



## Attachment 1: Designated Laws

This attachment is provided only as guidance to the Contractor. It is not an exhaustive list of all applicable laws and regulations. Contractor is responsible for ensuring compliance with all applicable state and federal laws.

### Applicable Government laws and regulations:

- Act 72 of September 7, 1993, including all of its amendments, known as "Puerto Rico Health Insurance Administration Law", and its applicable regulations.
- ASES General Rules and Regulations, No. 9068 of March 29, 2019.
- ASES Regulations for the Imposition of Fines and Economic Sanctions for Breach of Contract of Underwriters and/or Health Services Organizations and to Establish the Procedure for Resolution and Adjudication of Related Complaints, Regulation No. 8446.
-  Act 194 of August 25, 2000, as amended, known as the "Puerto Rico Patient's Bill of Rights and Responsibilities", and corresponding regulations, as applicable.
- Act 77 of June 19, 1957, as amended, known as "Puerto Rico Insurance Code" and corresponding regulations, as applicable.
-  Act 81 of March 14, 1912; as amended, known as "Organic Law for the Puerto Rico Health Department", and corresponding regulations, as applicable.
- Act 408 of October 2, 2000, as amended, known as "Puerto Rico Mental Health Code", and corresponding regulations, as applicable.
- Act 77 of June 24, 2013, as amended, known as the "Law of the Patient Advocate", and corresponding regulations, as applicable.
- Act 247 of September 3, 2004, as amended, known as the "Puerto Rico Pharmacy Law", and corresponding regulations, as applicable.
- Act 70 of August 5, 2017, as amended, known as "Ley de Vigilancia de Receta de Medicamentos Controlados"
- Act 7 of March 16, 2019, as amended, known as "Ley de Transparencia en el Precio de Medicamentos Recetados"
- Act 82 of July 30, 2019, as amended, known as "Ley Reguladora de los Administradores de Beneficios y Servicios de Farmacia"<sup>1</sup>

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<sup>1</sup> The implementation of this Act has been stayed by Order of Judge Laura Taylor Swain of the U.S. District Court for the District of Puerto Rico.

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- Act 139 of August 1, 2008, as amended, known as “Law for the Medical Licensing and Discipline Board”, and corresponding regulations, as applicable.
- Act 109 of June 28, 1962, as amended, known as “Law for the Puerto Rico Public Service”, and corresponding regulations, as applicable.
- Act 86 of August 16, 1997, as amended, known as “Law Granting Priority for Individuals with Pending Business traveling between Puerto Rico and Vieques and/or Culebra”, and corresponding regulations, as applicable.
- Act 227 of August 12, 1999, as amended, known as “Law for the Commission to Implement the Public Policy on Suicide Prevention” and corresponding regulations, as applicable.
- Act 243 of November 10, 2006, known as “Law to Establish the Public Policy Concerning the Use of the Social Security Number for Identification”, and corresponding regulations, as applicable.
- Act. 2 of January 4, 2018, known as “Anticorruption Code for the New Puerto Rico”, and corresponding regulations, as applicable.
- Act 1 of January 3, 2012, as amended, known as the “Government Ethics Law of 2011”, and corresponding regulations, as applicable.
- Act 38 of June 30, 2017, known as the “Puerto Rico Uniform Administrative Proceeding Law”, and corresponding regulations, as applicable.
- Act 111 of September 7, 2005, as amended, known as the “Law for Informing Citizens of the Security of Data Banks”, and corresponding regulations, as applicable.
- Act 80 of June 3, 2011, known as “Industrial and Trade Secret Protection Act of Puerto Rico”, and corresponding regulations, as applicable.
- Act 126 of October 31, 2013, as amended, known as the “Law for the Protocol of Interagency Services for the Elderly Population Living in Infrahuman Conditions”.
- Act 352 of December 22, 1999, known as “Law Requiring Coverage of General Anesthesia for Minor and Disable Individuals”.
- Act 212 of August 9, 2008, known as “Law for the Coverage of Clinical Services for Patients with Morbid Obesity and Metabolic Syndrome”.
- Act 120 of July 16, 2015, known as “Law to Include Pulmonary Hypertension in the Special Coverage Provided by the Health Insurance Administration”.
- Act 4 of June 23 of 1971, known as the “Controlled Substances Law of Puerto Rico”, and corresponding regulations, as applicable.
- Act 75 of July 25, 2019 known as the “Puerto Rico Innovation and Technology Service Act”.
- Act 148 of August 8, 2006, as amended, known as the “Electronic Transactions Act”
- Act 151 of 2004, as amended, known as “Electronic Government Act”.

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- Act 229 of September 2, 2003, as amended, known as the “Act to Guarantee Access to Information to Disabled Persons”
- ASES Normative Letters issued during the course of the contract period.

**Applicable Federal Laws and Regulations:**

- Puerto Rico Health Department’s State Plan (“Medicaid State Plan” and CHIP State Plan”).
- The Social Security Act, including Titles VII, XI, XIX and XXI.
- Federal regulations as established by the Center for Medicare & Medicaid Services (“CMS”) including, but not limited to:
  - 42 CFR part 438 (Medicaid managed care)
  - 42 CFR Part 447, Subpart I (covered outpatient drugs, rebates)
  - 42 CFR part 431, subpart E (fair hearings and appeals)
  - 42 CFR part 455 (fraud and abuse reporting, Medicaid provider enrollment)
  - 42 CFR part 447 (timely claim payment)
  - 45 CFR part 75 (federal awards)
  - 42 CFR part 433, Subpart D (third party liability)
- Davis-Bacon Act, 40 U.S.C. 276a et seq.
- 340B Drug Pricing Program, 42 CFR Chapter 1, Subchapter A, Part 10.
- Federal False Claims Act, 31 U.S.C. § 3729 and associated regulations.
- Copeland Anti-Kickback Act, 40 U.S.C 3145.
- Fair Labor Standards Act of 1938, 29 U.S.C 201 et seq.
- Title VI of the Civil Rights Act of 1964, as amended, 42 USC 2000d.
- Title VII of the Civil Rights Act of 1964, 42 USC 2000e.
- Title IX of the Education Amendments of 1972, as amended, 20 USC 1681.
- Clean Air Act, 42 U.S.C. 7401 et seq.
- Federal Water Pollution Control Act as Amended, 33 U.S.C. 1251 et seq.
- Federal Rehabilitation Act of 1973, 29 USC 794.

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- Byrd Anti-Lobbing Amendment, 31 U.S.C. 1352.
- The Clinical Laboratory Improvement Amendments of 1988.
- The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, including its Omnibus Rule ("HIPAA"), applicable provisions of the Health Information Technology for Economic and Clinical Health Act as incorporated in the American Recovery and Reinvestment Act of 2009 ("HITECH"), and their accompanying regulations, including the Privacy Rule (as defined herein) and the Security Rule (as defined herein). "Privacy Rule" means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR, part 160 and part 164, subparts A and E, providing for federal privacy protections for an individual's PHI held by entities subject to HIPAA requirements (each, a "Covered Entity") and describing patient rights with respect to their PHI. "Security Rule" means HIPAA Security Standards (45 C.F.R. Parts 160, 162, and 164).
- Substance Use Disorder (SUD) Privacy Rules, 42 CFR Part 2.
- Americans with Disabilities Act, 42 U.S.C. 12101 et seq.
- Age Discrimination Act, 42 USC 6101 et seq.
- Medicare Modernization Act of 2003, P.L. 108-173.
- Mental Health Parity and Addiction Equity Act of 2008, P.L. 110-343.
- American Recovery and Reinvestment Act of 2009, P.L. 111-5.
- Patient Protection and Affordable Care Act of 2010, P.L. 111-148.
- Debarment and Suspensions, 2 CFR Parts 180 and 376.
- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (referred to as the SUPPORT Act) (Pub. L. No. 115-271)

ASES reserves the right to modify requirements stated in this contract at any time by either a supplement to this contract or otherwise modifying the Model Contract, or as necessary based on any federal requirements or as may be required by CMS or any Government of Puerto Rico laws or regulations or any directives of the Financial Oversight and Management Board for Puerto Rico. The Model Contract may continue to be revised by ASES.

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