Government of Puerto Rico
Health Insurance Administration

GENERAL REGULATION OF THE HEALTH INSURANCE ADMINISTRATION OF PUERTO RICO

ASES
ADMINISTRACIÓN DE SEGUROS DE SALUD DE PUERTO RICO

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INTRODUCTION

Act No. 72-1993, as amended, created the Health Insurance Administration (hereinafter "ASES" or "Administration") for the primary purpose of implementing, administering and negotiating, through contracts with insurers and/or health services organizations, a health insurance system that would allow the medical-indigent population of Puerto Rico to receive quality medical-hospital health care. These efforts sought to do justice to the most disadvantaged sectors guaranteeing access to quality health care, regardless of their economic condition and ability to pay.

With this aspiration, the State has granted the Administration the authority to negotiate and contract with insurers and other organizations to provide the medical-hospital services of the Government's Health Plan (hereinafter "GHP"). For this, Act No. 72 allows the Administration to establish the necessary mechanisms to supervise the services offered under the GHP, to supervise and to ensure that these are provided efficiently and in accordance with the best administrative and medical practices.

The service model adopted by the Administration and approved by the Federal Government is focused on offering integrated health services, both in their physical and mental modalities. In addition, the model promoted by ASES gives special emphasis to preventive health for healthy lifestyles, vaccination of children and elderly people, control of alcohol and illicit substance abuse, early detection of HIV/AIDS and prenatal care for children and mothers.

On the other hand, Reorganization Plan No. Three (3) of July 29, 2010, authorizes, empowers and transfers powers to ASES to administer, negotiate, contract and manage health benefits for retired persons and public employees pursuant to Act No. 95 of 1963 and its Regulations.

This regulation is promulgated under the power conferred by Act No. 72 and Act No. 95 to ASES, to give a regulatory framework to the different functions that it must exert. This represents an advance in the healthy management of the Administration and is the first regulatory review since the implementation, for the first time in Puerto Rico, of the Health Reform of the nineties.

Also, this Regulation serves as an educational tool for the beneficiaries of the GHP, as it instructs on the mechanisms available to challenge the decisions by the insurers or contracted organizations that are deemed unfair or erroneous. Similarly, the Regulation clearly outlines the obligations and responsibilities of the insurers and other organizations contracted to provide health services, as well as those of their providers and subcontractors.

ARTICLE 1 – TITLE, APPLICABILITY AND PURPOSE OF THE REGULATION

A. TITLE: This document will be known as the "General Regulation of the Health Insurance Administration of Puerto Rico" (hereinafter, the "Regulation"). The abbreviated title of this regulation is the "General Regulation of ASES".

B. APPLICABILITY: This Regulation will apply to all Insurers and Health Services Organizations (HSO), service providers, Pharmacy Benefits Administrators, the beneficiaries of the insurance and health services of the State and any intermediary organization contracted by Insurers and the HSOs.

C. PURPOSE OF THE REGULATION: The purpose of this Regulation is to establish fair, uniform and efficient procedures governing all the insurance and health services of the State. This includes the hiring, auditing and evaluation of the services offered by the Insurers and HSO contracted by ASES to offer the medical-hospital services. Similarly, this Regulation will establish the administrative mechanisms that allow to address complaints, challenges and appeals of the beneficiaries and impose penalties and fines to those Insurers and HSO that have failed to fulfil their contractual obligations. Finally, this Regulation also establishes the conditions necessary to comply with the statutory and regulatory requirements of the federal government.

ARTICLE 2 – LEGAL BASIS

This Regulation is issued under Act No. 72-1993, Law of the Health Insurance Administration (hereinafter, "Act 72") and the Uniform Administrative Procedure Act of the Government of Puerto Rico, Act 38-2017 (hereinafter, the "LPAU") as amended. In addition, it is set within the legal framework established by Title XIX of the Social Security Act of 1935, as amended (hereinafter, the "Social Security Act"), the *Medicaid* Program and the *Children's Health Insurance Program* (hereinafter, "CHIP") and Act 95-1963.

ARTICLE 3 – DEFINITIONS

A. The following terms used in this Regulation have the meanings set forth below, except where the context clearly indicates a different meaning

1. ACCESS: Adequate availability of all health care services required and contemplated in the model of the contracted health insurance plan.

2. ADMINISTRATION or ASES: Health Insurance Administration of the Government of Puerto Rico

3. AFFILIATE: Beneficiary who subscribes to one of the Insurers or HSO to provide him/her with medical and hospital services.

4. APPEAL: A formal request from an affected party to review an adverse decision.

5. INSURER: Entity authorized by the Insurance Commissioner to do health insurance business in Puerto Rico or created by any special law for these purposes.

6. BONA FIDE ASSOCIATION: Organization constituted with the purpose that its associates and members can obtain health insurance or a medical plan in compliance with all the criteria established in the Insurance Code.

7. ASSMCA: Administration of Mental Health and Anti-Addiction Services of the Government of Puerto Rico.

8. AVERAGE WHOLESALE PRICE or AWP: The average price at which a brand name drug is available on the market in nationally recognized publications and for which its use is standard in the industry.

9. BENEFICIARY: Any person entitled to receive the benefits provided in the health insurance plans contracted by virtue of Act No. 72-1993, as amended and who has subscribed to the plan.

10. DOUBLE ELIGIBILITY BENEFICIARY: Individual who is eligible to receive benefits from both the Medicaid and Medicare Programs.

11. CENTERS FOR MEDICARE & MEDICAID SERVICES or CMS: Instrumentality within the Federal Health Department in charge of the Medicaid, Medicare and CHIPS Programs.

12. ELIGIBILITY CERTIFICATION: Determination performed by the Medicaid Program in Puerto Rico indicating that a person is eligible to receive services from the GHP.

13. CHILDREN'S HEALTH INSURANCE PROGRAM or CHIP: Federal Program established by Title XXI of the Social Security Act.

14. ELECTIVE SURGERY: Surgical procedure, medically necessary, and recommended by a physician-surgeon, which does not need to be carried out immediately because it does not represent an imminent risk to life,

permanent damage of a vital organ or danger of permanent disability to the beneficiary, therefore, it can be programmed.

15. CO-INSURANCE: Percentage share of the insured for each loss or portion of the cost of receiving a service.

16. BASIC COVERAGE: Set of medical-hospital physical and mental services in the GHP for all beneficiaries.

17. COMISSIONER: Officer in charge of the Insurance Commissioner Office of Puerto Rico.

18. INSURANCE CONTRACT: The contractual relationship between the Administration and the Insurers and public or private HSO or other entity contracted under some health insurance plan model.

19. CREDENTIALING: Process by which an Insurer, HSO or Pharmacy Benefits Manager determines that a provider is qualified to provide a specific health service.

20. HEALTH BENEFITS COVERAGE: All the benefits included in a health benefit plan.

21. CARE MANAGEMENT or MANAGED CARE: Administrative function composed of a series of steps or stages focused on the beneficiary with intensive or high-risk needs to ensure that he/she receives the necessary services in an effective, efficient, timely and cost-effective manner.

22. PRIMARY CARE: All medical care and laboratory services provided by a general practitioner, family physician, primary care physician, obstetrician/gynecologist, pediatrician or other licensed professional authorized by the Administration, to the extent that the provision of these services is legally authorized.

23. DEDUCTIBLE: Fixed and predetermined amount that the beneficiary has to pay the provider as his/her contribution to the cost of the benefits he/she receives.

24. DEPARTMENT: Health Department of the Government of Puerto Rico.

25. DISENROLLMENT: Termination of the subscription of a beneficiary with a determined Insurer or HSO.

26. ADVERSE BENEFIT DETERMINATION: The denial or limited authorization of a requested service, including the duration, the type or level of service; the reduction, suspension or termination of a previously authorized service, the requirements for adequacy of the medical necessity, the establishment or effectiveness of a covered benefit; the denial, in whole or in part, of the payment of a service (even in circumstances in which a beneficiary is obliged to pay a service); failure to provide services in a timely manner (within the time limits established in this Contract or established by the Administration); the fact that the Contractor has not acted within the time limits stipulated in 42 CFR 438,408 (b); or the denial of the request for a beneficiary to dispute a financial liability, including shared costs, copayments, premiums, deductibles, co-insurance and other financial liabilities of the beneficiary. In the case of residents of rural areas, as defined in 42 CFR 438.52, denial of a beneficiary's request to exercise his/her right to obtain out-of-network services.

27. DRUG or MEDICATION: A medicine or substance approved or regulated by the Federal Food and Drug Administration (FDA), which has been approved for marketing and whose supply and dispatch (written order of a licensed physician) is regulated by the laws of Puerto Rico and/or the United States.

28. MEDICAL EMERGENCY/IMPERATIVE NEED: A sudden and unforeseen medical condition that requires immediate medical attention to meet an imminent risk to life, permanent damage to a vital organ, or a risk of permanent disability.

29. EVALUATION: Review made by the Administration to determine the level of compliance of an Insurer, HSO, Pharmacy Benefit Manager or any of its providers with the obligations agreed as part of the physical and mental health services of the GHP. This includes those made to determine their level of preparation to begin to provide services to their beneficiaries as those performed periodically, not announced or as a product of any audit, inspection or otherwise as established by the Administration.

30. MEDICAL FILE or MEDICAL RECORD: It is the longitudinal and chronological compilation composed of demographic and physical and/or mental behavioral health information of the beneficiary, family health history, if required and/or provided by the beneficiary, which is completed, documented and guarded by the health service provider and originated and recorded electronically, in paper format or both mediums. This file includes, but is not limited to, the health history, diagnoses, drug history, allergies, progress notes made by the health care provider, treatments, ordered diagnostic test results (clinical laboratory, X-rays, nuclear tests, images, sounds, among others) and may include dental impressions. The term described in this subparagraph also applies to the file that a provider

generates in the course of providing health care services and is subject to the protection of privacy, confidentiality and security under federal and state regulations.

31. HEALTH FACILITIES: Those defined in Act No.101 of June 20,1905, as amended. These include, but are not limited to, hospitals, laboratories, outpatient services centers, and other facilities that provide mental physical health services to beneficiaries of the GHP, Medicaid, Medicare or CHIPS.

32. MEDICAL-HOSPITAL FACILITIES: Place in which physical and mental health services are provided to beneficiaries and which houses at least two (2) providers.

33. STATE MEDICAL-HOSPITAL FACILITIES: Medical-hospital facilities that belong to the Government or to some municipality.

34. PHARMACIST: Any person duly authorized to practice the profession of pharmacy in Puerto Rico according to Act No. 247-2004, as amended, known as "Puerto Rico Pharmacy Law".

35. PHARMACY: Health service establishment located physically in the jurisdiction of Puerto Rico, authorized and registered in accordance with the provisions of the law, to provide pharmaceutical services.

36. FRAUD: An intentional deception made with the knowledge that it could result in some unauthorized benefit or financial gain. Includes any act or omission that constitutes fraud under applicable state and federal laws.

37. PRIMARY MEDICAL GROUP or PMG: Group or association of primary care physicians and other providers, organized to provide medical-hospital services to beneficiaries of the Government's Health Plan.

38. ENROLLMENT: Process by which a beneficiary subscribes to a medical-hospital service plans of an Insurer.

39. BOARD OF DIRECTORS: Board of Directors of the Puerto Rico Health Insurance Administration.

40. MAXIMUM ALLOWABLE COST or MAC: The maximum price that a Pharmacy Benefits Manager or Insurer will pay to a pharmacy for generic drugs.

41. *MEDICAID*: Joint State and Federal medical assistance program under Title XIX of the Social Security Act.

42. *MEDICARE*: Federal medical assistance program for persons sixty-five (65) years of age or older pursuant to Title XVIII of the Social Security Act; some people with disabilities and people with end stage renal disease.

43. DOCTOR / PHYSICIAN: Doctor of medicine legally authorized to practice medicine and surgery in Puerto Rico.

44. SUPPORT PHYSICIAN: A participating professional provider that offers complementary services and support to primary care physicians. To obtain benefits from them, the beneficiary must be referred by the primary care physician. The following are considered support physicians: cardiologists, endocrinologists, neurologists, psychiatrists, ophthalmologists, radiologists, nephrologists, physiatrists, orthopedists, general surgeons and other physicians not included in the definition of primary care physician.

45. PRIMARY CARE PHYSICIAN*:* Participating professional provider who initially evaluates and gives treatment to the beneficiaries. He/she is responsible for determining the services that the beneficiary requires, providing continuity, referring beneficiaries to specialized services. The following are considered primary care physicians: general practitioners, intern physicians, family physicians, pediatricians, gynecologists and obstetricians.

46. LIAISON OFFICER: Officer or staff of the Administration appointed by this to serve as facilitator and coordinator with a Contractor under the GHP in general or in a specific area.

47. INSURANCE COMMISIONER'S OFFICE: Entity that regulates insurers and health services organizations In Puerto Rico.

48. HEALTH SERVICES ORGANIZATIONS or HSO: Medical primary care groups, medical support groups and groups of primary providers that comply with the contracting requirements established by the Administration to provide health services through a model of physical and mental health services. Health Services Organizations are included under this definition, as defined in Act No. 113 of June 2, 1976, as amended, known as the "Health Services Organizations Act", incorporated in the Puerto Rico Insurance Code, Art. 19,020 et. seq, (26 L.P.R.A. § 1902).

49. CAPITATION: That part of the premium paid to the Insurers and HSO for each beneficiary, so that these, in turn, pay their providers for the medical-hospital services provided to the beneficiaries. The fixed payment that the Administration makes in favor of the providers for each beneficiary is also included in this term.

50. SMALL AND MEDIUM ENTERPRISE (SME) EMPLOYER: Any person, firm, corporation, partnership, profit or non-profit association that has employed for at least fifty (50) percent of its working days of its previous calendar year, at least two (2), but not more than fifty (50) eligible employees.

51. ANNUAL FREE ENROLLMENT PERIOD: Annual period during which eligible beneficiaries of the GHP can join an Insurer and HSO.

52. CORRECTIVE ACTION PLAN: Detailed plan that the Administration requires an Insurer or HSO or another entity contracted under the Government Health Plan or under the provisions of Act 95-1963, or health services provider, due to a deficiency or failure identified by an audit, inspection or evaluation process.

53. HEALTH PLAN OF THE GOVERNMENT OF PUERTO RICO or GHP: Medical-hospital services plan for indigent people that includes beneficiaries eligible under the Medicaid, Medicare and CHIPS Federal Programs.

54. PRE-AUTHORIZATION / PRE-CERTIFICATION: Written document by which the Insurers and HSO authorize the beneficiary to obtain a benefit and without which the requested service will not be offered.

55. PREMIUM: Remuneration that the Administration was obliged to pay to Insurers and HSO for assuming the risk of providing agreed services by signing a health insurance contract.

56. PROVIDER: Natural person or facility authorized under the laws of the Government of Puerto Rico to offer health care services.

57. SME PROVIDER or PROVIDER OF BONA FIDES ASSOCIATIONS: Any entity authorized by the Commissioner to offer medical plans to the eligible employees of an SME or to the members of a bona fide association, in accordance with the provisions of Act No. 43-2018.

58. PREFERRED PROVIDER: All providers of health care services contracted by the Insurers to provide health care services to beneficiaries represented by the Administration and who belong to the Preferred Provider Network.

59. PARTICIPATING SUPPORT PROVIDERS: Providers of health care services that are needed to provide complementary and supportive services to the Selected Primary Care Physicians. In order to obtain benefits from these providers, the beneficiary must be referred by the Selected Primary Care Physician.

60. COMPLAINT OR GRIEVANCE: Statement of dissatisfaction with any matter or service that a beneficiary or provider makes and which does not constitute "Adverse Determination as to any Benefit" as defined in this Regulation.

61. CO-PAYMENT: A payment to be made by the beneficiary to a provider as part of an obligation shared with the Insurer to pay for a specific service that is predetermined by the Administration.

62. ELEGIBILITY RECERTIFICATION: Process performed by the Medicaid Program in Puerto Rico to determine that a person is again eligible to receive the benefits of the GHP.

63. GENERAL PROVIDER NETWORK or GENERAL NETWORK: All providers who maintain contracts to provide services with an Insurer or HSO and that do not belong to its group of Preferred Providers.

64. PREFERRED PROVIDER NETWORK or PREFERRED NETWORK: A group of providers to whom the beneficiaries can access without requiring a referral from their Primary Care Physician or a pre-authorization; and who provide services to beneficiaries without imposing co-payments or deductibles on Medicaid or CHIP beneficiaries.

65. AUTHORIZED REPRESENTATIVE: Person to whom the beneficiary gives a written authorization to make decisions concerning the beneficiary's health.

66. MENTAL HEALTH: For purposes of this Regulation, is a general term that collects the various mental health conditions that a person could have, including psychiatric conditions, mental and emotional disorders, substance abuse, addictions and chemical dependencies.

67. SECRETARY: Officer or person in charge of the direction of the Department of Health.

68. COMPLEMENTARY SERVICES: Professional services, including laboratory, radiology, physical therapy and respiratory therapy, are provided in combination with other types of medical or hospital care.

69. EMERGENCY SERVICES: Any physical or mental health services provided by a qualified provider in an emergency room, that is necessary to evaluate or stabilize an emergency physical or psychiatric condition.

70. COMPLAINTS AND APPEALS SYSTEM: A mechanism that Insurers, HSO and Pharmacy Benefit Managers must have in their administrative structure to address complaints, appeals and reconsiderations of their beneficiaries or providers, guaranteeing due process of law.

71. ELECTRONIC RECORD SYSTEM: Electronic record of information related to the health of a beneficiary that is created, compiled and consulted by authorized physicians and staff and certified by *The Office of the National Coordinator's Authorized Testing and Certification Bodies ("ONC-ATCBs").*

72. REQUEST FOR PROPOSAL or RFP: An informal and flexible procedure whereby the Government can acquire specialized or technical goods and services through the publication of a request detailing the need for services or goods and the requirements, factors and procedures so that any interested party may submit a proposal to meet the need; in accordance with relevant regulations, laws and jurisprudence.

73. SUB-CONTRACTOR: Any person or organization that is not a medical service provider of any GHP coverage, which is subcontracted by a principal contractor to perform any function or service to meet Government obligations, as agreed in a principal contract.

74. ADMINISTRATIVE HEARING: Hearing held in the administrative forum before an officer authorized by the Administration, in accordance with state and federal statutes and regulations, in which a beneficiary, Insurer and/or HSO may challenge or appeal adverse decisions or the imposition of fines and/or penalties.

ARTICLE 4 – GENERAL PROVISIONS

A. It is an essential element of public policy of the Government of Puerto Rico to have an integrated system of medical-hospital health services, both physical and mental, that emphasizes the prevention, promotion of healthy lifestyles and the offering of quality care services.

B. The Administration is the Agency to which Act No. 72 has entrusted duties and responsibilities regarding the provision of medical services under the Title XIX of the Social Security Act of 1935 (*Medicaid*), as amended, and under the Title XXI of the same law (*Children's Health Insurance Program or* "CHIP").

C. The Administration serves a diverse population under Medicaid, Medicare, CHIP, and other programs and special projects.

D. Article IV, section 2(p) of Act No. 72 empowers the Administration to approve, amend and repeal regulations to govern the affairs and activities of the Administration and to prescribe the rules and regulations necessary for the fulfilment of its functions and duties, as established in the LPAU.

ARTICLE 5 – APPLICABLE LAWS, RULES AND REGULATIONS

A. The following laws, rules and regulations are pertinent, in a non-exhaustive way, to ASES and the GHP:

1. 34 CFR ("Code of Federal Regulation");
2. OMB Omni circular 2 CFR Part 200 issued by the Federal Government's Office of Management and Budget (OMB);
3. Official Notification of Federal Funds Subsidy or "Grant Award Notification" (GAN);
4. Constitution of Puerto Rico;
5. Constitution of the United States;
6. Act No. 72-1993, Health Insurance Administration Act;
7. Puerto Rico Insurance Code;
8. Act No. 43-2018;
9. Act No. 38-2017, "Uniform Administrative Procedure Law";
10. Act No. 51-1996,"Comprehensive Services for People with Disabilities Act" or any law that replaces it;
11. Social Security Act of 1935, as amended;
12. Act No. 194-2000, also known as the Patient's Bill of Rights;
13. Act No. 11-2011, as amended, Law that creates the Patient's Advocate Office;
14. Act No. 408-2000, Mental Health Code of Puerto Rico;
15. *Health Insurance Portability and Accountability Act (HIPAA)* of 1996;
16. Health Information Technology for Economic and Clinical Health ("HITECH") Act: Public Law 111-5 (2009);
17. Act No. 95 of June 29, 1963, as amended.

ARTICLE 6 – HEALTH INSURANCE ADMINISTRATION

A. The Administration is responsible for the following minimum functions:

1. To implement medical-hospital service plans based in health insurance;

2. To negotiate and contract with Insurers and HSO, medical-hospital insurance coverages for the beneficiaries of the GHP;

3. To negotiate and contract directly with health care providers, those health services that the Administration deems appropriate, considering their capacity and structure;

4. To negotiate the purchase of medicines, as well as the management of pharmacy benefits with third parties, depending on the circumstances required for the best administration of funds and/or services. This includes, but is not limited to, the purchase of medicines directly from unique manufacturers or suppliers when such management impacts in a better management of finances and is in the welfare of the beneficiary, and the negotiation and award of reimbursements, subject to the relevant state and federal provisions.

5. To maintain a Division of Continuing Education and Prevention for the promotion, development, emphasis and strengthening of activities and training to participating health plan providers implemented and managed by the Administration;

6. To impose administrative fines, corrective measures and penalties on any Insurer, HSO, service provider, pharmacy benefit manager or any other subcontractor, which violates any provision of law or its concomitant regulations, instruction, norms or guideline of the Administration or for which it is responsible, as well as failure to comply with any obligation assumed under the contracts granted with the Administration in fulfillment of the responsibilities granted to this one by those Laws;

7. To administer contracts granted with Insurers, HSO, pharmacy benefits manager and/or other entities contracted to provide services to beneficiaries of the Government's Health Plan and/or ensure the provision of services to them.

8. To monitor the efficiency and performance of Insurers, HSO, pharmacy benefits manager and/or other entities contracted to provide services to beneficiaries of the Government's Health Plan and/or ensure the provision of services to them;

9. To supervise all operational aspects of Insurers, HSO, pharmacy benefits manager and/or other entities contracted to provide services to beneficiaries of the Government's Health Plan and/or ensure the provision of services to them;

10. To establish a secure electronic computer system whereby the Insurers and HSO can submit the documents required by the Administration guaranteeing the confidentiality of the files and safeguarding the privacy of the beneficiaries.

B. SERVICE DELIVERY MODEL

The GHP aspires to maintain a beneficiary-centered model that integrates physical and mental health services and that puts health prevention and education as a priority. Listed below are the elements that must be present in any service delivery model adopted to govern the GHP:

1. Model Recognized by CMS
    i. Regardless of the administration structure chosen for the provision of medical-hospital services, it must be recognized by CMS.

2. Comprehensive Nature of the Services
    i. Care received by beneficiaries must include integrated physical and mental health services.

3. Emphasis on Prevention
    i. Prevention is a priority; therefore, the areas of health education and related services must be strengthened.

4. Primary Care
    i. Primary care of the beneficiary will be the responsibility of the Primary Care Physicians. As part of his/her responsibilities, the Primary Care Physician must provide, coordinate and manage all the services of the beneficiary in a timely manner and strictly follow the guidelines, protocols and general practices of the profession.

5. Participation and Competition
    i. The chosen model must stimulate and encourage the participation and competition of health entities for the administration of the regions, in such a way that impacts in higher quality services.

6. Free selection
    i. Beneficiaries may select their Primary Medical Group and their Primary Care Physician within those contracted by Insurers and HSO to form their Provider Network.

7. Referrals
    i. Beneficiaries will not require referrals from their Primary Care Physicians to receive provider services in the Preferred Provider Network;
    ii. As a general rule, the referral will only be required when the beneficiary chooses to receive services from a provider of the General Provider Network;
    iii. Beneficiaries of special coverages shall not require referrals to receive services under the terms and conditions of such coverage.

8. The Administration may establish administrative requirements as referrals, and/or protocols and medical guidelines, uniform for all contracted Insurers and HSO.

9. Providers
    i. Insurers and HSO must have a number of physicians, specialists and facilities available within their provider networks, capable of efficiently serving their beneficiaries, without affecting the quality of the services and according to the standards of ASES and CMS.

    ii. If the Administration delegates the contracting of pharmacies to one or more Pharmacy Benefits Managers, the Pharmacy Benefits Managers must have available within their networks a number of pharmacies sufficient to serve the beneficiaries in an efficient way, without affecting the quality of the services and according to the standards of ASES and CMS.

10. Emergency Services
    i. Emergency room and ambulance transportation services will be considered high priority. They must be available to all beneficiaries twenty-four (24) hours a day, seven (7) days a week, throughout Puerto Rico. Providers must immediately provide health care services in emergencies when requested by the beneficiaries.

11. Centralized Quality Control Program
    i. Any delivery model must have and follow strict measures to ensure the efficiency and competence of the services received by the beneficiaries. This entails a coordinated and systematic effort to ensure healthy management and proper and efficient use of the program and its funds. Among the measures and mechanisms to be included for this are the following:

        a) To verify that the provider credentialing procedures that the Insurers and HSO perform, is in accordance with the applicable federal and state guidelines, regulations and laws;
        b) To make regular visits and inspections to the facilities where the GHP's health services are provided;
        c) To review the outpatient and hospital services offered to identify deficiencies;
        d) To analyze the services paid, in such a way that it is possible to ascertain that measures are being established to maximize the funds;
        e) To establish systems of pre-authorizations that avoid the abuse of services;
        f) To collect information to identify the level of satisfaction of beneficiaries with the services received;

g) Among other evidence-based practices and measures and accurate data.

12. Provider Network
    i. Insurers and HSO will have a General Provider Network and a Preferred Network.

13. Compliance with the State Plan
    i. Regardless of the administrative service delivery model chosen, it must always comply faithfully with the provisions established in the State Plan approved by the federal government.

C. All models will be reinforced by a health and prevention education system, with special emphasis on lifestyle, HIV/AIDS, drug addiction, and maternal and child health.

D. Benefits Coverage

1. In a general and non-exhaustive way, the coverage of the GHP guarantees the following services under contractual conditions with the Insurers and in accordance with the federal regulations and statutes:

    i. Preventives;
    ii. Diagnostic tests;
    iii. Rehabilitation;
    iv. Medical-Surgical;
    v. Maternity and Prenatal;
    vi. Emergency;
    vii. Emergency Transportation;
    viii. Hospital;
    ix. Mental Health;
    x. Pharmacy.

2. The coverage of services only includes the jurisdiction of Puerto Rico except for any exemption established by any federal program and that has been adopted by the Administration.

3. Pharmacy Services
    i. Pharmacy services must ensure a prompt and efficient dispatch of medications that in turn has robust inventory controls.

E. Contracting of Insurers and HSO

1. The administration will contract health insurance plans for eligible individuals

i. Only insurers who have been authorized by the Puerto Rico Insurance Commissioner to do health insurance business or who have been authorized by any special law to perform such duties shall be contracted;

ii. The Administration may use the Request for Proposal mechanism as part of the insurers contracting process.

2. Specifications regarding the process of Competitive Requests for Proposals:

i. The Administration may prepare and publish Requests for Proposals (RFPs) so that the entities authorized to contract with ASES can submit their proposals and participate in the competitive process of negotiated purchase, by meeting the requirements and criteria that the aforementioned Agency establishes.

ii. The content and form of Requests for Proposals must comply with applicable state and federal provisions, as well as jurisprudence. These requests must give specific instructions and include at least:

a) Instructions to bidders;
b) Procedures and rules for the submission of the proposal and the subsequent adjudication;
c) Specifications, definitions, terms and conditions;
d) Experience and utilization requirements;
e) Demographic data of the population to be cared for;
f) Quotation forms;
g) Among others.

3. Evaluation of Proposals

i. The proposals shall be deemed to be under evaluation or consideration immediately after receipt by the Administration within the established deadline and until the official adjudication of the selected proposal is notified;

ii. As long as the proposals are being evaluated, bidders, their representatives and other stakeholders must refrain from communicating in any way with any employee, officer or agent of the Administration who is participating in or coordinating the evaluation of the above-mentioned proposals;

iii. If necessary, the staff in charge of the process may require clarifications or additional information from any or all bidders, if this results in a better understanding of the proposals submitted;

iv. All proposals will be evaluated taking into consideration applicable leveling elements, in addition to the quoted price and which, in the opinion of the Administration, affect the desired service and/or the final cost;

v. The Administration will develop evaluation guidelines for the analysis and adjudication of the proposals. The criteria to be used, as well as the weight that they will have in the analysis, will be informed, in general, in the convocation that the Agency carries out. If a new evaluation criterion which has not been indicated in the Request for Proposal is subsequently added, it must be informed to all bidders and given the opportunity to submit any amendments to their proposals or additional information for the purpose of meeting the new criterion;

vi. The Administration may reject any proposal that:

a) does not comply with the requirements established in the convocation or its amendments; or that

b) has been delivered outside the established term;

vii. Rejections and adjudications of proposals shall be notified in writing to the bidder or his representative. In the case of rejection notifications, these shall contain the reasons for rejection of the proposal, as well as specifying the manner in which the bidder may submit a reconsideration of the decision;

viii. Any contract granted under the proposals submitted, and for the purpose of providing medical-hospital services, shall contain the necessary clauses to comply with state and federal requirements and regulations, and to ensure the offering of quality services to beneficiaries.

ARTICLE 7 – PREMIUMS, DEDUCTIBLES AND CO-PAYMENTS

A. The administration will negotiate with the insurers and OSS, the premium agreed with them independently

B. The Administration shall establish the deductibles and co-payments according to the beneficiary's income level and capacity to pay, which will be periodically reviewed by the Administration to implement the necessary adjustments.

C. The beneficiaries will have the obligation to make the co-payments according to the category of beneficiary to which they belong.

D. No provider may charge beneficiaries an amount exceeding that established as a deductible and/or coinsurance in its contract with the Administration.

E. Insurers and HSO will not be able to increase their premiums at any time or reduce the benefits in any of their policies as a mechanism to subsidize or level their losses or subsidize other premiums.

F. For purposes of structuring and setting costs or premiums, Insurers and HSO, will consider the group of beneficiaries of the GHP, as an independent unit of their other groups of beneficiaries, and will maintain a separate accounting system for them.

ARTICLE 8 – BENEFICIARIES

A. Eligibility

1. The following individuals may be qualified as eligible individuals for state health insurance pursuant to Act No. 72:

   i. Persons or families who have been certified, either in whole or in part, as medical-indigent by the Medical Assistance Program of the Health Department (including cohabitants and substantial dependents);

   ii. All beneficiaries who, by legislative provision, may benefit from the activities of the Administration and are sheltered under the provisions of Act No. 72.

2. The Health Department will identify and certify to the Administration the individuals eligible for the services according to their income level and their eligibility to receive health benefits, in accordance with current state and federal laws and regulations

B. Subscription / Enrollment

1. Insurers and HSO must accept, without restriction, the subscription of all eligible individuals who have been selected or assigned by the Administration within the terms set forth therein. In no way can they discriminate with eligible individuals on the basis of sex, sexual orientation, gender identity, gender expression or real or perceived sexual orientation, race, religion, nationality, origin, disability, developmental deficiency , health problems, pre-existing conditions or special health needs;

2. The Insurers and HSO will maintain the structure and operations necessary to ensure an efficient subscription system that facilitates the prompt offering of services. In addition, they will provide the necessary information to their

potential beneficiaries so that they can make a timely and informed decision;

C. Disenrollment

1. Beneficiaries shall have those disenrollment rights established in applicable laws and regulations including the 42 CFR 438.56(d)(2), and any other provision determined by the Administration.

D. Beneficiaries Rights and Responsibilities

1. Beneficiaries shall be entitled to:
   i. Receive quality medical services when they need them;
   ii. Easy access to medical services;
   iii. Select their Insurer or HSO from those contracted by the Administration under the GHP;
   iv. Select their Primary Care Physician or Group;
   v. Select their physician specialist taking into consideration the recommendations of their primary care physician;
   vi. Change their Primary Care Physician, Insurer or HSO;
   vii. Not be denied services under the coverage;
   viii. Easy and immediate access to emergency services
   ix. Receive the necessary education and information to know all the benefits that health insurance offers;
   x. not be discriminated against;
   xi. Initiate a formal complaint procedure with Insurers and HSO if they have a complaint or concern about the health care services offered to them under the plan;
   xii. Appeal any final determination of the Insurers or HSO before the Administration; or any final determination by the Administration before the Puerto Rico Court of Appeals.

2. Beneficiaries are responsible to:

   i. Keep their eligibility information updated under the Medical Assistance Program of the Department of Health;

   ii. Keep their health in good shape through the adoption of a healthy lifestyle and adherence to treatments recommended by their physicians;

   iii. Once notified of their eligibility, they must complete any further procedures required by the Administration as part of the GHP.

E. Selection and Changes of Primary Care Groups and Primary Care Physicians

1. Selection
   i. Beneficiaries may select their Physician and Primary Group;

   ii. Insurers and HSO may give suggestions to their beneficiaries as to the selection of their primary care physician, but they may not impose him/her.

2. Changes
   i. Beneficiaries may request changes of a Physician or Primary Group, which shall enter into force in accordance with the contractual terms agreed with the Administration.

   ii. Changes without specific cause:

      a) Any beneficiary may change his/her Primary Medical Group or Primary Care Physician without specific cause:

         1) Within ninety (90) days after the effective date of enrollment;
         2) Once a year, during the period specified by the Administration or notified by the Insurer or HSO; or any other period established or notified by the Administration.

   iii. Changes with specific cause

      a) Insurers and HSO may allow changes of a Physician or Primary Group at any time whenever any of the following specific causes are present:

         1) The moral or religious convictions of the beneficiary are in conflict with the services provided by the Physician or Primary Group;

         2) The beneficiary requires that the related services be provided concurrently, the services are not within the preferred network of providers and the primary care physician or other providers have determined that not receiving the services concurrently could represent a potential risk to the health of the beneficiary;

         3) Deterioration of the relationship between the provider and the beneficiary including the lack of comfort or trust of the beneficiary with him/her;

4) The beneficiary understands that the services received are of low quality or that the providers have little experience to meet his/her medical needs;

5) The beneficiary is constantly experiencing difficulty in scheduling appointments.

6) The Physician with whom the beneficiary has an active treatment no longer serves to the Primary Group.

3. Insurers and HSO may request to ASES the disenrollment of a beneficiary, or change the Primary Medical Group of the beneficiary at the request of the Primary Care Physician, when there is evidence that:

   i. The beneficiary's participation may affect the services that he or other beneficiaries receive;
   ii. The beneficiary demonstrates a pattern of disruptive or abusive behavior that is not produced by any disease;
   iii. The beneficiary has committed fraud or abusive use of the services (for example, allowing another person to use his/her identification to receive medical and hospital services).

4. In any instance of change, the Insurer or HSO shall ensure that access to the beneficiary's health services is not interrupted during the transition to a new Insurer or HSO, or a new Physician or Primary Group.

ARTICLE 9 – IDENTIFICATION CARDS

A. Insurers and HSO will issue identification cards (according to the format previously approved by the Administration) of a durable plastic material that serves as an identification so that the beneficiaries can receive the benefits covered by the providers.

B. The identification card shall be similar to those issued by the Insurers and HSO to the rest of its beneficiaries and shall not include information that may identify the beneficiary as a medically-indigent.

C. Insurers and HSO will be responsible for the distribution of identification cards. The enrollment process will culminate with the delivery of the identification cards to the beneficiaries and at that time they are eligible to receive health care services.

D. The cards provided by the Insurers and HSO will contain the minimum information required by the federal regulations and statutes and in compliance with the specifications agreed with the Administration.

E. Insurers and HSO will be obliged to provide a card replacement in the following circumstances and terms:

1. When the beneficiary requests a replacement: no more than ten (10) calendar days counted since he/she made the request;
2. When the subscriber reports a change of legal name: no more than ten (10) calendar days counted since the beneficiary reported the change;
3. When there is a change of the primary care provider or group: no more than twenty (20) calendar days counted since the beneficiary requested it.

F. Insurers and HSO may not issue identification cards other than those provided to other insured under different coverage plans.

G. The identification cards will be considered the property of the Insurers and HSO and they will be returned to them, once the beneficiary's eligibility has concluded or when he/she is going to change his/her Insurer or HSO.

ARTICLE 10 – INSURERS AND HEALTH SERVICES ORGANIZATIONS (HSO)

A. General Provisions

1. Every Insurer and HSO contracted by the Administration to offer medical and hospital services under the GHP must collaborate with the Government, diligently, to achieve the following objectives:

i. To ensure timely and appropriate access to covered services to the beneficiaries of the GHP, giving particular emphasis to health education, preventive care and the promotion of healthy lifestyles;

ii. To guarantee coverage to beneficiaries throughout Puerto Rico;

iii. To promote competition among contractors, subcontractors and service providers in such a way as to impact in the offering and maintenance of higher quality services;

iv. To require contractors, subcontractors and providers to associate with the State's specialized hospital institutions as established by the Administration;

v. To promote that contractors and subcontractors are associated with local providers such as primary medical

groups and provider groups or associations, to facilitate the use of the profession's best practices at the island level; as well as the permanence of the providers' relationship with the beneficiaries of the plan;

vi. To establish mechanisms to maximize the offering of services and to guarantee their quality, also ensuring that they are cost-efficient.

vii. To use industry best practices that are evidence-based using accurate and up-to-date data and information.

2. To maintain an organizational and administrative structure and the necessary personnel to carry out all the tasks, to provide all the services and to comply with all the responsibilities delegated by the Government in terms of the provision of health services.

3. The Administration shall inform the Insurers or HSO of the instructions applicable for the provision of coverage to those SMEs that request participation in the GHP under the applicable laws and regulations.

B. Location of corporate and administrative offices

1. All administrative offices of the Insurer, HSO and Pharmacy Benefits Manager shall be established within the jurisdiction of the United States. However, those offices or divisions that meet the following functions or service areas, including personnel with authority to make decisions on them, must be specifically located in Puerto Rico as applicable:

i. Care Management
ii. Marketing
iii. Pre-authorizations and service coverage
iv. Complaints and Appeals Division and/or Challenges
v. Beneficiaries services
vi. Provider Networks and Contracting Management
vii. Payments to providers

C. Corporate changes requiring written authorization from the Administration

1. Insurers, HSO and Pharmacy Benefits Manager require written authorization from the Administration to make changes concerning:

i. their contact information (telephones from their business offices, electronic mail, fax number and postal address, among others);
ii. status and nature of the corporation;

iii. place where their business offices are located;
iv. corporate structure;
v. owners and their contact information and corporate profile;
vi. status of incorporation processes.

D. Changes that require Insurers, HSO and Pharmacy Benefit Manager to notify the Administration in a timely manner:

1. Insurers, HSO and Pharmacy Benefit Manager shall notify the Administration, within a period not exceeding five (5) working days from the time it was informed, of any changes concerning:

i. solvency;
ii. location of corporate offices;
iii. its corporate officers or top executives;
iv. people in charge of executive positions;

E. Documentation and Information Materials

1. General Provisions

i. Every Insurer and HSO must have procedures and policies that govern the development and distribution of their documents.

ii. The documents and information materials to be used by the Insurer and HSO must be accessible in both Spanish and English.

iii. Any information material must be written in such a way that any beneficiary with at least a fourth grade of education can understand it.

iv. Insurers and HSO will be responsible for the preparation, publication and distribution of information brochures at their own cost.

v. Every Insurer and HSO must submit digitally and in a copy the information material they intend to provide to their beneficiaries before starting to use them.

vi. No information material may be published or distributed without the prior authorization of the Administration.

vii. The documentation, manuals or any other information material provided by the Insurer must comply with the contractual clauses agreed on this subject.

2. Information Material for Insured Persons

i. Among the information that the Insurers and HSO must provide to their insured are the following:

a) Coverage and benefits of the insured as well as its restrictions;
b) The comprehensive nature of the plan;
c) A "Beneficiary's Manual";
d) Rights and responsibilities;
e) Methods and mechanisms for obtaining mental health services;
f) Instructions for emergency cases
g) How and where to file a complaint or appeal an adverse determination;
h) How to report any suspicion of fraud or abuse;
i) Provider listing;
j) Insurers policies and procedures

ii. Insurers and HSO will also be responsible for the preparation and dissemination, at their own cost, of a community-orientation program covering the aspects of logistics related to the structure, use, benefits and accessibility of medical plan services for the beneficiaries of each health region.

iii. The information material of the Insurers and HSO must also be available electronically on their website for the easy access of their beneficiaries.

iv. Any information material must be made available to persons with disabilities in conformity with state and federal provisions.

3. Documentation to send to the Administration

i. Among the information material to be sent to the Administration for approval are the following;

a) Information brochures, as well as their distribution plan;
b) Beneficiary Handbook;
c) Providers Directory;
d) Format and content of identification cards;
e) Education material;
f) Policies and procedures;
g) List of services included in their coverage
h) Notifications to beneficiaries;

i) Any other information material requested by the Administration.

4. Changes in the Insurers policies or procedures

i. Insurers and HSO shall notify their beneficiaries in writing before any significant changes to any policy or procedure are entered into force in respect of:

a) The form and manner of applying for and making changes to Primary Medical Groups or to the Primary Care Physician;
b) Beneficiaries' rights and responsibilities;
c) The policies reported in the Beneficiary's Handbook

5. Beneficiary's Handbook

i. Insurers and HSO must develop a "Beneficiary Handbook" to be delivered to all new insureds in accordance with state and federal regulations and statutes and the terms and conditions agreed upon by the Administration.

ii. Manual Supplement

a) At least once a year, Insurers and HSO must mail or make electronically accessible a Supplement to the Beneficiary's Handbook to update the information pertinent to the beneficiary.

F. Complaints and Appeals Division or Area of Insurers, HSO and Pharmacy Benefits Manager:

1. Insurers, HSO and Pharmacy Benefits Managers who contract with the Administration to provide services under the GHP must establish a Complaints and Appeals Division or Area in their administrative structure.

2. The Administration shall develop guidelines or manuals to delineate the minimum requirements for the grievance procedures to be followed by all Insurers, HSO, Pharmacy Benefits Managers and Providers with whom it contracts under the GHP in such a way that they comply with the guarantees of due process of law as ordered by Article VI, Sect. 10 of Act No. 72.

3. Jurisdiction

i. This area or division shall receive, assist and resolve the complaints and appeals of its beneficiaries and suppliers;

ii. It will take care of requests for reconsideration;

iii. It shall report the right to administrative views in the Administration in accordance with the provisions of the Uniform Administrative Procedures Act.

4. Insurers, HSO and Pharmacy Benefits Managers will be responsible for establishing appropriate procedures to ensure beneficiaries and providers the filing, receipt and prompt adjudication of all complaints, appeals or reconsiderations that originate, and the responsible investigation that allows the submission of evidence submitted by the complainants.

5. The established mechanisms must ensure due process of law, in such a way that it is permissible to fully ventilate disputes with all the guarantees of law.

6. The adverse final decisions of the Insurers, HSO and Pharmacy Benefits Manager may be reviewed by the Administration, as provided in Article 14 of this Regulation.

G. Service Line

1. The Insurers and HSO will maintain a free telephone line equipped with the technology necessary to identify and distribute calls and to attend a high volume of calls competently.

2. Functions
   i. The service line has these main functions:

      a) Serve as an informative service in which the questions are answered and the complaints, doubts and concerns of the beneficiaries, their families and their authorized representatives are addressed (general customer service);

      b) Provide medical advice to beneficiaries so that they can resolve medical situations that do not constitute emergencies, as well as their mental health concerns (guidance and/or medical advice by competent personnel in the areas of physical and mental health).

3. Both the general customer service and the guidance and/or medical advice must have a trained and dedicated staff for such functions, as well as independent lines and numbers.

4. Requirements: Telephone line services must be capable of:

i. Perform daily analysis of the calls served and the manner in which they were served.

ii. Be monitored remotely by the Administration or a third party hired by the Administration for those purposes.

iii. Provide instructions and receive and record messages from customers during the hours or days when regular staff are not available to serve the beneficiary directly.

5. Log

i. Insurers and HSO must maintain detailed records of received calls, telephone numbers from where they were made, the time, date and duration of the wait and call, the requested service and the information and advice provided, among others.

H. Internet Page / Website

1. Insurers and HSO must maintain an Internet page in which the following can be found:

i. Information about the Government Health Plan
ii. Insurer's Coverage Plan
iii. Insurer's Provider Network
iv. Information related to the customer services offered
v. The telephone number of the Free Service Line
vi. Complaints and Appeals system information for beneficiaries and providers
vii. Insurer's contact information
viii. Service hours
ix. Beneficiary Handbook
x. Provider Directory
xi. Mechanisms for beneficiaries and providers to submit questions, concerns, doubts or complaints.

2. If the Administration contracts with pharmacy benefits managers, they must maintain an Internet Page where the following information is included as minimum as applicable:

i. Medications Forms
ii. Information related to the customer services offered
iii. Provider's Complaints and Appeals system information
iv. Pharmacy Benefits Manager contact information
v. Service hours
vi. Directory of pharmacies contracted by the GHP

vii. Mechanisms for providers to submit questions, concerns, doubts or complaints.

3. The page must be organized and structured efficiently, so that it is easy to navigate.

4. The portal must have technological security mechanisms that guarantee the confidentiality of the information of the beneficiaries and users of the page.

5. Both the content, its presentation and availability, as well as the technological infrastructure and cybersecurity measures must comply with all the regulations and laws, both state and federal, that govern the matter.

6. The Internet Page must have a link to the Administration's home page.

I. Marketing

1. Any marketing material related to the GHP must be submitted to the Administration in a timely manner and according to its guidelines.

2. Insurers, HSO and Pharmacy Benefit Managers are responsible for their providers and subcontractors to comply with the provisions of this subsection.

J. Screenings

1. The GHP has as priorities in its model of physical and mental health services, the prevention, the education in health and the promotion of healthy lifestyles, to the extent that this improves the quallty of life of the beneficiaries.

2. For this reason, both the Administration and the respective programs under CMS require that certain screenings and evaluations be carried out periodically, to obtain early diagnoses and to prevent potential health problems.

3. It is the responsibility of the Insurers and HSO to faithfully comply with the screenings and early assessment required by state and federal regulations and laws and in accordance with the contractual clauses agreed with the Administration.

K. Trainings and Continuing Education

1. The Administration has the task of improving the medical and hospital services received by the beneficiaries of the GHP. This includes the direct service received by the beneficiaries by the staff, whether medical or otherwise, who in some way serves the beneficiaries.

2. For this reason, the Insurers and HSO that contract with the Administration are obliged to maintain training programs and continuing education for their personnel, their providers and subcontractors.

3. This requirement is not only a contractual obligation, but is also a requirement of CMS, so it must comply with all applicable provisions of the aforementioned Agency, as well as those notified by the Administration.

L. Mental Health Services Provider

1. Insurers and HSO are required to subcontract ASSMCA as part of their mental health service providers.

M. Insurers, HSO and Pharmacy Benefits Manager are responsible to have credentialing mechanisms that allow them to corroborate, in an effective way, that all their providers comply with the credentialing requirements of the applicable state and federal regulations.

N. Provider Location Requirements

1. If the Insurer or HSO is required to assign beneficiaries to a Primary Medical Group or Primary Care Physician, it is the responsibility of the Insurer to allocate to their beneficiaries, Primary Medical Groups and Primary Care Physicians who are at a distance that does not represent an excessive burden on beneficiaries.

ARTICLE 11 – INSURERS AND HSO EVALUATION

A. The Administration will carry out annual evaluations of contracted Insurers and HSO. Such evaluations shall, for example, measure compliance with agreed provisions and clauses and whether the goals and objectives set out were achieved.

B. Among the areas to be assessed, without limitation, are the following:

1. Provider network composition;

2. Entity staff;

3. Credentialing system;

4. Quality of services offered;

5. Information and marketing materials;

6. Compliance with program goals;

7. Beneficiaries satisfaction;

8. Capacity of offer services;

9. Use of data and administrative and managerial capacity

10. Efficiency of processes for handling complaints and challenges;

11. Capacity and financial strength and information and management of finances;

12. Litigation history, concurrent lawsuits or government investigations and audits;

13. Management of information systems;

14. Any other element or criterion that the Administration understands necessary to evaluate in order to determine the level of fulfillment with the contractual obligations.

ARTICLE 12 – PROVIDER NETWORK

A. Compliance with federal provisions

1. All Insurers and HSO must comply with state and federal provisions concerning provider networks.

2. If the Administration delegates pharmacy contracting to one or more pharmacy benefits managers, they must also comply with state and federal provisions concerning provider networks.

B. Capacity and competence of the Network

1. Insurers, HSO and pharmacy benefit managers, as applicable, must establish and maintain a network of competent providers who are able to provide the services for which they were contracted;

2. The following factors should be taken into consideration when establishing the Provider Network (both General and Preferred):

    i. Demographic profile of the population to be served;
    ii. Geographic characteristics of the area;
    iii. Profile of provider in the network;
    iv. Types of facilities available;
    v. In the case of Insurers and HSO, the proportion of beneficiaries to providers and Group or Primary Care Physician;
    vi. Projections as to the services to be used and their cost

C. Providers for high risk populations

1. No Insurer, HSO or pharmacy benefit manager may discriminate, in any way, with those providers who serve high-risk or special-needs populations that represent a higher cost.

D. Network removal notification

1. When an Insurer or HSO denies a provider participation in their network, they must notify the provider in writing listing the reasons for such determination, so that the provider can file a reconsideration request to the Insurer or HSO to determine it.

E. Reimbursements

1. Insurers and HSO may negotiate with their providers the quantities and form and manner of the reimbursements they receive:

    i. Such payments do not have to be uniform to the extent that they are the product of the Insurer's particular negotiations and its provider.

2. Generic medications will be reimbursed according to the prices on ASES' MAC List, while the brand name medications will be reimbursed according to the AWP of the medication minus the discount established by the Administration. There will be an appeal process either in the Insurer, HSO or Pharmacy Benefits Manager, as applicable, so that the pharmacies request adjustment in cases where the price that the pharmacy pays for a

medication is greater than the price reimbursed by the GHP. If there is a pattern of appeals for the same medication, the price of that medication should be reassessed on the MAC list. The adjustment request processes will be established according to the guidelines issued by ASES.

3. Providers Sanctioned by Federal Programs

    i. No Insurer, HSO, or Pharmacy Benefits Manager may make payments to any provider who is the subject of penalties for violations or noncompliance under the Medicare, Medicaid, or CHIP Programs.

F. Quality Control and Costs

1. Insurers and HSO will be able to develop guidelines and establish measures that allow them to maintain quality health services as well as control their costs, without that consideration being detrimental to quality.

G. Facilities

1. Providers facilities must comply with state and federal laws and regulations and standards related to access for disabled persons established by the Administration.

H. Credentialing

1. All providers must comply with credentialing requirements, including physicians, hospitals, laboratories and outpatient or therapies facilities, pharmacies, among others.

I. Provider Responsibilities

1. To offer services of optimal quality, when they are necessary and without delay to the beneficiaries of the Program.

2. To provide the services that are necessary for the health care of the beneficiaries, regardless of whether the capitation has been consumed.

3. To not discriminate against beneficiaries of the GHP or offer inferior treatment to the one that they provide to patients insured by private health plans.

4. To notify Insurers, HSO, or Pharmacy Benefits Manager, as applicable, the problems they may face in offering services to beneficiaries.

5. To notify Insurers, HSO, Pharmacy Benefits Manager or the Administration of any situation that constitutes abuse, misuse or fraud on the part of the beneficiaries

ARTICLE 13 – REPORTS

A. All Insurers, HSO and Pharmacy Benefits Managers shall submit all reports and documents required by the Administration on time and in the manner agreed;

B. The delivery of such documents must be made both digitally and in a copy, as required;

C. Delay or failure to comply with this duty may result in the imposition of sanctions by the Administration, as well as by the state and federal agencies and instrumentalities with jurisdiction;

D. The Administration is authorized by Act No. 72 to go to the First Instance Court to request its intervention to request the delivery or reproduction of any required document or report that any Insurer, HSO or Pharmacy Benefits Manager refuses to provide, dilates or obstructs its delivery.

ARTICLE 14 – COMPLAINTS, APPEALS AND SACTIONS SYSTEM OF THE ADMINISTRATION

A. Jurisdiction

1. The processes described in this article will apply to:
   i. Insurers;
   ii. Beneficiaries;
   iii. HSO;
   iv. physical and mental health services providers;
   v. pharmacy benefits managers;
   vi. subcontractors of the aforementioned;

2. For the purposes of this article, the entities listed in the preceding subparagraph shall be collected under the generic term "Contractors".

B. As described in Article 10, subsection (D), all Insurers, Pharmacy Benefits Managers and Health Service Organizations providing medical and hospital services to the GHP must have a division or area of Complaints and Appeals;

C. Act No. 72 empowers the Administration to review, once the lower revision mechanisms have been exhausted, the final determinations adversely resolved against providers and beneficiaries who have filed a complaint;

D. In addition, Article VI, Sect. 10 of Act No. 72 empowers the Administration to establish corrective measures or impose penalties and fines on contractors for non-compliance with the obligations deriving from contracts granted with this for the provision of health services, violations of the laws and regulations of the Administration, or violations of orders, instructions and requirements issued and/or published under these by the Administration;

E. If, as a result of a request for revision, the Administration makes a final and firm determination against the applicant, such decision may be appealed to the Court of Appeals;

F. Accountability

1. In the discharge of its responsibility to ensure the fulfillment of the contracts on health services plans for which it negotiates and contracts, the administration will carry out:

    i. periodic and ongoing investigations to ascertain and verify compliance with the obligations arising from the contract between the parties and with applicable federal and local laws and regulations;

    ii. investigations following the notification of a complaint or confidence suggesting violation of the obligations arising from the contract between the parties or the applicable federal and local laws and regulations.

2. As part of a research process, the Administration may:

    i. perform desktop or field audits;

    ii. inspect facilities, administrative offices or any other location of the contractor providing services for the beneficiaries of the GHP;

    iii. require the delivery of any information, studies or documentation that is related to the fulfillment of its contractual obligations or with the laws and regulations relevant to the Administration (for which it may also go before the First Instance Court of Puerto Rico, to request a court order for such purposes);

    iv. take any other administrative or legal measures necessary for the investigation to be carried out in an expeditious and effective manner.

3. The enumeration of the preceding subparagraph should not be construed as a limitation. The Administration may become aware of any violation or

breach of contract or violation of the laws and regulations of the agency that arise publicly or which it is aware of.

G. Fines and Penalties (the following provisions are general and complementary to the Regulation of the Administration governing the fines and penalties):

1. If it is determined that a contractor breached a contractual obligation or violated a law or regulation of the Administration, it may impose those penalties established by Regulation or contract including:

   i. development and implementation of a "Corrective Action Plan";
   ii. compensation for damages in cash;
   iii. economic penalty;
   iv. administrative fine;
   v. retention of payments;
   vi. suspension of his/her participation in the GHP;
   vii. any other punitive measures contained in the respective contractual clauses.

2. Notification

   i. The Administration shall notify the entity of any determination relating to the imposition of a fine, penalty or corrective measure by copying to the authorized representative designated to receive this type of communication and to its lawyers, if it has them:

      a) by electronic mail, and/or;
      b) by certified mail to the authorized representative designated by the sanctioned entity to receive this type of communication.

   ii. The agency must file copy of the final order or resolution and the evidence of the notification.

H. Administrative Hearing

1. Request for Administrative Hearing

   i. Thirty (30) days from the date on the notification of an Insurer, HSO or Pharmacy Benefits Manager on its determination as to any objection or request for review made by the party concerned, that party may request the Administrative Hearing before an Examining Officer appointed by the Administration.
   ii. For those notifications sent by regular and certified mail, if the date in the notification is different from that of its deposit in the mail, the term will be calculated from the date of the deposit in the mail.

iii. The term for filing an administrative hearing request will be jurisdictional.

iv. In the request for the administrative hearing, the entity that requests it must enter all the arguments of fact and law and provide all the necessary evidence that proves the reasons that in his opinion justify the celebration of a hearing and for which fines and/or penalties notified should not be applied.

v. In all cases, the person designated to receive a complaint or request for an administrative hearing shall seal its first page, as well as that of all the annexes included with it, with clear and legible expression of the date and time of receipt, his/her name in print and his/her signature.

2. Hearing

i. Once a Request for an Administrative Hearing is received, on time and complete, it will be assigned to an officer who shall indicate as soon as possible the corresponding administrative hearing in accordance with the General Regulation of ASES or the regulation that is in force to govern the adjudicative procedures before the Administration and complying with all the provisions of the Uniform Administrative Procedures Act.

ii. Upon completion of the hearing process, the officer will forward the case file along with an "Administrative Hearing Report" to the Executive Director so that he/she can conduct his/her due evaluation and issue a Final Resolution and Order that will contain ASES' administrative determination, which will be notified to the parties with a clear expression of the date of their notification and file. It will be deposited in the mail on the same date of its notification and filing.

3. Reconsideration

i. The party adversely affected by a Final Resolution and Order of ASES may request reconsideration of this order. The request, notification and determination, as the terms that apply to this, will be governed by those that the Uniform Administrative Procedures Act, and the jurisprudence, have established for it.

ii. Similarly, the Administration may reconsider its resolutions or orders on its initiative according to the terms granted by the Uniform Administrative Procedures Act.

4. Judicial Review

i. If the administrative appeal is exhausted, the party which is not in conformity with the Resolution of its request for reconsideration may request the Judicial Review of the Final Resolution and Order, the reconsideration of which it requested by complying with the requirements established in the Uniform Administrative Procedure Act.

ii. The submission of a request for judicial review shall not suspend the effects of a Final Resolution and Order of the Administration.

ARTICLE 15 – DEROGATORY CLAUSE

The General Regulation of the Health Insurance Administration of Puerto Rico, No. 5253, is repealed.

ARTICLE 16 – SEPARABILITY

The declaration by a competent court that a provision of this Regulation is invalid, null or unconstitutional shall not affect the other provisions of this Regulation, which shall preserve its full validity and effect.

ARTICLE 17 – EFFECTIVE DATE

This Regulation shall be effective immediately after its approval by the State Department.

ARTICLE 18 – APPROVAL

I certify that this Regulation was approved by the Board of Directors of ASES at the meeting of February 7, 2019.

In San Juan, Puerto Rico, today February 15, 2019.

Angela M. Avila Marrero
Executive Director