deadliest diseases facing children in our country, our laws must keep up.

This legislation will ensure children have access to the most innovative treatments and therapies for cancer and rare disease, and it does that by doing the following.

It reauthorizes the FDA's pediatric priority voucher program for five years. The program expires September 23, 2024 and we cannot let critical tools to encourage the development of drugs for children to lapse.

It directs companies to conduct pediatric trials with combinations of drugs. More than 40 combination therapies are approved for adults, but only 2 are approved for children. This legislation fixes that inequity. Every member of the Energy and Commerce Committee and 392 Members of the House voted for this provision as part of the user fees package last Congress.

It brings the FDA's enforcement capabilities for children on par with that of adults, giving the FDA new options to ensure pediatric studies are completed on time. Today, the FDA can only remove a drug from the market if pediatric studies are not completed. This bill gives the FDA more flexibility to ensure companies follow the law.

The bill dedicates existing funds for pediatric research through the NIH's Best Pharmaceuticals for Children Act Program over the next three years, the program's first funding update since it was authorized in 2002. Zero new funding will be used.

This bill was advanced by the House Energy and Commerce Committee unanimously last week.

Children are not little adults. They deserve effective medicines, just as adults do. The Give Kids a Chance Act will get children what they deserve and save lives.

I urge my colleagues to vote for this critical legislation.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Indiana (Mr. BUCSHON) that the House suspend the rules and pass the bill, H.R. 3433, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

SENIORS' ACCESS TO CRITICAL MEDICATIONS ACT OF 2024

Mr. BUCSHON. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5526) to amend title XVIII of the Social Security Act to clarify the application of the in-office ancillary services exception to the physician self-referral prohibition for drugs furnished under the Medicare program, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5526

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Seniors' Access to Critical Medications Act of 2024''.

SEC. 2. CLARIFYING THE APPLICATION OF THE IN-OFFICE ANCILLARY SERVICES EXCEPTION TO THE PHYSICIAN SELF-REFERRAL PROHIBITION FOR COVERED OUTPATIENT DRUGS FURNISHED UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1877(b)(2) of the Social Security Act (42 U.S.C. 1395nn(b)(2)) is amended by adding at the end the following new sentence: ''With respect to services described in subsection (h)(6)(J) consisting of covered part D drugs (as defined in section 1860D–2(e)) furnished to an individual during the period beginning on January 1, 2025, and ending on December 31, 2029, such drugs shall be treated as having been furnished in accordance with subparagraph (A)(ii) if such drugs are picked up in a building described in subclause (I) or (II) of such subparagraph by such individual, or a family member or caregiver on behalf of such individual, or delivered to such individual by a mail, delivery, or courier service, but only if, during the 1-year period ending on the date such drugs were so furnished, such individual had a face-to-face encounter with the prescriber of such drugs (not including any such encounter conducted via telehealth), and only if such prescriber (or another physician or practitioner (as described in section 1842(b)(18)(C)) in the same practice as such prescriber (as determined by tax identification number)) furnished to such individual, during such 1-year period, another item or service for which payment was made under this title, and only if such individual has an ongoing relationship with such prescriber.''.

(b) REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that contains—

(1) the number of individuals who were furnished drugs in a manner that would constitute a violation of section 1877 of the Social Security Act (42 U.S.C. 1395nn) but for the amendment made by subsection (a);

(2) an analysis of the change in expenditures under title XVIII of such Act (42 U.S.C. 1395 et seq.) attributable to such amendment;

(3) a description of which drugs were furnished in a manner described in paragraph (1); and

(4) such amendment's impact on prices for such drugs.

SEC. 3. MEDICARE COVERAGE OF EXTERNAL INFUSION PUMPS AND NON-SELF-ADMINISTRABLE HOME INFUSION DRUGS.

Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) is amended by adding at the end the following new sentence: ''Beginning with the first calendar quarter beginning on or after the date that is one year after the date of the enactment of the 'Seniors' Access to Critical Medications Act of 2024', an external infusion pump and associated home infusion drug (as defined in subsection (iii)(3)(C)) or other associated supplies that do not meet the appropriate for use in the home requirement applied to the definition of durable medical equipment under section 414.202 of title 42, Code of Federal Regulations (or any successor to such regulation) shall be treated as meeting such requirement if each of the following criteria is satisfied:

''(1) The prescribing information approved by the Food and Drug Administration for the home infusion drug associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional.

''(2) A qualified home infusion therapy supplier (as defined in subsection (iii)(3)(D)) administers or supervises the administration of the drug or biological in a safe and effective manner in the patient's home (as defined in subsection (iii)(3)(B)).

''(3) The prescribing information described in paragraph (1) instructs that the drug should be infused at least 12 times per year—

''(A) intravenously or subcutaneously; or

''(B) at infusion rates that the Secretary determines would require the use of an external infusion pump.''.

SEC. 4. MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking ''$0'' and inserting ''$114,000,000''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Indiana (Mr. BUCSHON) and the gentleman from New Jersey (Mr. PALLONE) each will control 20 minutes.

The Chair recognizes the gentleman from Indiana.

GENERAL LEAVE

Mr. BUCSHON. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Indiana?

There was no objection.

Mr. BUCSHON. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, a silver lining of the COVID–19 pandemic, if there is one, was the proliferation of new, effective ways to deliver healthcare.

Of course, we saw the rise of telehealth, but we also saw an increased use of mail to deliver prescription drugs to patients. Mailing prescription drugs to patients, especially those who live in rural communities, helped increase access to care and medication adherence by reducing the need to travel long distances to your nearest pharmacy.

For seniors who may struggle with mobility, this change was especially important.

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Unfortunately, Federal laws limit the ability for seniors to take advantage of these benefits.

CMS states that if a Medicare beneficiary wants to see an independent physician that also owns a pharmacy, the Medicare beneficiary must pick up their drugs from that physician-owned pharmacy in person.

That pharmacy cannot mail the drug directly to the patient or let a family member pick up the drug on the Medicare patient's behalf.

During the COVID–19 pandemic, CMS relaxed this restriction. I have heard from countless oncologists across my home State about how during the COVID–19 pandemic era, those flexibilities improved access to care.

H.R. 5526 would clarify that seniors can get drugs from physician-owned pharmacies through the mail or have someone pick up those medications on their behalf, making it easier for seniors to get the care that they need.

I encourage my colleagues to support this bill, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 5526, the Seniors' Access to Critical Medications Act.

This bill amends the Physician Self-Referral Law, also known as the Stark Law, to permit Medicare patients to have their physicians dispense prescription drugs to them in narrow circumstances, either through a caregiver or through a mail courier. Congress enacted the Stark Law to ensure that physician financial considerations do not influence patient care. Under the Stark Law, physicians are prohibited from making referrals to entities in which the physician has a financial stake.

Medicare beneficiaries deserve the independent judgment of their physicians and access to treatment that is medically appropriate and necessary for them. The Stark Law is critical in ensuring that financial arrangements do not distort physician decision-making or raise healthcare costs.

Now, current law includes specific and narrowly tailored exceptions such as the in-office ancillary services exception. This exception permits a physician with an ownership stake to provide an outpatient prescription drug or certain services to a patient at his or her office as part of an in-person visit. This is for the convenience of the patient but also because there are more limited program integrity concerns when the item or service is being delivered as part of an in-person office visit.

While I continue to have strong concerns with significantly weakening the Stark Law, I believe there are also limited instances in which it may be necessary for a caregiver or a family member to pick up the prescription drugs for patients or for them to be mailed. I believe there are limited program integrity concerns in these instances.

This narrow Stark exception will help patients receive necessary medications more easily and protects Medicare beneficiaries by ensuring that financial considerations do not influence patient care.

I urge my colleagues to join me in voting ''yes'' on H.R. 5526, and I reserve the balance of my time, Mr. Speaker.

Mr. BUCSHON. Mr. Speaker, I yield 5 minutes to the gentlewoman from Tennessee (Mrs. HARSHBARGER).

Mrs. HARSHBARGER. Mr. Speaker, I rise today in strong support of H.R. 5526, the Seniors' Access to Critical Medications Act.

I thank my co-lead, Democrat Representative WASSERMAN SCHULTZ, and House Energy and Commerce Chair RODGERS and Ranking Member PALLONE for allowing me to advance this important legislation.

I spent 37 years working as a pharmacist in almost every area of pharmacy, and I know firsthand the importance of providing patients with serious illnesses timely and reliable access to their lifesaving medications.

Under the Centers for Medicare and Medicaid Services' interpretation of the physician self-referral law, which is known as the Stark Law, it states that it is unlawful for a medical practice, such as a community oncology practice, to deliver a prescribed and filled drug to a patient by mail or courier, UPS or Fed Ex. CMS' interpretation doesn't even allow for a family member or a caregiver to pick up the patient's drug on their behalf.

For Medicare seniors living in rural areas who don't have transportation or who are too sick to pick up their lifesaving drug, they are just simply out of luck in a lot of cases, or they are forced to rely on a nameless or faceless mail order pharmacy benefit manager, where these ''distant middlemen'' cannot quickly fine-tune necessary short-term changes or adjustments in their therapies.

Some patients will go without their oral chemotherapy medication because they can't get transportation to pick their prescription up. It can change the entire outcome for those patients. We shouldn't have obstacles in the way of patients receiving the medications they need.

The bipartisan Seniors' Access to Critical Medications Act simply ensures that cancer patients, as well as other patients, have timely access to the appropriate oral medications they need by allowing delivery of these medications or allowing family members or caregivers to pick up their medicines.

I have heard from dozens upon dozens of Tennessee oncologists and other specialty physicians and patients, as well as others around the country, who have been deeply impacted by the unnecessary hurdles created by CMS' misguided interpretation of the Stark Law.

During the pandemic, CMS recognized these barriers and issued a Stark waiver, lifting the restrictions that hindered patient access to these crucial medications.

This bill restores those flexibilities, and I urge all my colleagues to support H.R. 5526 to protect Medicare beneficiaries' ability to receive the medications they need when they need them.

Mr. PALLONE. Mr. Speaker, I support this legislation and urge its passage, and I yield back the balance of my time.

Mr. BUCSHON. Mr. Speaker, in closing, I encourage a ''yes'' vote on this bill, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. EDWARDS). The question is on the motion offered by the gentleman from Indiana (Mr. BUCSHON) that the House suspend the rules and pass the bill, H.R. 5526, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The title of the bill was amended so as to read: ''A bill to amend title XVIII of the Social Security Act to clarify the application of the in-office ancillary services exception to the physician self-referral prohibition for covered outpatient drugs furnished under the Medicare program, and to provide coverage of external infusion pumps and non-self-administrable home infusion drugs under such program.''.

A motion to reconsider was laid on the table.

CONGENITAL HEART FUTURES REAUTHORIZATION ACT OF 2024

Mr. BILIRAKIS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 7189) to amend the Public Health Service Act to reauthorize a national congenital heart disease research, surveillance, and awareness program, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 7189

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Congenital Heart Futures Reauthorization Act of 2024''.

SEC. 2. REAUTHORIZATION OF NATIONAL CONGENITAL HEART DISEASE RESEARCH, SURVEILLANCE, AND AWARENESS PROGRAM.

Section 399V–2 of the Public Health Service Act (42 U.S.C. 280g–13) is amended—

(1) by redesignating subsections (f) and (g) as subsections (g) and (h), respectively;

(2) by inserting after subsection (e) the following:

''(f) REPORT AND STRATEGY.—

''(1) REPORT.—Not later than 2 years after the date of enactment of the Congenital Heart Futures Reauthorization Act of 2024, the Secretary shall issue a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate including the following:

''(A) A description of past and present activities of the Department of Health and Human Services to increase awareness and knowledge of the public with respect to congenital heart disease, including efforts to address the lifelong needs of congenital heart disease patients.

''(B) An assessment of past and present activities of the Department of Health and Human Services to increase education and training of health care providers with respect to congenital heart disease, including efforts to address the lifelong needs of congenital heart disease patients.

''(C) A description of the current workforce capacity in the United States of health care providers who treat adult patients living with congenital heart disease.

''(2) STRATEGY.—

''(A) DEVELOPMENT; SUBMISSION TO CONGRESS.—Not later than 1 year after submitting the report required by paragraph (1), the Secretary shall develop and submit to Congress a strategy for improving efforts to increase awareness and knowledge of the public and education and training of health care providers with respect to congenital heart disease. Such strategy shall include findings and recommendations to—

''(i) address any public awareness and research gaps and opportunities related to the lifelong needs of congenital heart disease patients, including long-term health outcomes, quality of life, mental health, and health care utilization;

''(ii) address any shortages in the current workforce of health care providers who treat adult patients living with congenital heart disease, which may include strategies to enhance