request and free of charge, to the covered person or enrollee;

(iv) If the final adverse determination is based on a medical necessity, experimental or investigational treatment, or similar exclusion or limit, an explanation of the scientific or clinical judgment for making the determination;

(v) If applicable, instructions for requesting:

(I) A copy of the rule, guideline, protocol, or other similar criterion relied upon in making the adverse determination in accordance with clause (e)(iii); or

(II) A written statement of the scientific or clinical rationale for the adverse determination in accordance with clause (e)(iv);

(vi) A description of the procedures for obtaining an independent external review pursuant to the Chapter on Health Insurance Organization or Issuer External Review of this Code;

(vii) A statement indicating the covered person's right to bring a civil action in a court of competent jurisdiction;

(viii) The following statement, stressing the voluntary nature of the procedures: 'You and your health plan may have other voluntary alternative dispute resolution options, such as mediation or arbitration. One way to find out what may be available is to contact the Commissioner of Insurance'; and

(ix) A statement of a covered person or enrollee's right to contact the Office of the Commissioner of Insurance or the Office of the Patient's Advocate for assistance at any time. The statement shall include the telephone number and address of the Office of the Commissioner of Insurance and the Office of the Patient's Advocate.

(2) (a) A health insurance organization or issuer shall provide the notice required under this Section orally, in writing, or electronically.

(b) If notice of the adverse determination is provided orally, the health insurance organization or issuer shall provide written or electronic notice within three (3) days following the oral notification.

(3) None of these provisions shall be construed to limit the power of a health insurance organization or issuer to render an adverse determination ineffective without following the procedure set forth herein.

Chapter 54. Coverage for Newborn and Recently Adopted Children and Children Placed for Adoption

Section 54.010. -Title.-

This Chapter shall be known and may be cited as the Chapter on Coverage for Newborn and Newly Adopted Children and Children Placed for Adoption.

Section 54.020. -Purpose.-

The purpose of this Chapter is to provide for uniformity of coverage requirements for newborn and newly adopted children and children placed for adoption under both group and individual health plans.

Section 54.030. -Definitions.-

For purposes of this Chapter:

A. 'Health Plan' means a policy, contract, certificate, or agreement offered or issued by a health insurance organization or issuer to provide, deliver, arrange for healthcare service or pay for or reimburse the costs thereof.

Section 54.040. -Applicability.-

A. Except as provided in Subsection B, this Chapter shall apply to health plans that provide coverage for a dependent of a covered person or enrollee.

B. The provisions of this Chapter shall not apply to a group or individual health plan that provides coverage only for a specified disease, specified accident or accident-only coverage, credit, dental, disability income, hospital indemnity or other fixed indemnity coverage, vision care or any other supplemental benefit or a Medicare supplement policy, coverage under a plan through Medicare, Medicaid or the federal employees health benefits program, any coverage issued as supplemental to liability insurance, workers' compensation or similar insurance, automobile medical-payment insurance or any insurance under which benefits are payable with or without regard to fault.

Section 54.050. -Coverage Requirements.-

A. Each health plan subject to this Chapter shall provide coverage to:

(1) A newborn child of a covered person or enrollee from the moment of birth; or

(2) A newly adopted child of a covered person or enrollee from the earlier of:

(a) The date of placement in the home of the covered person or enrollee for the purpose of adoption and continues in the same manner as other dependents of the covered person or enrollee unless the placement is disrupted prior to legal adoption and the child is removed from placement;

(b) The date of entry of an order granting the covered person or enrollee custody of the child for purposes of adoption; or

(c) The effective date of adoption.

B. The coverage for newborn and newly adopted children and children placed for adoption shall meet the following requirements:

(1) Include coverage of injury or sickness healthcare services including the necessary care and treatment of medically diagnosed congenital defects and birth abnormalities; and

(2) Is not subject to any preexisting condition exclusion.

Section 54.060. -Notification Requirements.-

A. For a newborn child, the health insurance organization or issuer shall be required to provide covered persons or enrollees with reasonable notice of the following:

(1) If payment of a specific premium or subscription fee is required to provide coverage for a newborn child, as provided in this Chapter, the health plan may require the covered person or enrollee to notify the health insurance organization or issuer of the birth of the child and furnish payment of the required premium or fees within thirty (30) days after the date of birth.

(2) If notice and the payment described above are not provided, the health insurance organization or issuer may refuse to continue coverage for the child under the health plan beyond the thirty (30)-day period. However, if within four (4) months after the birth of the child the covered person or enrollee makes all past-due payments, coverage shall be restored.

(3) If payment of a specific premium or subscription fee is not required to provide coverage for a newborn child, the health insurance organization or issuer may request notification of the birth of the child, but shall not deny or refuse to continue coverage if the covered person or enrollee does not furnish the notice.

B. For a newly adopted child or child placed for adoption, the health insurance organization or issuer shall be required to provide covered persons or enrollees with reasonable notice of the following:

(1) If payment of a specific premium or subscription fee is required to provide coverage for a newly adopted child or child placed for adoption, the health plan may require the covered person or enrollee to notify the health insurance organization or issuer of the adoption or placement for adoption and furnish payment of the required premium or fees within thirty (30) days after coverage is required to begin under Section 54.050A(2).

(2) If the covered person fails to provide the notice or make the payment described in the preceding paragraph within the thirty (30)-day period, the health insurance organization or issuer shall treat the adopted child or child placed for adoption no less favorably than it treats other dependents, other than newborn children, who seek coverage at a time other than when the dependent was first eligible to apply for coverage.

Chapter 66. Long-term Care Insurance

Section 66.010. -Title.-

This Chapter shall be known and may be cited as the Chapter on Long-term Care Insurance.

Section 66.020. -Scope.-

The requirements of this Chapter shall apply to policies delivered or issued for delivery in Puerto Rico on or after the effective date thereof. This Chapter is

not intended to supersede the obligations of entities subject to this Chapter to comply with the provisions of other applicable insurance laws insofar as they do not conflict with this Chapter, except that laws and regulations designed and intended to apply to Medicare supplement insurance policies shall not be applied to long-term care insurance.

Section 66.030. -Purpose.-

The purpose of this Chapter is to promote the public interest, and the availability of long-term care insurance policies, to protect applicants for long-term care insurance, as defined, from unfair or deceptive sales or enrollment practices, to establish standards for long-term care insurance, to facilitate public understanding and comparison of long-term care insurance policies, and to facilitate flexibility and innovation in the development of long-term care insurance coverage.

Section 66.040. -Definitions.-

For purposes of this Chapter:

A. ‘Certificate’ means any certificate issued under a group long-term care insurance policy, policy has been delivered or issued for delivery in Puerto Rico.

B. ‘Qualified Long-term Care Insurance Contract’ or ‘Federally Tax-qualified Long-term Care Insurance Contract’ means an individual or group insurance contract that meets the requirements of the U.S. Internal Revenue Code of 1986, as amended, as follows:

(1) The only insurance protection provided under the contract is coverage of qualified long-term care services established in accordance with Federal income tax laws. A contract shall not fail to satisfy the requirements of this paragraph by reason of payments being made on a periodic basis (per diem or other period) without regard to the expenses incurred during such period;

(2) The contract does not provide for the payment or reimbursement of expenses incurred for services or items that are reimbursable under Title XVIII of the Social Security Act, as amended, or would be so reimbursable but for the application of a deductible or coinsurance amount. The requirements of this paragraph do not apply to expenses that are reimbursable under Title XVIII of the Social Security Act only as a secondary payor. A contract shall not fail to satisfy the requirements of this paragraph by reason of payments being made on a periodic basis (per diem or other period) without regard to the expenses incurred during such period;

(3) The contract is guaranteed renewable, as defined in the U.S. Internal Revenue Code of 1986, as amended;

(4) The contract does not provide for a cash surrender value or other money that can be paid, assigned, pledged as collateral for a loan, or borrowed except as provided in Section 66.040 B (1)(e) of this Chapter;

(5) All refunds of premiums, and all policyholder dividends or similar amounts, under the contract shall be applied as a reduction in future premiums or to increase future benefits, except that a refund on the event of death of the enrollee or a complete surrender or cancellation of the contract cannot exceed the aggregate premiums paid under the contract; and

(6) The contract meets the consumer protection provisions set forth in the U. S. Internal Revenue Code of 1986, as amended.

‘Qualified Long-term Care Insurance Contract’ or ‘Federally Tax-qualified Long-term Care Insurance Contract’ also means the portion of a life insurance contract that provides long-term care insurance coverage by rider or as part of the contract and that satisfies the requirements of the U. S. Internal Revenue Code of 1986, as amended.

C. 'Policy' means any policy, contract, subscriber agreement, rider or endorsement delivered or issued for delivery in Puerto Rico by an issuer authorized to market disability insurance in Puerto Rico.

D. 'Long-term Care Insurance' means:

(1) Any insurance policy or rider advertised, marketed, offered or designed to provide coverage for not less than twelve (12) consecutive months on an expense incurred, indemnity, prepaid or other basis; for one or more necessary or medically necessary diagnostic, preventive, therapeutic, rehabilitative, maintenance or personal care services, provided in a setting other than an acute care unit of a hospital.

(2) The term includes group and individual annuities and life insurance policies or riders that provide directly or supplement long-term care insurance. The term also includes a policy or rider that provides for payment of benefits based upon cognitive impairment or the loss of functional capacity. The term shall also include federally tax-qualified long-term care insurance contracts.

(3) Long-term Care Insurance may be issued by issuers authorized to issue disability insurance.

(4) Long-term Care Insurance shall not include any insurance policy that is offered primarily to provide basic Medicare supplement coverage, basic hospital expense coverage, basic medical-surgical expense coverage, hospital confinement indemnity coverage, major medical expense coverage, disability income or related asset-protection coverage, accident only coverage, specified disease or specified accident coverage, or limited benefit health coverage.

(5) With regard to life insurance, this term shall not include life insurance policies that accelerate the death benefit specifically for one or more of the qualifying events of terminal illness, medical conditions requiring extraordinary medical intervention or permanent institutional confinement, and that

provide the option of a lump-sum payment for those benefits and where neither the benefits nor the eligibility for the benefits is conditioned upon the receipt of long-term care. Notwithstanding any other provision of this Chapter, any product advertised, marketed or offered as long-term care insurance shall be subject to the provisions of this Chapter.

E. ‘Group Long-term Care Insurance’ means a long-term care insurance policy that is delivered or issued for delivery in Puerto Rico and issued to:

(1) One or more employers or labor organizations, or to a trust or to the trustees of a fund established by one or more employers or labor organizations, or a combination thereof, for employees or former employees or a combination thereof or for members or former members or a combination thereof, of the labor organizations; or

(2) Any professional, trade or occupational association for its members or former or retired members, or combination thereof, if the association:

(a) Is composed of individuals all of whom are or were actively engaged in the same profession, trade or occupation; and

(b) Has been maintained in good faith for purposes other than obtaining insurance; or

(3) An association or a trust or the trustees of a fund established, created or maintained for the benefit of members of one or more associations. Prior to advertising, marketing, or offering the policy in Puerto Rico, the association or the issuer of the association, shall file evidence with the Commissioner, since the beginning, that the association has been organized and maintained in good faith for purposes other than obtaining insurance; has been in active existence for at least one (1) year; and has a constitution and bylaws that provide that:

(a) The association holds regular meetings not less than annually to further purposes of the members;

(b) Except for cooperative banks, the association collects dues or solicit contributions from members; and

(c) The members have voting privileges and representation on the governing board and committees.

Thirty (30) days after the filing the association will be deemed to satisfy the organizational requirements, unless the Commissioner determines otherwise.

(4) To qualify as a group long-term care insurance, the issuer shall ensure that the minimum requirements regarding the number of covered persons or enrollees set forth in Chapter 14.010 of the Insurance Code of Puerto Rico are met.

F. 'Applicant' means:

(1) In the case of an individual long-term care insurance policy, the person who seeks to obtain insurance.

(2) In the case of a group long-term care insurance policy, the proposed certificate holder.

Section 66.050. -Extraterritorial Jurisdiction—Group Long-Term Care Insurance.-

No group long-term care insurance coverage may be offered to a resident of Puerto Rico under a group policy issued in another state to a group described in Section 66.040E, unless the Government of Puerto Rico, or the government of another state having statutory and regulatory long-term care insurance requirements substantially similar to those adopted in Puerto Rico, has made a determination that such requirements have been met.

Section 66.060. -Disclosure and Performance Standards for Long-Term Care Insurance.-

A. The Commissioner may adopt regulations that include standards for full and fair disclosure setting forth the manner, content and required disclosures for the sale of long-term care insurance policies, terms of renewability, initial and subsequent conditions of eligibility, non-duplication of coverage provisions, coverage of dependents, preexisting conditions, termination of insurance, continuation or conversion, waiting periods, limitations, exceptions, reductions, elimination periods, requirements for replacement, recurrent conditions and definitions of terms.

B. No long-term care insurance policy may:

(1) Be cancelled, nonrenewed or otherwise terminated on the grounds of the age or the deterioration of the mental or physical health of the enrollee or certificate holder; or

(2) Contain a provision establishing a new waiting period in the event existing coverage is converted to or replaced by a new or other form within the same company, except with respect to an increase in benefits voluntarily selected by the enrollee or group policyholder; or

(3) Provide coverage for skilled nursing care only or provide significantly more coverage for skilled care in a facility than coverage for lower levels of care.

C. Preexisting Condition.

(1) No long-term care insurance policy or certificate shall use a definition of 'preexisting condition' that is more restrictive than the following:

'Preexisting Condition means a condition for which medical advice or treatment was recommended by, or received from a provider of healthcare services,

within six (6) months preceding the effective date of coverage of a covered person.’

(2) No long-term care insurance policy or certificate may exclude coverage for a loss or confinement that is the result of a preexisting condition unless the loss or confinement begins within six (6) months following the effective date of coverage of a covered person.

(3) The definition of ‘preexisting condition’ does not prohibit an issuer from using an application form designed to elicit the complete health history of an applicant, and, on the basis of the answers on that application, from underwriting in accordance with that issuer’s established underwriting standards. Unless otherwise provided in the policy or certificate, a preexisting condition, regardless of whether it is disclosed on the application, need not be covered until the waiting period described in subsection C(2) expires. No long-term care insurance policy or certificate may exclude or use waivers or riders of any kind to exclude, limit or reduce coverage or benefits for specifically named or described preexisting diseases or physical conditions beyond the waiting period described in subsection C(2).

D. Prior hospitalization/institutionalization.

(1) No long-term care insurance policy may be delivered or issued for delivery in Puerto Rico if the policy:

(a) Conditions eligibility for any benefits on a prior hospitalization requirement;

(b) Conditions eligibility for benefits provided in an institutional care setting on the receipt of a higher level of institutional care; or

(c) Conditions eligibility for any benefits other than waiver of premium, post-confinement, post-acute care or recuperative benefits on a prior institutionalization requirement.

(2) (a) A long-term care insurance policy containing post-confinement, post-acute care or recuperative benefits shall clearly label in a separate paragraph of the policy or certificate entitled 'Limitations or Conditions on Eligibility for Benefits' such limitations or conditions, including any required number of days of confinement.

(b) A long-term care insurance policy or rider that conditions eligibility of non-institutional benefits on the prior receipt of institutional care shall not require a prior institutional stay of more than thirty (30) days.

(3) No long-term care insurance policy or rider that provides benefits only following institutionalization shall condition such benefits upon admission to a facility for the same or related conditions within a period of less than thirty (30) days after discharge from the institution.

E. The Commissioner may adopt regulations establishing loss ratio standards for long-term care insurance policies.

F. Right to Return. Long-term care insurance applicants shall have the right to return the policy or certificate within thirty (30) days of its delivery and to have the premium refunded if, after examination of the policy or certificate, the applicant is not satisfied for any reason. Long-term care insurance policies and certificates shall have a notice prominently printed on the first page or attached thereto stating in substance that the applicant shall have the right to return the policy or certificate within thirty (30) days of its delivery and to have the premium refunded if, after examination of the policy or certificate, the applicant is not satisfied for any reason. This subsection shall also apply to denials of applications. Any refund must be made within thirty (30) days of the return or denial.

G. Outline of Coverage:

(1) An outline of coverage shall be delivered to a prospective applicant or long-term care insurance at the time of initial solicitation. The outline shall be provided through means that prominently direct the attention of the recipient to the document and its purpose.

(a) The Commissioner shall prescribe a standard format, including style, arrangement and overall appearance, and the content of an outline of coverage.

(b) In the case of producer solicitations, a producer shall deliver the outline of coverage prior to the presentation of an application or enrollment form.

(2) The outline of coverage shall include:

(a) A description of the principal benefits and coverage provided in the policy;

(b) A statement of the principal exclusions, reductions and limitations contained in the policy;

(c) A statement of the terms under which the policy or certificate, or both, may be continued in force or discontinued, including any reservation in the policy of a right to change premium. Continuation or conversion provisions of group coverage shall be specifically described;

(d) A statement that the outline of coverage is a summary only, not a contract of insurance, and that the policy or group master policy contains governing contractual provisions;

(e) A description of the terms under which the policy or certificate may be returned and premium refunded;

(f) A brief description of the relationship of cost of care and benefits; and

(g) A statement that discloses to the policyholder or certificate holder whether the policy is intended to be a federally tax-qualified long-term care insurance contract.

H. A certificate issued pursuant to a group long-term care insurance policy that policy is delivered or issued for delivery in Puerto Rico shall include:

(1) A description of the principal benefits and coverage provided in the policy;

(2) A statement of the principal exclusions, reductions and limitations contained in the policy; and

(3) A statement that the group master policy determines governing contractual provisions.

I. If an application for a long-term care insurance contract is approved, the issuer shall deliver the contract or certificate of insurance to the applicant not later than thirty (30) days after the date of approval.

J. At the time of policy delivery, a policy summary shall be delivered for an individual life insurance policy that provides long-term care benefits within the policy or by rider. In addition to meeting all applicable requirements, the summary shall also include:

(1) An explanation of how the long-term care benefit interacts with other components of the policy, including deductions from death benefits;

(2) An illustration of the amount of benefits, the length of benefit, and the guaranteed lifetime benefits if any, for each covered person or enrollee;

(3) Any exclusions, reductions, and limitations on benefits of long-term care;

(4) A statement that any long-term care inflation protection option is not available under this policy;

(5) If applicable to the policy type, the summary shall also include:

- (a) A disclosure of the effects of exercising other rights under the policy;
- (b) A disclosure of guarantees related to long-term care costs of insurance charges; and
- (c) Current and projected maximum lifetime benefits.

K. Any time a long-term care benefit, funded through a life insurance vehicle by the acceleration of the death benefit, is in benefit payment status, a monthly report shall be provided to the policyholder or certificate holder. The report shall include:

- (1) Any long-term care benefits paid out during the month;
- (2) An explanation of any changes in the policy, e.g. death benefits or policy cash values, due to long-term care benefits being paid out; and
- (3) The amount of long-term care benefits existing or remaining.

L. If a claim under a long-term care insurance contract is denied, the issuer, or a representative thereof, within sixty (60) days of the date of a written request by the policyholder or certificate holder shall:

- (1) Provide a written explanation of the reasons for the denial; and
- (2) Make available all information directly related to the denial.

M. Any policy or rider advertised, marketed or offered as long-term care or nursing home insurance shall comply with the provisions of this Chapter.

Section 66.070. -Incontestability Period.-

A. For a policy or certificate that has been in force for less than six (6) months, an issuer may rescind a long-term care insurance policy or certificate or deny an otherwise valid long-term care insurance claim upon a showing of misrepresentation that is material to the acceptance for coverage or to the risk assumed by the issuer.

B. For a policy or certificate that has been in force for at least six (6) months but less than two (2) years, an issuer may rescind a long-term care insurance policy or certificate or deny an otherwise valid long-term care insurance claim upon a showing of misrepresentation that is both material to the acceptance for coverage and which pertains to the condition for which benefits are sought.

C. After a policy or certificate has been in force for two (2) years, it is not contestable upon the grounds of misrepresentation alone; such policy or certificate may be contested only upon a showing that the enrollee knowingly and intentionally misrepresented relevant facts relating to his/her health status.

D. Long-term care insurance policies or certificates may be field issued by third-party administrators if the compensation to the producer or third party administrator is not based on the number of policies or certificates issued. For purposes of this Section, 'field issued' means a policy or certificate issued by a producer or a third-party administrator pursuant to the underwriting authority granted to the producer or third-party administrator by an issuer and using the issuer's underwriting guidelines.

E. If an issuer has paid benefits under the long-term care insurance policy or certificate, the benefit payments may not be recovered by the insurer in the event that the policy or certificate is rescinded.

F. In the event of the death of the enrollee, this Section shall not apply to the remaining death benefit of a life insurance policy that accelerates benefits for long-term care. In this situation, the remaining death benefits under these policies shall be governed by the provisions of law applicable to life insurance. In all other situations, this Section shall apply to life insurance policies that accelerate benefits for long-term care.

Section 66.080. -Nonforfeiture Benefits.-

A. Except as provided in Subsection B, a long-term care insurance policy may not be delivered or issued for delivery in Puerto Rico unless the policyholder or certificate holder has been offered the option of purchasing a policy or certificate including a nonforfeiture benefit. The offer of a nonforfeiture benefit may be in the form of a rider that is attached to the policy. In the event the policyholder or certificate holder declines the nonforfeiture benefit, the issuer shall provide a contingent benefit upon lapse that shall be available for a specified period of time following a substantial increase in premium rates.

B. When a group long-term care insurance policy is issued, the offer required in Subsection A shall be made to the group policyholder.

C. The Commissioner shall promulgate regulations specifying the type or types of nonforfeiture benefits to be offered as part of long-term care insurance policies and certificates, the standards for nonforfeiture benefits, and the rules regarding contingent benefit upon lapse, including a determination of the specified period of time during which a contingent benefit upon lapse will be available and the substantial premium rate increase that triggers a contingent benefit upon lapse as described in subsection A.

Section 66.090. -Producer Training Requirements.-

A. The following requirements related to the sale, soliciting or negotiating long-term care insurance shall be met:

(1) An individual may not sell, solicit or negotiate long-term care insurance unless the individual has an insurance producer license which authorizes him/her to underwrite disability insurance and has completed the required training course. The training shall meet the requirements set forth in subsection B.

(2) An individual already licensed and selling, soliciting or negotiating long-term care insurance on the effective date of this Chapter may not continue to sell, solicit or negotiate long-term care insurance unless the individual has completed the required training course as set forth in subsection B, within one (1) year from the effective date of this Chapter.

(3) In addition to the training course required in paragraphs (1) and (2), an individual who sells, solicits or negotiates long-term care insurance shall complete ongoing training as set forth in subsection B.

(4) The training requirements of subsection B may be approved as continuing education courses under Rule 52 of the Insurance Code of Puerto Rico Regulations.

B. The training required by this Section shall be not less than eight (8) hours and the ongoing training required by this Section shall be not less than four (4) hours every twenty-four (24) months.

The training shall consist of topics related to long-term care insurance, long-term care services and, if applicable, qualified state long-term care insurance partnership programs, including, but not limited to:

(1) Commonwealth and Federal regulations and requirements and the relationship between qualified state long-term care insurance partnership programs and other public and private coverage of long-term care services, including Medicaid;

(2) Available long-term services and providers;

(3) Changes or improvements in long-term care services or providers;

(4) Alternatives to the purchase of private long-term care insurance;

(5) The effect of inflation on benefits and the importance of inflation protection; and

(6) Consumer suitability standards and guidelines.

The training required by this Section shall not include training that is issuer or company product specific or that includes any sales or marketing information, materials, or training, other than those required by Commonwealth or Federal law.

C. Issuers subject to this Chapter shall obtain verification that a producer receives training required by this Section before a producer is permitted to sell, solicit or negotiate the issuer's long-term care insurance products, maintain records subject to the Commonwealth's record retention requirements, and make that verification available to the Commissioner upon request. Issuers subject to this Chapter shall maintain records with respect to the training of its producers concerning the distribution of its partnership policies, if applicable, that will allow the Commissioner to provide assurance to the state Medicaid agency that producers have received the training described in this Section and that producers have demonstrated an understanding of the partnership policies, if applicable, and their relationship to public and private coverage of long-term care, including Medicaid, in Puerto Rico. These records shall be maintained in accordance with the Commonwealth's retention requirements and shall be made available to the Commissioner upon request.

D. The satisfaction of these training requirements in any state shall be deemed to satisfy the training requirements in Puerto Rico.

Section 66.100. -Rulemaking Authority.-

The Commissioner shall issue reasonable regulations to promote premium adequacy and to protect the policyholder or certificate holder in the event of substantial rate increases, and to establish minimum standards for producer

education, marketing practices, producer compensation, producer testing, penalties and reporting practices for long-term care insurance.

The Commissioner shall issue reasonable regulations to promote premium adequacy and to protect the policyholder or certificate holder in the event of substantial rate increases, and to establish minimum standards for producer education, marketing practices, producer compensation, producer testing, penalties and reporting practices for long-term care insurance [sic].

Section 66.130. -Penalties.-

In addition to any other penalties provided by the laws of Puerto Rico including the Insurance Code of Puerto Rico, any issuer and any producer found to have violated any requirement of Puerto Rico related to the regulation of long-term care insurance or the marketing of such insurance shall be subject to a fine which shall be the greater of the following amounts: up to three (3) times the amount of any commissions paid for each policy involved in the violation, or up to \$10,000.”

Section 2.- This Act shall take effect one hundred eighty (180) days after its approval.

CERTIFICATION

I hereby certify to the Secretary of State that the following **Act No. 194-2011 (S. B. 1856) (Conference)** of the **5th Session of the 16th Legislature** of Puerto Rico:

AN ACT to create the Puerto Rico Health Insurance Code; establish its general provisions and the manner in which this Code shall interact with the Insurance Code of Puerto Rico; regulate the management of prescription drugs by health insurance organizations or issuers, as defined; standardize the healthcare claims audit process in Puerto Rico; promote the availability of health plans to employers of small- and medium-sized businesses in Puerto Rico, regardless of the health conditions or claim experience of their employee group; prohibit the use of discretionary clauses in health plans and disability income protection coverage; etc.

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

In San Juan, Puerto Rico, on this 1st day of October, 2013.

Juan Luis Martínez Martínez
Acting Director