AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5074 OFFERED BY MR. SMITH OF MISSOURI

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 2023'' or the ''Kidney PATIENT Act of 2023''.

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.