AN ACT
PROVIDING A COMPREHENSIVE RENAL REPLACEMENT THERAPY (RRT) FOR PATIENTS WITH END STAGE RENAL DISEASE IN NATIONAL, REGIONAL, AND PROVINCIAL GOVERNMENT HOSPITALS, INCREASING THE PHILHEALTH PACKAGE RATE FOR RENAL REPLACEMENT THERAPY OF MEMBERS AND APPROPRIATING FUNDS THEREFOR

EXPLANATORY NOTE

Kidney diseases are the seventh leading cause of death in the Philippines. According to the Department of Health, 23,000 Filipinos underwent dialysis due to kidney failure in 2013, nearly four times higher than the 4,000 cases recorded in 2004, or a 10 to 15 percent increase a year.

Dialysis is very costly for most Filipinos who suffer from chronic kidney diseases. To have adequate treatment, a patient has to spend Php25,000 to Php46,000 per month.

This bill seeks to ease the financial burden of patients suffering from renal failure. It seeks to provide a comprehensive renal replacement therapy for patients with end stage renal disease in national, regional, and provincial government hospitals, increasing the PhilHealth package rate for renal replacement therapy of PhilHealth members.

In view of the foregoing, the passage of this bill is earnestly sought.

ALFRED VARGAS
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Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

SECTION 1. Short Title. – This Act shall be known as the "Comprehensive Renal Replacement Therapy Act"

SECTION 2. Declaration of Policy. – The State shall endeavor to make essential goods, health and other social services available to all the people at affordable cost. There shall be priority for the needs of the underprivileged sick, elderly, disabled women and children. The state shall endeavor to provide free medical care to the less fortunate.

It is hereby declared a policy of the State to adopt an integrated and comprehensive approach to health development that will provide Comprehensive Renal Replacement Therapy (RRT) to improve the delivery of health care services to patients diagnosed with End Stage Renal Disease (ESRD), and to encourage them to have a kidney transplant, primarily within the first two (2) years of dialysis treatment.
SECTION 3. Definition of Terms. – As used in this Act:

a. **Dialysis facility** refers to a health facility that provides treatment for ESRD to indigent patients and disseminates information on the various forms of RRT such as kidney transplantation, peritoneal dialysis and hemodialysis;

b. **End Stage Renal Disease or ESRD** refers to the final stage of chronic kidney disease in which the kidneys no longer function well enough to meet the needs of daily life;

c. **Hemodialysis or HD** refers to a medical procedure to remove fluid and waste products from the blood and to correct electrolyte imbalances. This is accomplished using a synthetic membrane or dialyzer which is also referred to as an “artificial kidney”;

d. **Indigent** refers to a patient who has no source of income or whose income is not sufficient for family subsistence as identified by the Department of Social Welfare and Development (DSWD) through the National Household Targeting System (NHTS) for Poverty Reduction, or those patients who are indigents but are not listed in the NHTS as assessed by the municipal social development officer;

e. **Kidney transplant or KT** refers to a surgical procedure to place a kidney from a live or deceased donor into a person whose kidneys no longer function sufficiently to sustain the person’s life;

f. **National, Regional, and Provincial hospitals** refer to hospitals and stand-alone dialysis facilities operated and maintained either partially or wholly by the national, regional, and provincial government or other political subdivisions, or any department, division, board or other agency thereof;

g. **No Balance Billing** refers to the government policy of not charging the medical expenses incurred over and beyond the PhilHealth package rates to a PhilHealth member who has undergone medical treatment;

h. **Peritoneal dialysis or PD** refers to a treatment for kidney failure and a type of dialysis that uses the person’s peritoneum (Lining of abdominal cavity) as the membrane through which fluid and toxic substances are exchanged with blood;

i. **PD First Policy** refers to the policy where peritoneal dialysis, when feasible, is offered as the first dialysis modality to RRT patients;

j. **Renal replacement therapy or RRT** refers to the therapy that partially replaces the functions of the normal kidney. This may be in the form of kidney transplantation, peritoneal dialysis, and hemodialysis.
SECTION 4. Establishment of Dialysis Service Wards or Units in National, Regional, Provincial, Government Hospitals. – Within five (5) years from the effectivity of this Act, all national, provincial, and regional government hospitals, including all stand alone dialysis facilities are hereby required to establish, operate and maintain a dialysis service facility in their hospital, including both peritoneal dialysis and hemodialysis. The same hospitals and dialysis facilities should also be mandated to train nephrologists, dialysis nurses, dialysis technicians, and operating room nurses in both peritoneal dialysis and hemodialysis.

All national, provincial and regional government hospitals, including stand alone dialysis facilities shall have a dialysis service area compliant with the licensing and accreditation requirements imposed by the Department of Health (DOH) and Philippine Health Insurance Corporation (PhilHealth), respectively for private dialysis clinics. It shall be provided with the necessary personnel and equipped with complete dialysis equipment and supplies for both hemodialysis and peritoneal dialysis, as required by the DOH and the PhilHealth from private dialysis clinics.

All patients diagnosed with ESRD must be referred to a DOH-accredited transplant facility to attend a pre-transplant orientation and to be counseled on the advantages of undergoing transplantation as the best treatment for kidney failure. They will undergo medical evaluation for sustainability for transplantation. For those found medically suitable for transplantation, all potential organ donors of the patient shall be evaluated to determine compatibility and medical suitability. If no living donors are available then the patient will be enrolled in the deceased organ donor waiting list. This will ensure that all patients with ESRD are offered the option of kidney transplantation.

SECTION 5. Chronic Kidney Disease (CKD) Prevention and Health Promotion – All national, provincial and regional government hospitals, and stand alone dialysis facilities should establish CKD prevention strategies and health promotion activities which include: advocacy activities targeting relatives of dialysis patients who are at high risk for developing CKD themselves, the provision of instructional materials and regular educational activities on the common symptoms of kidney disease, the most common causes of kidney failure, and advisories on the appropriate protocols for the diagnostic evaluation of possible kidney disease.

Patients and their relatives should be informed about the availability of the proper medicines from government health centers such as those for diabetes and hypertension, and the importance of the regular intake of
medicines and monitoring of kidney function through regular laboratory testing and regular clinic follow-up with a qualified physician. All activities pertaining to the aforementioned programs should be documented accordingly.

SECTION 6. Quality Standards of Dialysis and Transplant Facilities. – Hospitals, dialysis centers for both hemodialysis and peritoneal dialysis, and transplant facilities shall comply with the safety and quality standards of dialysis or transplant services which shall be strictly monitored by the PhilHealth Facilities and Services Regulatory Bureau of the DOH.

SECTION 7. Philippine Renal Disease Registry. – Private and public hospitals, dialysis centers for both hemodialysis and peritoneal dialysis, and transplant facilities shall be mandated to report to the Philippine Renal Disease Registry of the DOH the incidence and prevalence of patients receiving peritoneal dialysis or hemodialysis treatment, and who have received a kidney transplant as a requirement for the renewal of their respective DOH license to operate a dialysis center or transplant facility. Registration of all dialysis patients in the PhilHealth Dialysis database will be required prior to receiving benefits for both peritoneal dialysis and hemodialysis.

SECTION 8. PhilHealth Benefit for Kidney Transplantation. – The PhilHealth benefit for kidney transplantation from living donors shall be expanded accordingly. This shall include the cost of laboratory work-up for both recipient and donor candidate, hospitalization for the transplant operation including induction immunosuppression and maintenance oral immunosuppression, machine perfusion of procured organs, the cost for organ retrieval, all medications required during the hospital stay, as well as post discharge laboratories up to one (1) month for the recipient, and up to one (1) year for the donor.

The cost for organ retrieval and machine perfusion will be established by the DOH-Philippine Organ Donation Program for all organ procurement organizations.

The PhilHealth benefit package for kidney transplantation shall cover the evaluation and screening of the kidney donor and recipient up to the transplant procedure and post transplantation procedures and remedies. This is inclusive of both pre- and post-kidney transplantation measures for the benefit of End Stage Renal Disease patients.

In order to support kidney transplantation as the best treatment option that provides the highest quality of life for End Stage Renal Disease patients
and ensures the return of the patient to full rehabilitation, the PhilHealth and the Philippine Charity Sweepstakes Office (PCSO) shall provide support for all maintenance immunosuppression for the lifetime of the transplant patient, as long as the transplanted organ is functioning and the patient remains dialysis-independent.

All renal replacement therapy facilities shall be required to engage in regular organ donation advocacy activities that will provide education for all Filipinos to carry the organ donor card. Facilities will likewise establish a potential deceased organ donor referral system that will identify all potential deceased organ donors to the Philippines Network for Organ Sharing.

SECTION 9. *PhilHealth Benefit for Dialysis Treatment.* — The PhilHealth shall increase the Z-benefit package rate for the principal member and each of one’s qualified dependents on maintenance dialysis per year for peritoneal dialysis covering three (3) peritoneal dialysis exchanges per day for three hundred sixty-five (365) days, while the package rate for hemodialysis treatment shall be increased annually to cover a span of ninety (90) hemodialysis sessions per year. The professional fee of the attending physician and hospital charges shall be included in the PhilHealth benefits for dialysis treatment.

The remaining sessions for both peritoneal dialysis and hemodialysis shall be paid for by the Philippine Charity Sweepstakes Office.

For the purposes of providing optimal financial risk protection to the most vulnerable groups including the poorest of the poor, the “No Balance Billing Policy” of the government is hereby provided for indigents.

The breakdown of the PHIC hemodialysis benefit package shall include standard HD treatment inclusive of the dialyzer and all other supplies needed as well as the minimum basic laboratory tests consisting of complete blood count, creatinine, calcium, phosphorus, potassium, albumin, hepatitis B surface antigen (HBsAg) and anti-hepatitis C virus (Anti-HCV). The laboratory tests shall be done at a frequency of at least four (4) tests per year for the first six (6) tests, and twice a year for the last two (2) tests. The schedule of these tests shall be determined by the attending physician during the course of the annual dialysis treatment sessions.

SECTION 10. *Periodic Assessment and Benefit Package Adjustments for End Stage Renal Disease Patients.* — A periodic assessment and reasonable adjustments of the benefit package for dialysis and transplant patients shall
be made by the PhilHealth after taking into consideration its financial sustainability and changes in the socio-economic conditions of the country.

SECTION 11. **Free Dialysis Treatment to Indigent Patients.** – Dialysis treatment in all national, regional, and provincial government hospitals shall be provided free of charge to indigent patients as identified by the Department of Social Welfare and Development using the National Household Targeting System for Poverty Reduction. A PD First Policy shall be established for all indigent patients, unless there is a contraindication to its use in a particular patient.

SECTION 12. **Treatment Options.** – The PhilHealth shall develop a package that will provide the highest benefit for kidney transplant, followed by peritoneal dialysis, then hemodialysis.

   The benefit package shall include a screening test for both the donor and recipient shall include the following:

   1) For the donor, the screening testing include blood typing, complete blood count, fasting blood sugar, creatinine, hepatitis B surface antigen, anti-hepatitis C antibody, urinalysis, chest x-ray and ultrasound of the kidneys, ureter, and urinary bladder.

   2) For the recipient, cardiac evaluation and many other tests as needed.

During the availment of the full benefits of dialysis within the first two (2) years of dialysis initiation, the cost of dialysis treatment shall be paid for by the PhilHealth and the PCSO as described in Section 8. These options are provided to encourage more patients to have a kidney transplant and attain full rehabilitation.

If the patient passes the criteria for the PhilHealth benefit package for transplantation, the expenses for lab work-up shall be reimbursed to the patient by the healthcare institution after the PhilHealth pays the benefit to the healthcare institution.

The cost of the operation for transplantation shall be included in the PhilHealth Z-benefit package which includes a month of post-hospital discharge laboratory tests for the recipient and a none (1) year follow up laboratory tests for the donor. The Z-benefit package shall be expanded accordingly.
The immunosuppression medications needed by the transplant patient, if there is no graft rejection, shall be lifelong. For PhilHealth patients, these medicines shall be provided for one (1) year by PCSO. After the first year, the patient may reapply with the PCSO for assistance for such medications.

SECTION 13. Rehabilitation Program. – The DOH, in coordination with the Department of Labor and Employment, Technical Education and Skills Development Authority, and the DSWD and other pertinent agencies, shall establish a comprehensive rehabilitation program for ESRD patients who have undergone kidney transplant in order to help them reach their fullest physical, psychological, social, and vocational avocational, and educational potential consistent with their physiologic or anatomic condition, environmental limitations, life plans and desires.

SECTION 14. Dialysis Facility. – A dialysis facility shall be compliant with the licensing requirements imposed under DOH Administrative Order No. 2012-0001 dated January 26, 2012 for hemodialysis, and PhilHealth-Accreditation for peritoneal dialysis facilities. Hospitals without dialysis facilities first put up the necessary equipment and qualified staff to perform peritoneal dialysis services. For hospitals with existing hemodialysis facilities, a peritoneal dialysis unit shall be established immediately so that this more cost-effective dialysis option can be made available to patients. Hospitals shall preferentially be provided with the necessary personnel, equipment and supplies as required by PhilHealth for accredited facilities.

SECTION 15. Training for Peritoneal and Hemodialysis Treatment and Services. – The DOH, National Kidney and Transplant Institute (NKTI) and the Philippine Society of Nephrology (PSN) shall provide training for medical personnel such as physicians to take charge of the hemodialysis and peritoneal dialysis centers, hemodialysis and peritoneal dialysis nurses, hemodialysis and peritoneal dialysis technicians, operating room nurses, transplant ward nurses, transplant coordinators, and non-medical barangay health workers to support home based peritoneal dialysis. The NKTI shall accredit the centers that can provide training for the above personnel and training should include hands-on workshops for dialysis.

SECTION 16. Establishing a Chronic Kidney Disease (CKD) Counseling Clinic. – All RRT facilities shall establish a chronic kidney disease (CKD) counseling clinic with separate personnel trained to engage patients and explain to them the normal functions of the kidney, the stages of CKD, the laboratories routinely performed for CKD patients, the common medications required that can control the progression of kidney disease, the metabolic complications of ESRD, and the indications for renal replacement. These
clinics shall monitor the kidney function of patients so that a timely referral to a nephrologist or internists/pediatrician with specialized training in CKD can be made, with the timely initiation of Renal Replacement Therapy to prevent requiring emergency treatment.

The NKTI shall provide education and training modules for the medical staff of CKD counselling clinics.

**SECTION 17. Creation of a Renal Disease Control Program (REDCOP).** - All RRT facilities shall create a Renal Disease Control Program (REDCOP), following the model of the NKTI, that shall promote the early recognition of kidney disease, identify persons at high risk for the development of kidney disease and initiate preventive strategies to either prevent the development of kidney disease (i.e., From diabetes and hypertension) or to delay its progression to end stage renal disease. The DOH will establish a database of these patients to ensure that they are regularly monitored for disease progression and that they are receiving appropriate treatment for CKD.

**SECTION 18. Authority to Receive Donations and Exemptions from Donor’s Taxes, Customs and Tariff Duties.** - The DOH shall be authorized to receive donations, gifts and bequests in order to augment the funding for the establishment of the dialysis wards/units created in accordance with this Act. All Donations, contributions or endowments which may be made by persons or entities to the dialysis wards/units in national, regional and provincial, hospitals and the importation of medical equipment and machineries, spare parts and other medical equipment used solely and exclusively by the dialysis wards or units shall be exempt from income or donor’s taxes, any other direct or indirect taxes, wharfage fees and other charges and restrictions.

**SECTION 19. Penalty.** - Any hospital chief, administrator or officer-in-charge of hospitals, dialysis centers, and health facilities who fails to comply with Sections 5 and 6 of this Act shall be meted with a fine of Fifty Thousand Pesos (PhP50,000.00) but not more than One Hundred Thousand Pesos (PhP 100,000.00).

Likewise, persons receiving free treatment of medicines for End Stage Renal disease or PD or HD services from government hospitals and its agencies (i.e. PCSO, PHIC) who are found selling these medications or services instead of using them for their own treatment, shall be penalized with the suspension of their PhilHealth membership and shall be ineligible for assistance from PCSO and other government agencies for a period of one (1) year. If these persons are found to be engaged in the selling of medications or
services allotted for their care for the second time, they shall be permanently ineligible to receive government assistance.

SECTION 20. Appropriations. – The initial amount necessary to implement the provisions of this Act shall be charged against the current year’s appropriation of the DOH. Thereafter, such sum as may be necessary for the continued implementation of this Act shall be included in the annual General Appropriations Act.

SECTION 21. Implementing Rules and Regulations. - Within sixty (60) days from the effectivity of this Act, the Secretary of Health, in coordination with the President of PhilHealth, the Executive Director of the NKTI, and other relevant stakeholders, shall issue the implementing rules and regulations to implement the provisions of this Act.

SECTION 22. Repealing Clause. – All laws, presidential decrees, executive orders, letter of instruction, administrative order, rules and regulation contrary to or inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SECTION 23. Separability Clause. – If any provision of this act is held invalid or unconstitutional, the other provision not affected hereby shall remain valid and subsisting.

SECTION 24. Effectivity. – This Act shall take effect fifteen (15) days after its publication either in the Official Gazette or in a newspaper of general circulation.

Approved,