

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

20th Congress
First Regular Session

House Bill No. **7331**



Introduced by **REPRESENTATIVES EMIGDIO P. TANJUATCO III, ROLANDO M. VALERIANO**

EXPLANATORY NOTE

Every Filipino has the constitutional right to health and to access equitable, affordable, and quality health services. However, persons living with rare diseases (PLWRDs) remain among the most overlooked populations in the health system. For many of them, the rarity of their condition results in delayed diagnosis, limited access to treatment, financial hardship, and lifelong disability or premature death.

Republic Act No. 10747, or the Rare Diseases Act of 2016, was enacted to address these gaps. Yet almost a decade later, full implementation remains limited due to the absence of a functional governance structure, inadequate financing mechanisms, workforce shortages, lack of regional service delivery, and delayed access to orphan drugs and advanced therapy medicinal products (ATMPs). The Rare Disease Registry is not yet operational, and the majority of rare disease services remain centralized in Luzon, leaving many patients—especially in geographically isolated and disadvantaged areas—without care.

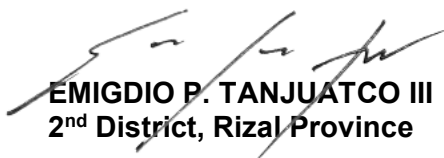
Globally, rapid advancements in genomic science, artificial intelligence–assisted diagnostics, cell and gene therapy, enzyme replacement therapy, and precision medicine are transforming the rare disease landscape. Countries such as Singapore, Japan, South Korea, the United States, and members of the European Union have adopted innovative financing models, regulatory reforms, and patient-centered governance frameworks to accelerate access and reduce inequities. The Philippines must not fall behind.

This proposed measure strengthens and expands the provisions of RA 10747 by:

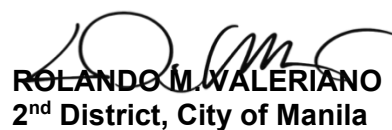
1. Creating a **National Rare Disease Council** with strengthened governance, expanded representation, and regional implementation councils;
2. Establishing a **Rare Disease Trust Fund** using a hybrid financing structure involving government appropriations, PhilHealth contributions, and matched public donations;

3. Institutionalizing access to medicines, including **gene therapy, RNA therapeutics, medical foods, orphan drugs, and ATMPs**;
4. Establishing the **National Biobank and Genomic Resource Center**, and institutionalizing the National Rare Disease Registry;
5. Decentralizing services through **Centers of Expertise and Regional Satellite Clinics**;
6. Providing a **Modified Rare-Disease Specific HTA pathway** to ensure timely technology access;
7. Strengthening rare disease workforce development through scholarships, certification, and Continuing Professional Development (CPD);
8. Ensuring **automatic PWD recognition, employment and education support**, and social protection mechanisms; and
9. Creating the **Congressional Oversight Committee on Rare Diseases** to ensure accountability, transparency, and continuity of implementation.

This bill is aligned with the Universal Health Care Act, Philippine Development Plan, and ASEAN and global rare disease frameworks on equity-based access to care. Most importantly, it responds to the urgent and long-standing calls of Filipino families who have waited years for comprehensive care, dignity, and hope. In view of the foregoing, the immediate passage of this bill is earnestly sought.



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AN ACT
STRENGTHENING THE RARE DISEASES ACT OF THE PHILIPPINES, AMENDING
REPUBLIC ACT NO. 10747, AND FOR OTHER PURPOSES

Be it enacted by the [Senate and House of Representatives of the Philippines]
in Congress assembled:

SECTION 1. Short Title. — This Act shall be known as the “Rare Diseases Act of 2025.”

SECTION 2. Declaration of Policy. — It is the policy of the State to uphold the right to health of all Filipinos, including persons living with rare diseases (PLWRDs), through equitable access to timely diagnosis, comprehensive care, and innovative therapies. The State shall integrate rare disease care into the Universal Health Care (UHC) framework and ensure that no Filipino is left behind due to rarity of condition. To achieve this, the State shall establish a comprehensive, sustainable, and inclusive national system for the prevention, diagnosis, treatment, rehabilitation, research, and social integration of PLWRDs through collaboration among government, private sector, academe, and patient organizations.

SECTION 3. Objectives. — The objectives of this Act are to:

1. Guarantee inclusion of rare disease services within the UHC system;
2. Accelerate diagnosis through genomic medicine, AI-assisted tools, and pilot newborn whole-genome sequencing;
3. Establish sustainable financing mechanisms through the Rare Disease Trust Fund;
4. Ensure access to innovative therapies including orphan drugs, medical food, enzyme replacement therapy, gene, RNA, cellular, and advanced therapy medicinal products (ATMPs);
5. Operationalize a secured, interoperable National Rare Disease Registry;

6. Decentralize service delivery through Centers of Expertise and Regional Satellite Clinics;
7. Develop the rare disease workforce through scholarships, training, and CPD;
8. Strengthen social protection and automatic PWD recognition;
9. Promote national research, clinical trials, biobanking, and genomic innovation; and
10. Institutionalize governance, monitoring, and accountability through a National Rare Disease Council and regional councils.

SECTION 4. Definition of Terms. — Section 4 of RA 10747 is hereby amended as follows:

- (a) Rare Disease — a health condition affecting not more than one (1) in twenty thousand (20,000) Filipinos, or as recognized by the Department of Health (DOH) in accordance with international standards.
- (b) Advanced Therapy Medicinal Products (ATMPs) — therapeutic innovations including but not limited to gene therapy, somatic-cell therapy, tissue-engineered products, RNA-based medicines, viral vector platforms, and genome editing technologies.
- (c) Genomic Medicine — the application of whole genome sequencing, long-read sequencing, optical genome mapping, artificial intelligence-assisted analysis, and other next-generation molecular platforms for diagnosing and managing rare diseases.
- (d) Rare Disease Registry — a secured, digital, interoperable registry maintained by DOH, integrating clinical, genomic, epidemiologic, and outcomes-based data, compliant with the Data Privacy Act.

SECTION 5. National Rare Disease Council. — A National Rare Disease Council (NRDC) is hereby created as the national policymaking, coordinating, and regulatory oversight body for rare disease care, attached to the DOH.

SECTION 6. Composition of the Council. — The Council shall be composed of the following:

1. As Ex-Officio Members:

- (a) Secretary of Health, or representative not lower than Assistant Secretary — Chairperson
- (b) Secretary of Social Welfare and Development (DSWD)
- (c) Secretary of Labor and Employment (DOLE)
- (d) Secretary of Interior and Local Government (DILG)
- (e) Secretary of Science and Technology (DOST)
- (f) Philippine Health Insurance Corporation President and CEO (PhilHealth)
- (g) Director General, Food and Drug Administration (FDA)
- (h) Chancellor, University of the Philippines Manila or designated representative

- (i) Director, UP-NIH Institute of Human Genetics (IHG)
- (j) Director, UP-NIH Newborn Screening Reference Center (NSRC)

2. As Appointed Voting Members:

- (k) Four (4) medical doctors, representing Family Medicine, Pediatrics, Internal Medicine, and Surgery
- (l) Three (3) representatives of registered rare disease patient organizations:
 - (1) Metabolic rare diseases (newborn screening-amenable)
 - (2) Non-metabolic, childhood-onset
 - (3) Non-metabolic, adolescent/adult-onset

The term of appointed members shall be three (3) years, renewable once.

Regional Rare Disease Councils shall be established to ensure full of the Act implementation in the regional level.

SECTION 7. Roles and Functions. — The Council shall:

- (a) Determine and periodically update the list of disorders classified as rare diseases;
- (b) Determine orphan drugs, products, medical devices, and technologies used in rare disease care;
- (c) Formulate regulatory frameworks for orphan drug and product designation and certification;
- (d) Set national clinical practice standards, patient pathway protocols, and accreditation requirements;
- (e) Oversee national access programs for orphan drugs and ATMPs including managed entry agreements;
- (f) Develop a Modified Rare Disease-Specific HTA Pathway incorporating equity, rarity-adjusted cost analysis, international evidence, and real-world data monitoring in lieu of standard HTA requirements;
- (g) Develop workforce development strategies including training, scholarships, and CPD;
- (h) Strengthen multisectoral and multistakeholder partnerships;
- (i) Ensure meaningful participation of patient and family representatives;
- (j) Establish Key Performance Indicators and conduct annual monitoring and evaluation; and
- (k) Submit annual report as mandated under Section 15.

SECTION 8. Rare Disease Trust Fund. — A Rare Disease Trust Fund is hereby created to sustain service delivery, innovation, and patient access. The Fund shall utilize a hybrid financing model derived from:

- (a) Annual appropriations under the General Appropriations Act (GAA);
- (b) Dedicated PhilHealth allocation under the Universal Health Care Act;
- (c) Percentage allocation from PCSO and PAGCOR health earmarks;

(d) Donations, grants, and private sector contributions; and

SECTION 9. Service Delivery and Human Resources. — DOH shall establish Centers of Expertise and Regional Satellite Clinics and ensure multidisciplinary care teams. CHED, DOH, and DOST shall support training, scholarships, and certification programs.

SECTION 10. National Rare Disease Registry. — DOH, through UP-NIH, shall operationalize a secure interoperable registry within twelve (12) months.

SECTION 11. Research, Biobanking, and Innovation. — A National Biobank and Genomic Resource Center is hereby created under UP-NIH.

SECTION 12. Access to Innovative Therapies. — FDA shall streamline approval processes for orphan drugs and ATMPs. PhilHealth shall establish benefit packages ensuring no catastrophic out-of-pocket cost.

SECTION 13. Social Protection. — PLWRDs shall automatically be recognized as PWDs under RA 7277.

SECTION 14. National Rare Disease Awareness Week. — The last week of February is declared as National Rare Disease Awareness Week.

SECTION 15. Annual Report. — The Secretary of Health shall submit an annual report ****not later than January 28 of every year**** to:

- The Office of the President
- The Senate Committee on Health
- The House Committee on Health
- The Congressional Oversight Committee on Rare Diseases (hereby created)
- DBM and NEDA for budget alignment

SECTION 16. Congressional Oversight Committee on Rare Diseases. — There is hereby created a Congressional Oversight Committee on Rare Diseases (COCRD) to ensure the effective implementation of this Act.

The Committee shall be composed of:

(a) Five (5) Members of the Senate, to include:

- (1) The Chairperson of the Senate Committee on Health and Demography, as Co-Chairperson.
- (2) One (1) representative from the Senate Committee on Finance; and
- (3) Three (3) Members of the Senate to be designated by the Senate President; and

(b) Five (5) Members of the House of Representatives, to include:

- (1) The Chairperson of the House Committee on Health, as Co-Chairperson;
- (2) One (1) representative from the House Committee on Appropriations; and
- (3) Three (3) Members of the House to be designated by the Speaker.

The Congressional Oversight Committee shall exercise the following powers and functions:

- (1) Monitor and evaluate the implementation of this Act, including the performance and compliance of national government agencies, PhilHealth, regulatory bodies, regional Rare Disease Councils, and Centers of Expertise;
- (2) Review and assess the annual Rare Disease Program budget and the utilization of the Rare Disease Trust Fund, including allocations from PhilHealth and other earmarked institutional contributions;
- (3) Ensure alignment of the National Rare Disease Program and budgetary allocations with the Universal Health Care Act and other national health priorities;
- (4) Review annually the list of recognized rare diseases, orphan drugs, medical devices, medical foods, ATMPs, and designated benefit packages, based on the reports submitted by the National Rare Disease Council;
- (5) Conduct periodic hearings and consultations with rare disease experts, patient organizations, relevant agencies, and stakeholders to evaluate gaps, constraints, and system improvements; and
- (6) Recommend necessary legislation, budget adjustments, or policy reforms to strengthen rare disease governance, access, and equity.

The Committee shall convene within ninety (90) days from the effectivity of this Act and shall meet at least twice a year, or as necessary.

Administrative, secretariat, and logistical support for the Committee shall be jointly provided by the Senate and House of Representatives.

The Congressional Oversight Committee on Rare Diseases shall exist for a period of ten (10) years from the effectivity of this Act, unless extended by Congress through subsequent legislation.

SECTION 17. Implementing Rules and Regulations. - Within one hundred eighty (180) days from the approval of this Act, the Secretary of Health, in consultation with the Council and other concerned stakeholders, shall promulgate the necessary rules and regulations for the effective implementation of this Act.

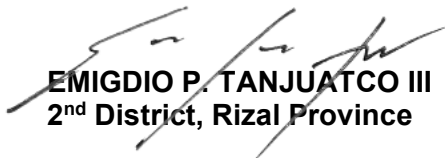
SECTION 18. Appropriations. — Funding for the implementation of this Act shall be included in the annual General Appropriations Act, subject to the usual budget preparation, authorization, and availability of funds.

SECTION 19. Separability Clause. - If any provision of this Act is declared unconstitutional, the remainder of this Act or any provision not affected thereby shall remain in full force and effect.

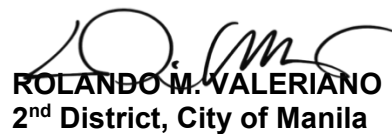
SECTION 20. Repealing Clause. - All laws, presidential decrees or issuances, executive orders, letters of instruction, administrative orders, rules or regulations inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SECTION 21. Effectivity. - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation. and submission to UP-ONAR.

Approved,



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