118TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 118–548
Part 1

KIDNEY PATIENT ACCESS TO TECHNOLOGICALLY INNOVATIVE AND ESSENTIAL NEPHROLOGY TREATMENTS ACT OF 2024

JUNE 11, 2024.—Ordered to be printed

Mr. SMITH of Missouri, from the Committee on Ways and Means, submitted the following

R E P O R T

[To accompany H.R. 5074]

The Committee on Ways and Means, to whom was referred the bill (H.R. 5074) to amend the American Taxpayer Relief Act of 2012 to delay implementation of the inclusion of oral-only ESRD-related drugs in the Medicare ESRD prospective payment system, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Kidney Patient Access to Technologically Innovative and Essential Nephrology Treatments Act of 2024" or the "Kidney PATIENT Act of 2024".

SEC. 2. PROHIBITION OF IMPLEMENTATION OF ORAL-ONLY POLICY FOR CERTAIN DRUGS UNDER MEDICARE ESRD PROSPECTIVE PAYMENT SYSTEM.

(a) IN GENERAL.—Section 632(b) of the American Taxpayer Relief Act of 2012 (42 U.S.C. 1395rr note) is amended—

(1) in the heading, by striking "TWO-YEAR DELAY" and inserting "DELAY"; and

(2) in the first sentence of paragraph (1), by striking "may not implement" and all that follows through "January 1, 2025." and inserting "may not implement the policy under section 413.174(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD-related drugs in the ESRD prospective payment system) with respect to such drugs indicated for the reduction, management, or control of the serum phosphate of an individual before January 1, 2027.".

(b) STUDY.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress and make available on the public website of the Centers for Medicare & Medicaid Services a report containing data from 2022 through 2024 on—

(1) the number of individuals entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) or enrolled under part B of such title (42 U.S.C. 1395j et seq.) with end-stage renal disease who are enrolled under a prescription drug plan under part D of such title (42 U.S.C. 1395w–101 et seq.) or under an MA–PD plan under part C of such title (42 U.S.C. 1395w–21 et seq.), along with a specification of any gaps in coverage under such prescription drug plans or MA–PD plans;

(2) the amount of expenditures under such part D attributable to oral-only drugs related to the treatment of end-stage renal disease and the amount of cost sharing incurred by such individuals for such drugs;

(3) such individuals' adherence to prescriptions for such drugs, including as measured by serum phosphate levels, reported through the end-stage renal disease quality reporting system;

(4) adverse events of such individuals related to hyperphosphatemia and estimated costs attributable to such adverse events under such title; and

(5) any recommended strategies or standards of practice to increase adherence to prescribed phosphate binders or lowering agents or other strategies to reduce costs to such individuals and expenditures under such program for such agents.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The policy would allow patients to continue to access kidney disease therapies through their Medicare Part D benefit until 2027 and require the Department of Health and Human Services (HHS) to submit a report on the effects of providing these drugs through Medicare Part D.

B. BACKGROUND AND NEED FOR LEGISLATION

Certain noninjectable oral drugs ("oral-only") for patients with end-stage renal disease (ESRD) are included in a patient's traditional Medicare Part D drug coverage, allowing patients to access these drugs at their local pharmacy. This includes drugs such as "phosphate binders" which help ESRD patients maintain healthy

levels of phosphate in the blood. The Centers for Medicare and Medicaid Services (CMS) plan to move these drugs from Medicare Part D coverage to the ESRD payment "bundle" in 2025. The ESRD bundle is an all-inclusive payment to dialysis providers under Medicare Part B; the base payment for 2024 is $271.02 per dialysis session; intended to cover dialysis treatments, but not extra costs such as noninjectable drugs. When new ESRD drugs are eligible for treatment, an additional time-limited add-on payment is added to the ESRD bundle to encourage adoption, known as Transitional Drug Add-on Payment Adjustment (TDAPA).

C. Legislative History

Background

H.R. 5074 was introduced on July 28, 2023, and was referred to the Committee on Energy and Commerce and the Committee on Ways and Means.

Committee Hearings

The Committee on Ways and Means held the following hearing(s) concerning the policy in H.R. 5074:

On Wednesday, May 10, 2023, the Committee on Ways and Means Health Subcommittee held a hearing titled, "Examining Policies that Inhibit Innovation and Patient Access" to explore regulatory and legislative barriers to patient access to innovative treatments.

Committee Action

The Committee on Ways and Means marked up H.R. 5074, the Kidney PATIENT Act of 2023, on March 6, 2024, and favorably reported the bill, as amended, to the House of Representatives (with quorum being present).

D. Designated Hearing

Pursuant to clause 3(c)(6) of rule XIII, the following hearing was used to develop and consider H.R. 5074:

On Wednesday, May 10, 2023, the Committee on Ways and Means Health Subcommittee held a hearing titled, "Examining Policies that Inhibit Innovation and Patient Access" to explore regulatory and legislative barriers to patient access to innovative treatments.

II. EXPLANATION OF THE BILL

A. Reasons for Change

CMS plans to move oral-only ESRD drugs from Medicare Part D coverage to the ESRD bundle.

The ESRD bundle is a limited, all-inclusive payment, so dialysis providers may not be able to invest in and provide innovative oral-only drugs to patients. Dialysis providers would need to expand their infrastructure to dispense oral-only drugs. Phosphate-lowering therapies, which are oral-only drugs, must be taken with a meal and therefore cannot be administered by a provider while patients dialyze and the common starting dose for phosphate therapies is more than 100 pills/month.

Allowing oral-only drugs to move to the bundle would result in higher costs for patients. The TDAPA add-on payment for new drug adoption is anticipated resulting in higher cost sharing for patients. Keeping these drugs in Medicare Part D will allow patients to utilize certain cost sharing protections and provide patients with better access to the full-range of drugs that may be necessary to manage their hyperphosphatemia.

B. Explanation of Provisions

This policy delays drugs that treat high levels of phosphate in the blood and do not have an injectable alternative from entering the ESRD payment bundle until 2027.

The policy also requires the Secretary of HHS to report information based on data from 2022 through 2024 on the prescription drug coverage of patients with ESRD, Medicare spending and patient cost sharing under Part D for oral-only ESRD related drugs, patient adherence, patient adverse events related to hyperphosphatemia and estimated costs to the Medicare program, and any recommended strategies to increase patient adherence.

C. Effective Date

The bill would become effective upon enactment.

III. VOTES OF THE COMMITTEE

In compliance with the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means during the markup consideration of H.R. 5074, the "Kidney PATIENT Act of 2023," on March 6, 2024.

H.R. 5074 was ordered favorably reported to the House of Representatives as amended by a roll call vote of 41 yeas to 1 nay (with a quorum being present). The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Smith (MO)	X			Mr. Neal	X		
Mr. Buchanan	X			Mr. Doggett		X	
Mr. Smith (NE)	X			Mr. Thompson	X		
Mr. Kelly	X			Mr. Larson	X		
Mr. Schweikert	X			Mr. Blumenauer	X		
Mr. LaHood	X			Mr. Pascrell	X		
Dr. Wenstrup	X			Mr. Davis	X		
Mr. Arrington	X			Ms. Sánchez	X		
Dr. Ferguson	X			Ms. Sewell	X		
Mr. Estes	X			Ms. DelBene	X		
Mr. Smucker	X			Ms. Chu	X		
Mr. Hern	X			Ms. Moore			
Ms. Miller	X			Mr. Kildee	X		
Dr. Murphy	X			Mr. Beyer	X		
Mr. Kustoff	X			Mr. Evans	X		
Mr. Fitzpatrick	X			Mr. Schneider	X		
Mr. Steube	X			Mr. Panetta	X		
Ms. Tenney	X			Mr. Gomez	X		
Mrs. Fischbach	X						
Mr. Moore	X						
Mrs. Steel	X						
Ms. Van Duyne	X						
Mr. Feenstra	X						
Ms. Malliotakis	X						
Mr. Carey	X						

IV. BUDGET EFFECTS OF THE BILL

A. Committee Estimate of Budgetary Effects

With respect to clause 3(d) of rule XIII of the Rules of the House of Representatives, a cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not made available to the Committee in time for the filing of this report.

B. Statement Regarding New Budget Authority and Tax Expenditures Budget Authority

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involved no new or increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

V. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE

With respect to the requirements of clause 3(c)(2) of rule XIII of the Rules of the House of Representatives and section 308(a) of the *Congressional Budget Act of 1974* and with respect to requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the *Congressional Budget Act of 1974*, the Committee has requested but not received a cost estimate for this bill from the Director of Congressional Budget Office. The Chairman of the Committee shall cause such estimate and statement to be printed in the Congressional Record upon its receipt by the Committee.

VI. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. Committee Oversight Findings and Recommendations

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee made findings and recommendations that are reflected in this report.

B. Statement of General Performance Goals and Objectives

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill does not authority funding, so no statement of general performance goals and objectives is required.

C. Information Relating to Unfunded Mandates

This information is provided in accordance with section 423 of the *Unfunded Mandates Reform Act of 1995* (Pub. L. No. 104–4).

The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

D. CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

E. DUPLICATION OF FEDERAL PROGRAMS

In compliance with clause 3(c)(5) of rule XIII of the Rules of the House of Representatives, the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program; (2) a program included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139; or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant to the Federal Program Information Act (Pub. L. No. 95–220, as amended by Pub. L. No. 98–169).

VII. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

AMERICAN TAXPAYER RELIEF ACT OF 2012

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TITLE VI—MEDICARE AND OTHER HEALTH EXTENSIONS

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Subtitle C—Other Health Provisions

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SEC. 632. REVISIONS TO THE MEDICARE ESRD BUNDLED PAYMENT SYSTEM TO REFLECT FINDINGS IN THE GAO REPORT.

(a) ADJUSTMENT TO ESRD BUNDLED PAYMENT RATE TO ACCOUNT FOR CHANGES IN THE UTILIZATION OF CERTAIN DRUGS AND BIOLOGICALS.—Section 1881(b)(14) of the Social Security Act (42

U.S.C. 1395rr(b)(14)) is amended by adding at the end the following new subparagraph:

"(I) For services furnished on or after January 1, 2014, the Secretary shall, by comparing per patient utilization data from 2007 with such data from 2012, make reductions to the single payment that would otherwise apply under this paragraph for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of drugs and biologicals described in clauses (ii), (iii), and (iv) of subparagraph (B) (other than oral-only ESRD-related drugs, as such term is used in the final rule promulgated by the Secretary in the Federal Register on August 12, 2010 (75 Fed. Reg. 49030)). In making reductions under the preceding sentence, the Secretary shall take into account the most recently available data on average sales prices and changes in prices for drugs and biological reflected in the ESRD market basket percentage increase factor under subparagraph (F).".

(b) [TWO-YEAR DELAY] *DELAY* OF IMPLEMENTATION OF ORAL-ONLY ESRD-RELATED DRUGS IN THE ESRD PROSPECTIVE PAYMENT SYSTEM; MONITORING.—

(1) DELAY.—The Secretary of Health and Human Services [may not implement the policy under section 413.174(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD-related drugs in the ESRD prospective payment system), prior to January 1, 2025.] *may not implement the policy under section 413.174(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD-related drugs in the ESRD prospective payment system) with respect to such drugs indicated for the reduction, management, or control of the serum phosphate of an individual before January 1, 2027.* Notwithstanding section 1881(b)(14)(A)(ii) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(A)(ii)), implementation of the policy described in the previous sentence shall be based on data from the most recent year available.

(2) MONITORING.—With respect to the implementation of oral-only ESRD-related drugs in the ESRD prospective payment system under subsection (b)(14) of section 1881 of the Social Security Act (42 U.S.C. 1395rr(b)(14)), the Secretary of Health and Human Services shall monitor the bone and mineral metabolism of individuals with end stage renal disease.

(c) ANALYSIS OF CASE MIX PAYMENT ADJUSTMENTS.—By not later than January 1, 2016, the Secretary of Health and Human Services shall—

(1) conduct an analysis of the case mix payment adjustments being used under section 1881(b)(14)(D)(i) of the Social Security Act (42 U.S.C. 1395rr(b)(14)(D)(i)); and

(2) make appropriate revisions to such case mix payment adjustments.

(d) UPDATED GAO REPORT.—Not later than December 31, 2023, the Comptroller General of the United States shall submit to Congress a report that updates the report submitted to Congress under section 10336 of the Patient Protection and Affordable Care Act (Public Law 111-148; 124 Stat. 974). The updated report shall include an analysis of how the Secretary of Health and Human Services has addressed points raised in the report submitted under such section 10336 with respect to the Secretary's preparations to

implement payment for oral-only ESRD-related drugs in the bundled prospective payment system under section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)).

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